FSIS Public Health Veterinarian (PHV) Training Program

Class Workbook Part 1 of 2

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Presented by the United States Department of Agriculture (USDA)

Food Safety and Inspection Service (FSIS)

NOTE: This workbook is to be used for training purposes only.

U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

TO: Field Operations Attending Training

FROM: Training Operations & Training Management Staffs

SUBJECT: Food Safety and Inspection Service PHV Training Class

Congratulations on being selected to attend the Public Health Veterinarian (PHV) Training course. This is an opportunity to gain significant knowledge about the skills and abilities needed to perform your job duties.

Please use this opportunity to learn as much as you can from the training and to actively participate by asking questions and engaging in class activities.

You represent FSIS and your conduct must reflect a high degree of professionalism. Improper conduct and unprofessional behavior will not be tolerated. Individuals exhibiting unprofessional behavior may be removed from class.

Finally, your feedback is very important. Please take the time to complete the class evaluation survey and let us know what worked well and what could be improved.

Thank you for maintaining a positive and professional work environment.

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Learning Objectives

ONE HEALTH (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Become familiar with the “One Health” perspective.

FSIS ORIENTATION – BIG PICTURE

1. Define the USDA’s role within the Executive Branch and its mission statement.
2. Describe the role of FSIS within USDA and the food safety mission.
3. Give an overview of FSIS’s authority as a public health regulatory agency.
4. Describe FSIS’s vision to protect public health.
5. Describe the functions of each office within FSIS.

ESSENTIALS OF A PUBLIC HEALTH REGULATORY AGENCY

1. Describe what makes FSIS a public health regulatory agency.
2. Describe your role as a Public Health Veterinarian in FSIS.

HUMAN RESOURCES BASICS

1. Become familiar with the FSIS policies concerning the following topics: performance management, probationary employees, official personnel files, general pay schedule, within grade increases, staffing methodology, career counseling, merit promotion, civil rights, ethics, and work unit meetings.

PERFORMANCE MANAGEMENT (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Recognize your basic supervisory responsibilities under Performance Management.
2. Understand how to evaluate employee performance.
3. Explain how to provide feedback to an employee on their performance.
4. Recognize the importance of documentation in Performance Management.

SANITARY DRESSING, PROCEDURES CONTROLLING CONTAMINATION, FOOD MICROBIOLOGY (PRE-HARVEST)

1. List potential situations of concern in the Delivery/Holding context, e.g., food defense, ramifications for pathogens, etc.
2. Identify and explain conditions in the Delivery/Holding area that can affect sampling conducted during Processing.

PROFESSIONALISM AND ETHICS

1. Distinguish between appropriate and inappropriate behaviors by IPP and establishment employees.
2. Create an action plan to address employee misconduct.
3. Identify when a PHV should contact a Labor and Employee Relations specialist.
4. Demonstrate professional behavior when communicating with establishment personnel.
5. Demonstrate effective communication and teambuilding skills in correlations with IPP and FSIS Work Unit Meetings.

IN-PLANT SAFETY (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Be familiar with the FSIS health and safety program, the official forms used to report accidents, and what you can do to prevent accidents.
2. Be familiar with Lockout and Tagout procedures.
3. Be familiar with occupational hazards with a public health significance at ante- and post-mortem.

NONCOMPLIANCE RECORDS

1. Given scenarios in the Slaughter/Kill Floor context, identify situations that warrant a regulatory control action (RCA).
2. For those situations that warrant an RCA, write a supportable noncompliance record (NR) including the correct inspection task and regulatory citations.
3. In a Slaughter/Kill Floor context, demonstrate when and how to associate NRs within the Public Health Information System (PHIS).
4. Demonstrate how to document discussions of noncompliance trends in a Memorandum of Interview (MOI).

HUMANE HANDLING/GOOD COMMERCIAL PRACTICES

Scientific:

1. Select acceptable methods for moving a conscious, disabled livestock to a different area.
2. Given a scenario, recognize conditions in or around the livestock holding pens in an establishment that might cause injury to animals.
3. Given scenarios, observe an establishment's Good Commercial Practices (GCP) and evaluate the GCPs according to prescribed standards.

Regulatory/Administrative:

1. Differentiate between situations in which a PHV would document an MOI, e.g., an isolated observation of mistreatment of a single live bird as opposed to other situations demonstrating a loss of process control in which a PHV would document a noncompliance.
2. Given scenarios, explain the actions IPP take upon observing inhumane treatment due to facility deficiency or disrepair, egregious actions by an establishment employee, or improper stunning.
3. Given scenarios, recognize the humane handling responsibilities in the Delivery/Holding context that apply to FSIS, the establishment, or both, and use the Humane Methods of Slaughter Act and the Title 9 Code of Federal Regulations Part 313 (9 CFR 313) to determine whether an establishment's animal handling is compliant.

ANTE-MORTEM INSPECTION

Scientific:

1. Given a sample context, perform ante-mortem inspection and make supportable ante-mortem dispositions according to 9 CFR part 309 (livestock) and 381.70-381.75 (poultry).
2. Given those scenarios, identify and demonstrate the appropriate regulatory actions, if any.
3. Given scenarios, determine whether given conditions in an establishment are insanitary and unacceptable according to 9 CFR 307.2 for livestock and as per FSIS Directive 6100.3 for poultry.
4. Verify whether an establishment uses compliant methods to dispose of an animal that a PHV has condemned upon ante-mortem inspection.

Regulatory/Administrative:

1. Recognize and access FSIS form 6150-1 for livestock inspection.
2. Given sample scenarios, complete FSIS form 6150-1 for livestock inspection.
3. Given those scenarios, complete a pen card.
4. Identify accountable items used during ante-mortem inspection.

WORKERS COMPENSATION (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Gain familiarity with Workers' Compensation.

REQUIREMENTS TO DEMONSTRATE PROCESS CONTROL

1. Given pathogen data from scenarios in a Slaughter/Kill Floor context, interpret the data to determine whether the establishment's process controls and sanitary dressing procedures are in control or trending out of control.
2. Given a scenario depicting a process out of control, identify regulatory control actions (RCAs) that IPP (inspection program personnel) may take.
3. Identify points of potential contamination during the slaughter process.
4. Demonstrate how to evaluate sanitary dressing procedures during the slaughter process.
5. Given details in the Slaughter/Kill Floor context, assess whether an establishment has adequately measured the effectiveness of its sanitary dressing procedures.

LABOR RELATIONS (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Gain familiarity with the Labor-Management Agreement

POST-MORTEM INSPECTION OVERVIEW

1. Define the purpose of post-mortem inspection.
2. Identify the statutes that provide FSIS the authority for conducting post-mortem inspection.
3. Identify the regulations that cover post-mortem inspection.
4. List the directives that provide instructions on conducting post-mortem inspection.
5. Identify the establishment responsibilities regarding conducting post-mortem inspection.
6. Describe the process of conducting post-mortem inspection procedures.
7. Given a scenario involving a presentation check at a line inspector station, evaluate the establishment's method of presentation.
8. Define "salvage" and "reprocessing," and describe how IPP assess compliance with these procedures.
9. Define how the establishment must dispose of condemned products.
10. Describe how to complete post-mortem reports.

REASONABLE ACCOMMODATION (GUEST - MATERIALS PROVIDED SEPARATELY)

1. Recognize your basic supervisory responsibilities related to Reasonable Accommodation.
2. Identify when to refer a direct report to Reasonable Accommodation.
3. Explain how to refer a direct report to Reasonable Accommodation.

MULTI-SPECIES DISPOSITION BASICS, DISEASES OF/NOT OF PUBLIC HEALTH SIGNIFICANCE

1. Describe the thought process used in making a disposition.
2. Identify the public health significance of diseases and conditions found commonly in the slaughter environment.
3. Describe the difference between public health significance and regulatory disposition requirements.
4. Identify disease and conditions which are required by regulation to result in carcass or parts condemnation.
5. Identify the proper regulatory dispositions in given scenarios using the thought process.

RESIDUE DETECTION

Scientific (Delivery/Holding context):

1. Explain the key aspects of directed and inspector-generated sampling techniques.
2. Given a scenario in the Delivery/Holding context, perform residue detection sampling, both directed and inspector-generated.

Scientific (Slaughter context):

1. Given a scenario, describe how to perform directed and inspector-generated sampling for detecting residue.
2. Given a scenario, interpret the results of KIS™ tests.
3. Demonstrate the appropriate action for a PHV when a KIS™ test is positive.
4. Given four different outcomes of a residue test – i.e., not detected, detected-not violative, detected-not quantified-violative, and detected-violative – identify the PHV's correct response to each.

Regulatory/Administrative (Delivery/Holding context):

1. Given an in-plant scenario, identify the conditions and animal classes that call for a PHV to perform inspector-generated, in-plant residue testing using FSIS Directives 10800.1, 10800.2, and 10800.3.

Regulatory/Administrative (Slaughter context):

1. Identify the conditions and animal classes that call for a PHV to perform an in-plant residue test, based on FSIS Directive 10800.3.
2. Describe how to use LIMS-Direct to access residue laboratory test results.

FOREIGN ANIMAL AND REPORTABLE ANIMAL DISEASES

Scientific (Delivery/Holding context):

1. Given a scenario, identify specific ante-mortem signs in livestock or poultry that suggest a foreign or other reportable animal disease (FAD or RAD).
2. Demonstrate how to convey to IPP a professional commitment to FAD/RAD in this work context.
3. Demonstrate how to train IPP to recognize specific ante-mortem signs of FAD/RAD and report them to a PHV.

Scientific (Slaughter context):

1. Given a scenario in the Slaughter/Kill Floor context, identify specific post-mortem signs in livestock and poultry that suggest a FAD or RAD.

2. Given a post-mortem inspection scenario, demonstrate how to respond to a suspected FAD or RAD.
3. Demonstrate how to train IPP to recognize post-mortem signs of FAD/RADs and report them to a PHV.

Regulatory/Administrative (Delivery/Holding context):

1. Given a scenario in the delivery/holding context, follow FSIS Directive 6000.1 to respond to ante-mortem signs of FAD/RAD.
2. Locate and explain the instructions in FSIS Directive 10400.1 regarding BSE surveillance.
3. Given a scenario, identify the process described in FSIS Directive 10400.1 regarding an animal condemned for suspected rabies.
4. Given a scenario involving notification of a highly pathogenic avian influenza (HPAI) outbreak, respond according to the instructions in FSIS Directive 6020.1.
5. Given a scenario in the Delivery/Holding context involving cattle suspected of tuberculosis, demonstrate ante-mortem inspection, correct disposition, and sampling, and verify segregation and documentation involved.
6. Identify internationally notifiable animal diseases recognized by the World Organisation for Animal Health.
7. Identify animal diseases that PHVs must report to the District Office (DO).
8. Explain how to teach IPP, establishment management, and the general public ways in which FAD and RAD could be introduced into U.S. livestock and poultry and the economic and health consequences.

Regulatory/Administrative (Slaughter context):

1. Given a scenario in the Slaughter/Kill Floor context, follow instructions in FSIS Directive 6100.4 to verify that a beef establishment's controls for specified risk materials (SRM) during processing comply with regulatory requirements.
2. Given a scenario, conduct inspection, sampling, and disposition of animals suspected of FAD/RADs according to FSIS Directive 6240.1, Guideline No. 4, and APHIS-VS TB Sample Submission Manual for Meat Inspection Personnel.

PREPARATION FOR MENTORING

1. Become familiar with the concept of being a mentor.
2. Become familiar with the requirements of mentees.
3. Become familiar with the interpersonal and professional relationship aspects of a mentorship situation.

STATUTES AND YOUR ROLE

1. Understand the purpose of the Acts.
2. Identify key definitions from the Acts.
3. Understand the statutory authority for FSIS activities.
4. Understand how those activities plus authorities in the statutes support enforcement actions.

MEAT, POULTRY AND EGG PRODUCTS RECALLS

1. Explain the key steps in the product recall process, i.e., identification, outbreak notification, investigation, evidence collection, decision document, event assessment committee, recall, and follow-up.
2. Identify the points in the product recall process at which a PHV would become involved and the PHV's role at those points in the process.

3. Explain how the PHV interacts with other entities involved in a recall.
4. List allergens of concern in the Processing context.

ADMINISTRATIVE ENFORCEMENT ACTION DECISION-MAKING/ METHODOLOGY & CRITICAL THINKING

1. Explain and/or list the following concepts: What is critical thinking? What is the importance of critical thinking to the administrative enforcement process?
2. Explain the role of the PHV in the administrative enforcement process.
3. Explain the role of administrative enforcement within the FSIS regulatory framework.
4. List and describe the main supporting components of the AER case file.
5. Accurately document a Memorandum of Interview.
6. List two "other" sources of information pertinent to the administrative enforcement process.

FOOD MICROBIOLOGY AND MICROBIAL SAMPLING

Scientific:

1. List pathogens of concern in the Slaughter and Processing contexts.
2. Given a scenario, review an example of how an establishment may analyze and interpret microbiological data using process control charts.
3. Explain how establishment sampling may be used to validate and support the establishment's food safety system.
4. Given a scenario about an establishment's sampling practices, identify and explain observable pitfalls that could skew sampling results.
5. Identify and give an example of observable pitfalls that could skew FSIS sampling results.
6. Demonstrate correct techniques for collecting FSIS samples (raw beef cloth sampling, RTE sampling, and *Salmonella*/*Campylobacter* sampling of poultry).

Regulatory/Administrative:

1. Identify FSIS sampling programs related to Slaughter and Processing.
2. Identify the pathogens of focus for each of those FSIS programs and products eligible for sampling.
3. Identify and locate the directives and notices related to those FSIS sampling programs.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT (SBREFA)

1. Explain the PHV's role in meeting the agency's SBREFA requirements.
2. Identify effective techniques and agency resources that PHVs can use and provide when communicating with establishment management about assistance with establishment compliance.

WELLNESS

Scientific:

1. Recognize the causes and symptoms of job stress and isolation.
2. Identify remedies for job stress and isolation, such as networking to create a supportive work environment.
3. Recognize the causes and symptoms of the most common, repetitive stress injuries.

4. Identify ways to prevent or minimize repetitive stress injuries.

Regulatory/Administrative:

1. Identify and locate agency resources available to help personnel, including supervisors, cope with stresses related to the in-plant environment that may lead to misconduct or workplace violence.

IPPS & STAR

1. Use FSIS Directive 4430.3 to conduct IPPS and STAR assessments.
2. Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, and HACCP verification, etc. during IPPS assessments.
3. Create a follow-up plan to address an identified deficiency in employee knowledge or performance.

NON-FOOD SAFETY CONSUMER PROTECTION

1. Given a scenario in the poultry slaughter context, apply prescribed NFSCP criteria to score poultry pre-chill and post-chill to verify the establishment's process control.
2. Using reference material provided, apply pre- and post-chill criteria to a 10-bird sample in the field/establishment setting.
3. Explain the establishment's responsibility when pre-chill or post-chill tests exceed established limits.
4. Given a scenario involving verification tasks in the Processing context, apply labeling regulations, FSIS Directive 7000.1, the NIST Handbook, and the Calculation Aid to verify NFSCP compliance.
5. Given a scenario in the Processing context, provide appropriate feedback and guidance to an IPP when they incorrectly perform a non-food safety consumer protection task.
6. Given a scenario in the Processing context, identify the NFSCP noncompliance and the task to document the NR in, whether a recall is likely, and select the appropriate action regarding the product involved.
7. Given a scenario in the Processing context, apply post-chill finished product standards (FPS) criteria to poultry samples, i.e., sampling of 10 birds at least twice per line per shift.

HACCP

1. Given a scenario, use the verification methods in FSIS Directive 5000.1 to determine whether an establishment meets HACCP regulatory requirements for a specific production.
2. Given a scenario, use the verification methods in FSIS Directive 5000.6 to determine whether an establishment's HACCP prerequisite program adequately prevents identified hazards.
3. Given a scenario, use the verification methods in FSIS Directive 5000.6 to determine whether an establishment's records for its HACCP prerequisite programs support decisions made during the establishment's hazard analysis to designate particular hazards as Not Reasonably Likely to Occur (NRLTO).
4. Given a scenario, use the verification methods in FSIS Directive 5000.6 and the Meat and Poultry Hazards and Controls Guide to analyze the adequacy of an establishment's hazard analysis.
5. Given a scenario, use the verification methods in FSIS Directive 5000.1 to verify that an establishment's corrective actions meet regulatory requirements when a deviation from a critical limit occurs at a critical control point (CCP).

6. Given a scenario, use the verification methods in FSIS Directive 5000.1 to verify that an establishment's corrective actions meet regulatory requirements when an unforeseen hazard occurs.

EXPORT CERTIFICATION

1. Demonstrate facility in using the Export Library and FSIS Directive 9000.1 and FSIS Directive 13000.5 for the following:
   - Locating requirements of individual countries.
   - Locating instructions for export certification.
   - Locating documents used in export certification.
2. Identify the appropriate export circumstances for the following:
   - Letterhead certificate
   - Replacement certificate
   - Transit certificate
   - Continuation form
   - Export certificates that cannot be certified
3. Recognize CSI inspection activities for export certification, evaluate the accuracy and completeness of sample applications and certificates, and distinguish the CSI's role from the PHV's role in export certification.
4. Describe some circumstances where you are justified in your refusal to sign an export certificate and the follow-up actions you would take in documenting this.
5. Recognize accountable items in export certification, such as stamps, logs, and other documents.

FSIS Orientation – Big Picture

OBJECTIVES

1. Define the USDA's role within the Executive Branch and its mission statement.
2. Describe the role of FSIS within USDA and the food safety mission.
3. Give an overview of FSIS's authority as a public health regulatory agency.
4. Describe FSIS's vision to protect public health.
5. Describe the functions of each office within FSIS.

RESOURCE MATERIALS

USDA Website Homepage
FSIS Website Homepage

INTRODUCTION

In 2021, U.S. Consumers, businesses, and government entities spent $2.12 trillion on food and beverages in grocery stores and other retailers and on away-from-home meals and snacks. Livestock products are one of the leading U.S. agricultural exports.

Meat and poultry product purchases in the United States make up a large portion of the monies spent on U.S. produced products. Not only do we have an enormous supply of product, but we have one of the safest supplies of meat, poultry, and egg products. How is this possible?

Behind safe product production is an army of public health professionals and support personnel. The safety of our products is largely a result of sustained regulatory surveillance, research, and the educational efforts of the USDA. Some examples of these front-line and behind-the-scenes professionals are in-plant inspection teams, veterinarians, chemists, microbiologists, analysts and statisticians, secretaries and specialists, economists, training teams; and the list goes on and on. To understand how the system works and how these individuals play a role in it, let's review the "BIG PICTURE."

THE "BIG PICTURE"

We begin our review with the U.S. Constitution. The Constitution prescribes the responsibilities of the government's three branches:

- Legislative
- Executive
- Judicial

These three branches all have roles to ensure the safety of the U.S. food supply.

Congress, the Legislative Branch, enacts statutes or laws that are designed to ensure the safety of the food supply and establishes the Nation's level of protection. The Executive Branch is responsible for the implementation of these laws. They do so by developing and enforcing regulations. When enforcement actions, regulations, or policies lead to disputes, the Judicial Branch

is charged to render impartial decisions on the development, implementation, and/or enforcement of those laws. Under which branch would you expect to find your role in the "BIG PICTURE"?

FSIS personnel find themselves in the same branch of government as the President of the United States, the Executive Branch. This branch, headed by the President, consists of the Vice President, department heads, and the heads of independent agencies.

The independent agencies help carry out policy or provide special services. Examples of these special services are environmental protection, federal banking, merit systems protection, and personnel management to name a few. The Department Heads, also known as the Cabinet, advise the President on any issues that relate to their respective offices. Within the Cabinet, we have 15 Executive Departments, including the Department of Agriculture.

The Department of Agriculture is one of the largest departments in the federal government.

U.S. DEPARTMENT OF AGRICULTURE EXECUTIVES

Heading the Department of Agriculture is the Secretary of the U.S. Department of Agriculture. This position is an appointed position and was created to ensure oversight of the entire Department. As head of the department the Secretary oversees the Nation's farm and food programs.

The name of the current Secretary of Agriculture can be found at this link.

The Deputy Secretary of Agriculture assists the Secretary of Agriculture by overseeing the day-to-day activities of the U.S. Department of Agriculture and helps support the mission of USDA.

The name of the current Deputy Secretary of Agriculture can be found at this link.

USDA'S MISSION

USDA's mission statement reads:

"To serve all Americans by providing effective, innovative, science-based public policy leadership in agriculture, food and nutrition, natural resource protection and management, rural development, and related issues with a commitment to deliverable equitable and climate-smart opportunities that inspire and help America thrive."

The USDA provides leadership in agriculture issues. These issues include the management of traditional farm programs, private lands conservation, domestic food assistance, agriculture research and education, agricultural marketing, international trade, meat and poultry inspection, forestry, rural development programs, and trade and foreign agricultural affairs.

The Department of Agriculture is divided into eight mission areas. These areas are listed below. More about these areas can be found at this link.

- Farm Production and Conservation
- Food, Nutrition and Consumer Services
- Food Safety
- Marketing and Regulatory Programs
- Natural Resources and Environment
- Research, Education, and Economics

- Rural Development
- Trade and Foreign Agricultural Affairs

The Food Safety mission area ensures that the Nation's commercial supply of meat (including Siluriformes), poultry, and egg products are safe, wholesome, and correctly labeled and packaged. This mission area also plays a key role in the President's Council on Food Safety and has been instrumental in coordinating a National Food Safety Strategic Plan among various partner Agencies (the Department of Health and Human Services, the Environmental Protection Agency (EPA), and others).

An Under Secretary heads each mission area and oversees the policies and programs of the area. FSIS is in the Food Safety mission area.

Just as in the overall structure for USDA, the Under Secretary for Food Safety is assisted by the Deputy Under Secretary. The duties of this office include overseeing the policies and programs of FSIS.

The names of the current Under Secretary and Deputy Under Secretary for Food Safety can be found at this link.

THE FOOD SAFETY AND INSPECTION SERVICE

Under the Food Safety mission area is our agency, FSIS. FSIS administers the federal meat and poultry inspection program, and the egg products program; to ensure safety, wholesomeness, and truthful labeling of these products. This is done under the authority afforded to us under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

Our Agency sets standards for food safety and regulates all raw and processed meat (including Siluriformes), poultry, and egg products sold in interstate commerce (including imported products). We also conduct food safety consumer education programs.

Although the Under Secretary and the Deputy Under Secretary for Food Safety are responsible for overseeing the food safety policies and programs, the Administrator of FSIS is responsible for the day-to-day food safety activity oversight. FSIS has embraced the vision of being "a trusted public health regulatory agency" along with the goals which align us with the Food Safety mission area.

The Administrator of FSIS is responsible for managing FSIS's food safety activities. In this role, the Administrator carries out the activities to support the Agency's vision of being "a trusted public health regulatory agency."

Assisting the Administrator is the Deputy Administrator. The Deputy Administrator directs the Agency's strategies and initiatives for public affairs, media, congressional relations, consumer education, and employee communications.

The names of the current FSIS Administrator and Deputy Administrator can be found at this link.

USDA HEADQUARTERS

USDA's Headquarters complex buildings are located in Washington, DC on the National Mall at 1400 Independence Avenue, SW. The Jamie L. Whitten Building houses USDA employees, including the

Secretary of Agriculture, the Secretary's Chief of Staff, the Policy Staff, the Operations Staff, the Scheduling Staff and White House Liaison, and the Under Secretaries and FSIS Administrator.

Across the street is the South Building, which is a six-story masonry building. It became known as the USDA's "South Building" as a result of sitting south of the Whitten Building. Until the Pentagon was built in 1942, the South Building was the world's largest office building. Within the South Building, we find the headquarters office of FSIS's Offices and Program Areas. The South Building connects to the Whitten Building by an underground tunnel running under Independence Avenue and by two walkways built over this same street.

Also, we have some of our headquarters personnel housed at the Aerospace Center, the George Washington Carver Center, and the Congressional Quarterly.

FSIS: A PUBLIC HEALTH REGULATORY AGENCY

FSIS is a "trusted public health regulatory agency." But what is a public health agency?

Historically, public health focused on the absence of disease, disease prevention, and control. For FSIS, public health is improving the health status of the citizens. This includes protecting, promoting, and enhancing the health status of the American public. However, FSIS is also a regulatory agency.

In what aspects are we a regulatory agency?

Earlier, we discussed the three branches of government. We said that the Legislative Branch, or Congress, enacts statutes or laws that are designed to ensure the safety of the food supply. In our earlier discussions, we also discussed the Acts that were enacted by the Legislative Branch: the FMIA, PPIA, and EPIA.

As part of the Executive Branch, it is FSIS's responsibility to implement these laws. We regulate meat (including Siluriformes), poultry, and egg products. Thus, our role as a "regulatory agency" is to use the Acts to improve the health status of the American public.

As public health employees, we look at the entire meat, poultry, and egg products operation, not just specifically the regulatory component. In addition, through scientific and educational components, we reduce the level of pathogens and outbreaks of foodborne illness, and educate establishment officials, food handlers, and consumers. We ensure security of our food supply from biological, chemical, and physical contamination. There are many other activities we do that fall under the public health definition other than providing a safe product.

FSIS VISION

It is essential that everyone in FSIS, regardless of their role, recognize that we all play a part in achieving our common vision:

> *Everyone's food is safe.*

Achieving our vision must be carried out on two levels - collectively and individually. On a collective level, there are three basic functions which we apply in order to operate as a successful public health agency. The first function is assessment, which simply means we identify public health problems. The

second function is policy development, where we determine what actions and resources are needed to solve the problems. And the third function is assurance, where we make sure the job gets done.

As individuals, employees may specialize in a particular function. For example, our field employees specialize in assuring the American public that the job gets done. Many of the employees at Headquarters are responsible for identifying public health problems; and others, for using that information to develop policies. Thus, it is a multitude of individual efforts which each one of us employs every day that contribute to FSIS being “a trusted public health regulatory agency.”

FSIS: THE ORGANIZATION

As a part of our FSIS family, we want to make sure that you have what you need to make your new transition as easy as possible. Our standard is to provide you with quality services and benefits, which hopefully exceed your expectations.

FSIS OFFICES

The organizational structure of FSIS enables us to better execute our responsibilities as a World Class Public Health Regulatory Agency. We are a large agency with employees housed throughout the Nation.

We will visit each of these units and see how we work together to accomplish our food safety activities. More information on each program area can be found at this link.

PROGRAM AREAS AND OFFICES

- Office of the Administrator
- Office of Field Operations
- Office of Investigation, Enforcement and Audit
- Office of Public Health Science
- Office of Policy and Program Development
- Office of the Chief Financial Officer
- Office of International Coordination
- Office of Employee Experience and Development
- Office of the Chief Information Officer
- Office of Management (Human Resources)
- Office of Public Affairs and Consumer Education
- Internal Affairs
- Office of Planning, Analysis and Risk Management
- Significant Incident Preparedness and Response Staff

OFFICE OF THE ADMINISTRATOR

The Office of the Administrator (OA) oversees FSIS’s major programs. The Office of the Administrator oversees the Civil Rights Staff, the emergency coordination function, and the food defense assessment function.

The Civil Rights Staff provides leadership, direction, coordination and support to FSIS Civil Rights efforts.

OFFICE OF FIELD OPERATIONS

The Office of Field Operation (OFO) manages a program of regulatory oversight and inspection to assure that meat, poultry, and egg products are wholesome, safe, and properly packaged and labeled. OFO is the largest program area within FSIS, managing about 85% of the Agency's resources and about 90% of its human resources. Field Operations employs field inspection personnel including Food Inspectors, Consumer Safety Inspectors, Public Health Veterinarians, Veterinary Medical Specialists, District Veterinary Medical Officers, and Enforcement, Investigation and Analysis Officers. OFO manages inspection and enforcement activities regulated under the FMIA, PPIA, and EPIA in over 6,000 establishments throughout the United States, Guam, the Virgin Islands, Puerto Rico, American Samoa, and the Northern Mariana Islands. OFO manages the international inspection functions and includes the Import Inspection Division. The inspection personnel are managed through a network of 10 district offices located throughout the United States. OFO oversees FSIS outreach functions.

Field Operations manages a nationwide program of public health protection through inspection and verification of Hazard Analysis and Critical Control Point (HACCP) systems. This Office is also responsible for enforcing the Humane Methods of Slaughter Act (HMSA) for livestock. It also verifies that other consumer protection requirements are met at all federally inspected establishments. OFO staff collects samples during food processing to ensure control of microbiological, physical, and chemical hazards; and as needed, verify that establishments appropriately conduct recall procedures. Inspection activities that inspection personnel perform include ante-mortem inspection of live animals brought to the establishment including livestock (cattle, swine, sheep, goat) and poultry. Each animal also receives post-mortem inspection (carcasses and their associated parts) after they are slaughtered. Regulatory and enforcement activities continue throughout the processing, packaging, and labeling of numerous meat and poultry products such as sausages, bacon, hotdogs, hams, meat pies, egg rolls, chicken tenders, turkey rolls, and many others.

Under the Food Conservation and Energy Act of 2008 (also known as the 2008 Farm Bill) and the 2014 Farm Bill, FSIS was mandated to inspect Siluriformes, including catfish. Siluriformes inspection programs manage a nationwide program of regulatory oversight to ensure the safety, security, and wholesomeness of domestic and imported Siluriformes. Some of their responsibilities include planning and formulating domestic and international Siluriformes policies, establishing Agency policies and procedures for conducting Siluriformes equivalence evaluations and foreign Siluriformes inspection system audits, conducting audits of foreign country Siluriformes inspection systems, and conducting regulatory compliance activities pertinent to federally inspected establishments and ports of entry.

OFFICE OF PLANNING, ANALYSIS AND RISK MANAGEMENT

The Office of Planning, Analysis and Risk Management (OPARM) supports food safety and protects public health through strategic planning, evaluation, data analysis and visualization, as well as enterprise risk management and internal controls Agency-wide.

OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT

The Office of Investigation, Enforcement and Audit (OIEA) conducts surveillance and investigation of regulated and in-commerce meat, poultry, and egg products facilities; investigation of foodborne illness outbreaks; response to natural disaster and intentional contamination events; execution and application of enforcement of FSIS criminal, civil, and administrative sanctions and authorities; verification that state meat and poultry programs are conducted in a manner at least equal to the federal program; and verification that meat, poultry, and egg products imported into the United States are produced under

equivalent standards. OIEA is also responsible for defending the Agency before third parties concerning complaints of discrimination, appeals of adverse actions, and unfair labor practice charges.

OFFICE OF PUBLIC AFFAIRS AND CONSUMER EDUCATION

The Office of Public Affairs and Consumer Education (OPACE) ensures that the Agency's food safety information reaches external stakeholders, public health partners and all Agency employees. OPACE works to inform the public, members of Congress, and USDA regulated industries of vital food safety policies or changes and assesses the impact and effectiveness of messaging and education efforts on public health.

OFFICE OF PUBLIC HEALTH SCIENCE

The Office of Public Health Science (OPHS) is responsible for collecting, analyzing, and reporting scientific information. OPHS scientists develop science-based and data driven advice and recommendations (including risk assessments) for use by Agency decision makers. OPHS oversees three Field Service Laboratories, which analyze samples collected from FSIS regulated products nationwide to monitor for pathogens, chemical residues, allergens, species verification and more. OPHS also provides administrative oversight for one of the Agency's advisory committees, the National Advisory Committee on Microbiological Criteria for Foods.

OFFICE OF MANAGEMENT

The Office of Management (OM) delivers a full range of human resources and administrative management services to FSIS. Its HR portfolio spans across the human capital lifecycle, including talent acquisition and retention, performance management, workforce planning, personnel suitability, and employee/labor relations. Its administrative management portfolio includes acquisition management, real property and fleet management, supply management, safety, physical security, and information management services. Additionally, the Significant Incident Preparedness and Response Staff (SIPRS) develops and coordinates all FSIS activities to prevent, prepare for, respond to, and recover from significant incidents. The SIPRS portfolio is comprised of food defense, emergency management and continuity of operations functions.

OFFICE OF POLICY AND PROGRAM DEVELOPMENT

The Office of Policy and Program Development (OPPD) is responsible for developing and publishing all policy for FSIS. OPPD also develops and publishes all instructions to the field necessary to implement policy. In addition, OPPD develops guidance to ensure industry understands Agency policy. OPPD also reviews and approves labels of product under FSIS jurisdiction and reviews and approves new technologies and ingredients for such product. Finally, OPPD provides administrative oversight for the Agency's National Advisory Committee on Meat and Poultry Inspection.

OFFICE OF EMPLOYEE EXPERIENCE AND DEVELOPMENT

The Office of Employee Experience and Development (OEED) is responsible for employee development, education, and training programs designed to ensure public health and food safety through both inspection and enforcement. It is also responsible for employee engagement activities such as i-Impact, the Federal Employee Viewpoint Survey, and the Administrator's Awards for Excellence throughout FSIS.

SUMMARY

Now you have a closer look at FSIS and our many food safety activities. FSIS protects the public's health by ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled.

You have joined us, and together we can accomplish our mission. Let's work daily toward supporting our mission:

Protect public health by preventing illness from meat, poultry, and egg products.

Essentials of a Public Health Regulatory Agency

OBJECTIVES

1. Describe what makes FSIS a public health regulatory agency.
2. Describe your role as a Public Health Veterinarian in FSIS.

RESOURCE MATERIALS

FSIS Strategic Plan and Annual Plan

BASIS FOR FSIS AS A PUBLIC HEALTH REGULATORY AGENCY: STATUTES

The work that you do is based on three statutes that were enacted by Congress.

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Products Inspection Act (EPIA)

The FMIA was first enacted in 1906 after the public outrage stirred up by the writings of Upton Sinclair's book, "The Jungle." The book contained graphic and detailed descriptions of the insanitary and abhorrent conditions that existed in meat plants at the turn of the century in the city of Chicago, which was the heart of the meat processing industry at the time. Excerpts from the book were published in newspapers. Due to public concern, Congress enacted a statute to ensure that public health was protected. The statute provided for a federal inspection service in livestock slaughter establishments.

The PPIA was modeled after the FMIA. The PPIA was enacted in 1957 based on the growing poultry industry. Initially, there were two separate Agencies – one responsible for enforcing the provisions of the FMIA and one responsible for enforcing the provisions of the PPIA. This explains why, in some cases, establishments that process both meat and poultry products have two establishment numbers. But today, these statutes form the basis of one public health regulatory agency focused on ensuring food safety.

The Acts provide for the basis for FSIS's ability to perform as a public health agency. For example, see these excerpts from Section 602 of the FMIA, Congressional statement of findings:

"Meat and meat food products are an important source of the Nation's total supply of food." "It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are ***wholesome, not adulterated and properly marked, labeled, and packaged****."*

These three objectives - verifying that meat or poultry products are (1) wholesome, (2) not adulterated, and (3) properly marked/labeled, and packaged – are the essentials of the job you have in protecting public health. All of your activities focus around one or more of these objectives.

The Congressional statement of findings in the Poultry Products Inspection Act (Section 451) is almost identical to that of the FMIA. It emphasizes public health, and it emphasizes the same three objectives – wholesome, not adulterated, and properly marked/labeled, and packaged.

Another foundational principle is outlined in Section 452 of the PPIA which indicates that inspection is authorized to prevent products from entering commerce that are adulterated or misbranded. Remember, **all the things you do or supervise as part of your job can be traced back to the statutes to make sure that any meat, poultry, or egg product that is adulterated or misbranded does not enter commerce to protect the public health.** You will do that through the enforcement authorities that you will learn about later.

THE PUBLIC HEALTH MODEL

There are some key features of a public health agency. These features are outlined in the public health model. This model applies to all types of public health institutions – such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC) – as well as to FSIS.

The 3 parts of the public health model are:

- Assessment
- Policy Development
- Assurance

The Assessment Component:

The first area, "Assessment," is the activity by which known or potential public health problems are identified and assessed with respect to the magnitude of the problem and the potential impact on public health. The assessment component is focused on gathering, analyzing, and interpreting data about public health problems using science. The part of FSIS that has primary responsibility for assessment in FSIS is the Office of Public Health Science, or OPHS. However, you will do some of this in your daily work as well.

The Policy Development Component:

The second area is "Policy Development." The word "policy" includes legal regulations, guidance and other rules, documents and strategies issued by FSIS. Policy development is defined as the process by which society makes decisions about problems, chooses goals and the proper means to reach them, handles conflicting views about what should be done, and allocates resources to deploy those policies. The Agency's policies serve to translate issues affecting public health into a course of action that minimizes the risk of foodborne illnesses. The Office of Policy and Program Development (OPPD) has the major responsibility for policy development in FSIS. You will be responsible for carrying out the policies in your day-to-day activities.

The Assurance Component:

The third area is "Assurance." Assurance is the activity that verifies FSIS performance measures and targets and validates that the Agency is effective in achieving the desired results. This is the function of providing services and implementing Agency policies and procedures to meet public health needs. One aspect of this is done through policy evaluation and the enforcement of established statutory and regulatory responsibilities which hold industry accountable for ensuring that meat, poultry, and processed egg products are safe, secure, wholesome, and accurately labeled. FSIS assurance also

occurs through domestic and import inspection activities and verification testing. We must assure the American public that the USDA mark of inspection found on meat, poultry, and egg products means what it says – that product is safe, wholesome, and properly labeled.

The Office of Field Operations (OFO) has the primary role for assurance in FSIS. You, as a PHV, are assigned to work within OFO.

FSIS STRATEGIC PLANNING

To provide the direction to fulfill its mission, FSIS identified three strategic goals, each with its outcomes and objectives developed to accomplish these goals. The first goal, “Prevent Foodborne Illness and Protect Public Health,” focuses directly on FSIS’s public health mission and its activities, including verification, enforcement, investigation, and outreach to prevent and respond to foodborne illnesses linked to the products it regulates and ensures that a culture of food safety remains at the forefront. The second goal, “Transform Inspection Strategies, Policies, and Scientific Approaches to Improve Public Health,” ensures FSIS’s activities are designed to improve how the Agency conducts food safety activities. This involves assessing the results of the Agency’s verification, enforcement, and other activities and combining those assessments with the best available data and science to develop policies and regulations that best protect the public’s health. The third goal, “Achieve Operational Excellence,” recognizes that having a strong foundation through internal FSIS functions is necessary to provide the support the Agency needs to meet Goals 1 and 2. This includes focusing on all internal services from information technology to financial management; having an empowered and well-trained workforce; and implementing a strong governance structure.

A link to the FSIS Strategic and Annual Plans can be found here. Within the Strategic Plan you will find the goals mentioned above, as well as FSIS’s Core Values (Accountable, Collaborative, Empowered, Solution-Oriented) and the FSIS mission and vision.

FSIS: PART OF THE FOOD SAFETY SYSTEM

FSIS, along with FDA, Animal and Plant Health Inspection Service (APHIS – part of USDA), and EPA are among the primary food safety agencies that are supported by a number of other agencies that have food safety responsibilities. You will learn that as part of the food safety system, at times, you may work with others outside of FSIS in your role as a PHV. For more information from the U.S. Department of Health and Human Services, use this link.

FSIS LEADERSHIP COMPETENCIES

Competencies are behaviors that encompass the knowledge, skills, behaviors, and other attributes required to build a high-performance organization capable of meeting current and future challenges. The FSIS Leadership Competency Model is made up of 18 competencies divided into two categories:

- Foundational Competencies – represent the basic and minimum competencies expected of an FSIS leader. Examples include Integrity & Honesty, Oral and Written Communication, and Public Service Motivation.
- Core Leadership Competencies – build on the Foundational Competencies to include leader-specific skills. Examples include Adaptability, External Awareness, Problem Solving, and Team Building.

FSIS developed a Leadership Competency Model to build upon and sustain a foundation of qualified and trained professionals like you to meet our current and future needs. More information can be found

in IPP Help (located under FSIS Applications) within the Leadership Competency Portal (VPN required).

SUMMARY

FSIS has an important role to play to protect public health. As a PHV, you are on the front line of our public health workforce.

Human Resources Basics

OBJECTIVES

1. Become familiar with the FSIS policies concerning the following topics: performance management, probationary employees, official personnel files, general pay schedule, within grade increases, staffing methodology, career counseling, merit promotion, ethics, and work unit meetings.

RESOURCES

USDA Departmental Regulation 4040-430
Office of Personnel Management eOPF landing page
OPM General Schedule Overview
OPM Within Grade Increase Fact Sheet
FSIS Civil Rights Website
USDA Office of Ethics Website

PERFORMANCE MANAGEMENT

Performance standards are established for each position in FSIS. The supervisor must provide each employee with a "Performance Plan and Appraisal" Form AD-435 at the beginning of each performance year or when the employee is assigned to a different position with substantially different duties and responsibilities, for example, promotion, reassignment, or a detail or temporary promotion for 90 or more days. The supervisor meets with the employee quarterly to discuss and review their performance with regard to each element in the performance plan. Rating officials and employees use a web-based application called Enterprise Performance Management Application (EPMA) to sign and date that the review took place.

Supervisors are obligated to advise an employee when the employee's performance drops below the fully successful level. When an employee's performance drops below the fully successful level, contact the Labor and Employee Relations Division (LERD) for assistance in:

- Monitoring the employee's performance; and
- Providing the employee an opportunity to demonstrate better performance if it is less than the acceptable level.

PROBATIONARY EMPLOYEES

Newly hired federal employees must undergo a one-year probationary period. If a new employee is not performing at the minimum acceptable level, the supervisor needs to address the problem well before the one-year period expires. Contact LERD for assistance at least 90 days before the expiration of the probationary period. While "just cause" is required to terminate a probationary employee, the purpose of this one-year period is to permit the federal government to identify those employees not suitable for continued federal employment. Similarly, if a probationary employee exhibits conduct problems, the supervisor should immediately contact LERD.

OFFICIAL PERSONNEL FOLDER

OPF is the common acronym for the Official Personnel Folder. “The OPF is the official repository of records and reports of personnel actions affected during an employee’s civilian government service, and documents and papers required in connection with such actions.” Examples of documents contained in your OPF are the SF-50s indicating pay increases, your election or non-election form for the federal life insurance program, SF-52s indicating selections for promotions, details, or lateral assignments, health insurance forms, beneficiary forms for life insurance and TSP funds, and other related documents.

Your OPF is established when you first become employed with the federal government. You may access your electronic OPF (eOPF) online at this link.

GENERAL SCHEDULE SYSTEM

The general schedule system, established in the late 1940s, focused on centralized planning and the application of uniform methods for a specific job series (e.g., position rather than performance).

Certain federal employees are hired at a specified General Schedule (GS) level. There are 15 grade levels (GS-1 through GS-15) and there are 10 steps within each GS grade level. Cost of Living Allowances (COLA) are increases to the GS pay scale that are determined annually by Congress and the President. Certain cities and metropolitan areas with a high cost-of-living are given a larger annual increase, called a “locality pay” differential (e.g., an employee in Los Angeles, a high cost-of-living city, receives a slightly higher annual pay rate than an employee in a city with a standard cost-of-living, such as Jacksonville, FL). The Office of Personnel Management’s website contains listings of the various locality pay rates of high cost-of-living cities and areas in the U.S.

WITHIN GRADE INCREASES

Within Grade Increases (WGIs) are regularly occurring pay increases given to GS employees in grades 1-15.

The typical employee starts at the Step 1 level, and for employees in any grade, a WGI occurs:

- At Steps 2-4, every year
- At Steps 5-7, every 2 years
- At Steps 8-10, every 3 years

If an employee’s performance is not at a fully successful level, a WGI is not granted. The supervisor must have documentation reflecting the employee’s unacceptable level of performance. Supervisors need to involve LERD in this process well before the 90 days prior to the WGI anniversary date. The employee is given an opportunity to bring their performance up through a Demonstration Opportunity of usually 30-60 days.

STAFFING METHODOLOGY

Staffing levels are determined by OFO management personnel by assessing the workload in an establishment. Full-time staffing options include hiring from the outside, reinstatement of former employees, and reassignment of an employee from another position. When a full-time staffing vacancy in an establishment occurs, the District Office (DO) sends Form SF-52 to the Human Resources Field Office to initiate the re-staffing process.

Use of Intermittent Employees (WAE- When Actually Employed)

There are often “temporary” staffing vacancies at the in-plant level caused by employees using leave, attending training or a meeting, etc. The supervisor should contact their Frontline Supervisor (FLS) and/or DO in advance of these short-term staffing vacancies (when possible) for guidance on using an Intermittent or WAE employee. The ability to use an Intermittent, or WAE, is sometimes affected by budget concerns.

The DO, and the Human Resources Field Office, strives to maintain a number of eligible intermittent employees in the local areas for use in these short-term staffing vacancies. Intermittent employees are only eligible to work 1,280 hours per year and are hired on an on-call basis.

Intermittent employees are not regular part-time federal employees. They do not receive the benefits of regular part-time and full-time FSIS employees and do not accrue leave. Intermittent employees are provided on-the-job training at the establishment where their services are used.

CAREER COUNSELING

Employees can discuss career opportunities with a supervisor, an experienced employee in the same occupation series for which they might qualify, or a representative of a professional association, such as the National Association of Federal Veterinarians (NAFV) or the Association of Technical and Supervisory Personnel (ATSP). The Veterinary Career and Life Cycle Model has information on the different types of veterinary careers in FSIS and can be found on the IPP Help button ((located under FSIS Applications) within the Career Pathways Charts and Job Competencies (VPN required).

Supervisors should seek advice from their manager on how to counsel subordinates. The IPP Help button (located under FSIS Applications) contains multiple resources that can help Agency employees plan and develop their careers. Supervisors can assist direct reports by reviewing inspectors’ job applications, as long as they are not involved in the selection for that particular vacancy. All employees should be encouraged to discuss developmental needs with a supervisor at their performance review meetings.

MERIT PROMOTION

Federal employees who want to advance their career opportunities within the federal government must look for job opportunities and submit an application. A “vacancy announcement” is prepared and distributed which advertises a vacant position, with a request for all qualified applicants. The vacancy announcement will contain the area of consideration, which lets potential applicants know if they are eligible to apply. If the area of consideration is “internal to an agency”, only internal employees can apply; if it is “competitive service”, all federal employees can apply; if it is “open to the public”, this means anyone within or outside the federal government can apply. The application solicitation period is indicated on the vacancy announcement and usually runs 1-2 weeks.

Applications for field positions are sent to the Human Resources Field Office in Minneapolis, and for Headquarter positions to the Human Resources Division in Washington, DC. Applicants submit a résumé which addresses the knowledge, skills, and abilities required and must also attach a copy of their last performance appraisal.

To be considered for selection, applicants must:

- Apply by the deadline contained on the vacancy announcement.
- Be evaluated based on the vacancy requirements (e.g., degrees, knowledge, skills, and abilities) stated in the vacancy announcement.

The Human Resources Office will:

- Screen each application for basic eligibility.
- Identify which qualified applicants must compete for the position and which do not.
- Refer the applications of non-competitive, qualified applicants to the hiring manager.
- Rank competitive applicants for inclusion in the “best qualified” group.
- List the “best qualified” applicants in alphabetical order on the certificate.
- Refer “best qualified” applicants to the manager for selection consideration.

Managers can select from the “best qualified” list, a list of non-competitive applicants, or they can fill the position from a different source, e.g., re-announcing or expanding the geographic area of consideration.

Merit Promotion and Interviewing

When Recommending Officials conduct interviews, they must use Behavioral Event Interviewing (BEI) methodology. BEI asks questions that will predict how an applicant will perform in the workplace. The questions asked are based on the skills required of the position, e.g., leadership, cognitive, managerial.

CIVIL RIGHTS STAFF

The Civil Rights Staff is located at Headquarters in Washington, DC with representatives in various field locations. The staff conducts mediation, team building, and other conflict resolution services.

If you have a question or concern about the Civil Rights Division policies and practices, visit the FSIS Civil Rights Website.

ETHICS

If you have any questions concerning an ethical matter, you can seek advice and guidance from your supervisor, and/or an Employee Relations Specialist in LERD to resolve conflicts of interest. You can also contact a U.S. Department of Agriculture Ethics Advisor at this website.

Because of our regulatory role in official establishments, bribery situations can and do occur. FSIS employees who are offered a bribe, or who believe that a bribe was offered to, solicited by, or accepted by another employee, should immediately contact the USDA Office of the Inspector General (OIG) (without disclosing this information to the person offering the bribe). OIG will provide instructions on how to proceed.

WORK UNIT MEETINGS

Work unit meetings are an opportunity to discuss new policies, conduct training, correlate procedures, and solicit the concerns of the group. They are often conducted when IPP are on-duty, but the establishment is not operating (e.g., on a “dark day,” a day the establishment is not working during normal operating hours). However, if overtime proves to be necessary, be sure to get pre-approval from your FLS, since expenditure of funds is involved. If the work unit meeting is scheduled in advance, you

also need to notify the local National Joint Council (NJC) union representative of the time and date to give them an opportunity to attend.

Some work unit meetings are initiated by the DO or the FLS, who will often direct that a work unit meeting be held. These meetings should be held during regular tours of duty, not at lunch or on designated breaks.

Sanitary Dressing, Procedures Controlling Contamination, and Food Microbiology (Pre-Harvest)

OBJECTIVES

1. List potential situations of concern in the Delivery/Holding context, e.g., food defense, ramifications for pathogens, etc.
2. Identify and explain conditions in the Delivery/Holding area that can affect sampling conducted during Processing.

RESOURCES

FSIS Meat and Poultry Hazards and Controls Guide
Pre-Harvest Management Controls and Intervention Options for Reducing STEC in Cattle: Overview
FSIS Industry Guideline for Minimizing the Risk of STEC in Beef (including Veal) Slaughter Operations
FSIS Guideline to Control *Salmonella* in Swine Slaughter and Pork Processing Establishments
FSIS Guideline for Controlling *Salmonella* in Raw Poultry
FSIS Guideline for Controlling *Campylobacter* in Raw Poultry
FSIS Food Defense Risk Mitigation Tool: Slaughter & Meat/Poultry Processing: Slaughter

INTRODUCTION

Per 9 CFR 417.2(a)(1), every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. FSIS recommends that establishments focus on pre-harvest controls and requires effective sanitary dressing and processing controls to prevent microbiological contamination and the creation of insanitary conditions.

This module focuses on how establishments may address biological hazards and control contamination prior to slaughter. FSIS encourages pre-harvest interventions as the first control steps in the slaughter food safety system.

The FSIS Meat and Poultry Hazards and Controls Guide provides information to help FSIS inspection program personnel evaluate different aspects of a meat or poultry establishment's hazard analyses. The guide describes potential biological hazards and frequently used controls and preventative measures at the Livestock Slaughter "receiving and holding" step and the Poultry Slaughter "receiving live birds and live bird hanging" step. **Note:** This is a guidance document. Differences between the guide and an establishment's hazard analysis are not, in themselves, sufficient to support noncompliance.

PRE-HARVEST FACTORS AFFECTING CONTAMINATION

There are a variety of pre-harvest factors that may impact incoming pathogen load on live animals. FSIS developed guidelines for cattle, swine, and poultry which describe how establishments may minimize the risk of pathogens in their operations. These guidelines include information on pre-harvest interventions and management practices to prevent or reduce incoming pathogen load.

Livestock Pre-Harvest Factors: Cattle

Livestock farm/feedlot management practices may reduce fecal shedding during transport and handling. Fecal shedding in cattle is a hazard that occurs at pre-harvest and can continue in the holding pens at the establishment. This shedding may result in contamination of the hides, which can subsequently be transferred to the exposed carcass during carcass handling/preparation (dressing). FSIS recommends that slaughter establishments receive their cattle from beef producers that implement one or more documented pre-harvest management practices to reduce fecal shedding. FSIS guidelines describe the current research on pre-harvest best practices to reduce the spread of Shiga toxin-producing *Escherichia coli* (STEC). Some examples include:

- Clean water and feed
- Clean environment that is appropriately drained (minimize brisket contamination)
- Reduced animal density
- Biosecurity (exclusion of wildlife to extent possible, pest management)
- Cross-contamination among animals from different farms (during transport, holding)
- Transportation (stress of handling and transportation may affect fecal shedding of STEC)
- Hide washing
- Water mist in holding pens (to reduce dust)
- Mud scoring system
- Live animal treatments (bacteriophage, vaccines)
- Determine incoming bacterial load on animals
- Determine whether age, type of cattle (veal), or season (high prevalence) represent a concern

Livestock Pre-Harvest Factors: Swine

As described above for cattle, swine farm/feedlot management practices may reduce fecal shedding during transport and handling. FSIS recommends establishments work closely and establish communication with their swine suppliers. This is to identify and address on-farm controls as a means of targeting multiple areas of swine production through pre-harvest control of *Salmonella*. Control of *Salmonella* at the herd level is critical to prevent the spread on-farm, before hogs reach the slaughter line. Pre-harvest controls and interventions provide the establishment an opportunity to reduce the spread of *Salmonella* and improve the condition and quality of hogs entering the slaughter environment. FSIS Guideline to Control *Salmonella* in Swine Slaughter and Pork Processing Establishments describes a variety of pre-harvest measures and best practices. Some examples are listed below.

Pre-harvest measures to control *Salmonella* (Swine)	**Best practice example**
Farm Rearing, Housing, and Biosecurity	Pest control for rodents and arthropods
Water and Feed Management	Acidification of feed/water using organic acids
Vaccine and Bacteriophage Interventions	Vaccinate to reduce shedding in herds
Live Animal Transport	Prolonged transport may induce pathogen shedding
Lairage	Minimize time hogs are held in lairage

Poultry Pre-Harvest Factors

In poultry, pathogens (*Salmonella* and *Campylobacter* spp.) are usually present on incoming live birds. Establishments should use multiple steps in the process to reduce these hazards to an acceptable

level. Pre-harvest and transport practices may reduce pathogen loads so that later controls (for example, sanitary dressing procedures and antimicrobial interventions) function as intended to control the hazards.

There are numerous routes of exposure to pathogens during pre-harvest including transmission through the egg from the breeder flock to chicks (*Salmonella*); transmission between birds during hatch and grow-out; exposure to contaminated water, feed, and bedding in the grow-out house; and environmental exposures due to poor biosecurity practices and inadequate pest control.

FSIS recommends that establishments manage pre-harvest colonization of poultry with *Salmonella* and *Campylobacter* by receiving birds from breeder flocks, hatcheries, and grow-out houses that use recognized pre-harvest interventions to decrease contamination of the live birds. Alternatively, establishments may test incoming birds before entry into the establishment and make processing decisions based on those test results. For example, the establishment could use these test results to implement a scheduled slaughter and processing plan based on the presence or absence of the pathogens.

FSIS guidelines provide six categories of approach to reduce pre-harvest exposure to *Salmonella* and *Campylobacter*, along with recommended best practices for each. The approaches and an example are listed below. You can find more examples in the respective FSIS Guidelines for Controlling *Salmonella* and *Campylobacter* in Poultry.

Approach to reduce pre-harvest pathogens (Poultry)	**Best practice example**
Breeder Flock & Hatchery	Obtain chicks from pathogen-free breeder flocks
Grow-out House	Implement on-farm biosecurity and hygiene plans
Bedding	Downtime between flocks to allow moisture removal and desiccation of litter
Feed	Time feed withdrawal appropriately
Water	Clean water distribution systems between flocks
Transportation	Clean and disinfect transport crates between loads

PRE-HARVEST FOOD DEFENSE PRACTICES

IPP follow instructions in FSIS Directive 5420.1 “Food Defense Tasks and Threat Notification Response Procedures for the Office of Field Operations” when conducting food defense activities and observing and reporting food defense vulnerabilities. Examples of food defense mitigation strategies an establishment may utilize can be found using the FSIS Food Defense Risk Mitigation Tool. For example, inputting “Slaughter & Poultry Processing” and “Slaughter” into the tool will provide example mitigation measures for pre-harvest, such as “limit access to production/slaughter and holding-pen areas to facility employees and FSIS inspection personnel” and “when selecting transportation companies and suppliers, consider the company’s ability to safeguard the security of the product/animals being shipped.”

Professionalism and Ethics

OBJECTIVES

1. Distinguish between appropriate and inappropriate behaviors by IPP and establishment employees.
2. Create an action plan to address employee misconduct.
3. Identify when a PHV should contact a Labor and Employee Relations (LERD) specialist.
4. Demonstrate professional behavior when communicating with establishment personnel.
5. Demonstrate effective communication and teambuilding skills in correlations with IPP and FSIS Work Unit Meetings.

RESOURCES

FSIS Directive 4735.7 – Industry Complaints Against FSIS Program Employees (see attachment 2-1)
FSIS Directive 4735.9 – OFO Assignment Restrictions and Rules on Gifts from Regulated Industry
USDA Office of Ethics
14 General Principles of Ethical Conduct
Hatch Act Illustrated and Explained (video)
Supervisor Help: Conduct vs. Performance (VPN required)
Supervisor Help: Reasonable Accommodations (VPN required)
FSIS Workplace Violence Resources and Policies

INTRODUCTION

Professionalism is critical in achieving FSIS's mission and in protecting the public's health. To achieve our public health mission, we must maintain a safe and professional workplace. We must have management and accountability systems in place. Like all professionals, we have a set of tools that we use in our work – the Acts, due process, and professionalism.

Conduct and behavior affect how we regard each other and industry's perception of the FSIS workforce. Conduct perceived as "unprofessional" adversely affects our integrity, consumer confidence, and our ability to carry out our public health mission. Protecting our employees and the public is essential to FSIS.

The consequences of "unprofessional conduct and behavior" put you and the public at risk relative to food safety and biosecurity, because it detracts from inspection responsibilities, authority to enforce food safety standards, and effectiveness.

FSIS values each and every one of you. You represent FSIS and that means being a person of integrity and honesty, respecting others, taking pride in your work, and being committed to excellence.

CHARACTERISTICS OF A PROFESSIONAL

Professionalism is defined as "the conduct, aims, or qualities that characterize or mark a professional person". So, what characteristics define a professional? An FSIS professional is someone who:

1. Displays personal integrity and honesty;

2. Is committed to excellence;
3. Shows respect for others;
4. Takes pride in public service; and
5. Protects the public's health.

Attachment 2-1 in FSIS Directive 4735.7 "Industry Complaints Against FSIS Program Employees" provides "Relationship Principles" which help establish and foster better relationships with industry. You should consider these principles and incorporate them in your daily work activities. Your actions will contribute towards creating a safe, professional workplace.

ETHICAL CONDUCT

FSIS Directives 4735.3 "Employee Responsibilities and Conduct" and FSIS Directive 4735.9 "OFO Assignment Restrictions and Rules on Gifts from Regulated Industry" cover FSIS employee conduct and ethics. They outline FSIS employee responsibilities, ethical conduct requirements, prohibited activities, and specific procedures regarding ethical employee conduct (such as employee assignment restrictions and gifts from regulated establishments).

Employees who have questions about the application of ethics requirements or specific situations should seek advice from an Agency Ethics Official. Ethics questions can be sent to Ethics-FoodSafety@usda.gov. Frequently asked questions, training, and other guidance is available on the USDA Office of Ethics website.

FSIS employees are required to maintain high standards of honesty, integrity, impartiality, and conduct. We are required to carry out our responsibilities following Agency policies to retain the confidence of citizens. Citizen confidence in the Agency is influenced not only by the manner in which employees serve the public but in the way they conduct themselves in the eyes of the public. The avoidance of misconduct and conflicts-of-interest through informed judgment is indispensable to the maintenance of these standards.

Standards of Ethical Conduct

In accordance with 5 CFR 2635.101, each employee has a responsibility to the United States Government and its citizens to place loyalty to the Constitution, laws, and ethical principles above private gain. To ensure that every citizen can have complete confidence in the integrity of the federal government, each employee shall respect and adhere to the principles of ethical conduct set forth in applicable laws, regulations, and executive orders.

All matters covering ethics, such as employment restrictions, outside employment and activities, financial interests and land ownership, gifts and gratuities, purchase of product, and political activity, are covered under Standards of Ethical Conduct for Employees of the Executive Branch.

The department that advises on these rules and regulations is the USDA's Office of Ethics. They have a dedicated email inbox for ethics issues specific to FSIS: sm.oe.foodsafety@usda.gov.

Reporting Misconduct

All employees are responsible for reporting misconduct and should promptly report it to their supervisors (or next higher-level supervisor if they think their supervisor may be involved). Employees are to disclose waste, fraud, abuse, and corruption to the USDA, Office of Inspector General (OIG) at www.usda.gov/oig/hotline.htm or by phone at 800-424-9121.

Employees are to report bribery or attempted bribery directly to OIG. The employee shall not disclose the information reported or that it was reported without the prior OIG or FBI approval. Federal law protects federal employees against reprisal for whistleblowing.

Conflict of Interest and Misuse of Position

Employees who find themselves in an actual conflict, a potential conflict, or in a situation that could give the appearance of a conflict of interest shall immediately make known to their supervisor the nature of the situation. FSIS Directive 4735.9 "OFO Assignment Restrictions and Rules on Gifts from Regulated Industry" specifically addresses assignment restrictions and family or personal relationships, as well as gifts from outside sources.

Under the primary criminal conflict of interest law (18 USC 208), you must not participate in any matter, as part of your official duties, if it would have a direct predictable effect on your financial interests, or those of your spouse, minor child, general partner, outside employer including any organizations you serve as officer, director, trustee, general partner or employee, or any person or organization with whom you are negotiating or have any arrangement concerning prospective employment.

If your friends or relatives have any kind of dealing with FSIS or USDA, you cannot use your position to try to intercede on their behalf and help them. If your duties affect the financial interests of a friend, relative, or other person connected to you outside of government, there may be an appearance of misuse of position or preferential treatment depending on the circumstances. You cannot use your position to endorse any product, service or company, except where it is part of your official duties to do so. You cannot use nonpublic information (information you receive in the course of your job that is not available to the general public) for the financial gain of yourself or others. You cannot use government property for any reason other than government purposes. This includes government buildings, telephones, computers, office equipment, supplies, government vehicles, etc.

Refer to 5 CFR 2635.401-403 regarding conflicting financial interests and to 5 CFR 2635.701-705 for misuse of position.

Impartiality

The impartiality rule focuses on appearances that the performance of your official duties would be affected by your outside affiliations and relationships. This rule applies even when the employee is free of financial conflicts of interest.

Briefly stated, the impartiality rule requires an employee to consider appearance concerns before participating in a particular matter if someone close to the employee is involved as a party to that matter or represents a party to the matter. This requirement to refrain from participating (or "recuse") is designed to avoid the appearance of favoritism in government decision-making.

If you are in a situation where a reasonable person would question your impartiality, you must not work on that matter unless you have informed your supervisor and the Agency's ethics official about it and have been cleared to participate. The impartiality rule is the most applicable ethics regulation when dealing with assignment policy issues.

Refer to 5 CFR 2635.501-502 regarding impartiality in performing official duties.

Assignment Restrictions and Family or Personal Relationships

FSIS Directive 4735.9 "OFO Assignment Restrictions and Rules on Gifts from Regulated Industry" states that employees shall not be assigned to any establishment where:

1. A member of the employee's immediate family (i.e., mother, father, sister, brother, spouse, or child) is employed by the establishment regardless of the positions held by either party;
2. Extended family members (i.e., in-laws, stepparents, step children, step siblings, half siblings, aunt, uncle, niece, nephew, cousin, grandparents, and grandchildren) work in a supervisory, managerial or policy-making capacity at the establishment or are employed by the establishment and reside with the employee; or the employee and an establishment employee are engaged in a personal relationship (i.e., dating, living with, engaged, or involved financially e.g., through child support, alimony, palimony, or general household finances).

The analysis to go through when encountering this situation is:

1. Would the assignment violate the FSIS policy in FSIS Directive 4735.9?
2. If yes, then does FSIS want to pursue an exception? (coordinate with your District Office and chain of command)
3. Does an ethics law or regulation prohibit FSIS from granting the exception? (because an underlying ethics law or regulation will be violated)

**Generally, the Office of Ethics should only become involved where an exception to the FSIS assignment policies is being considered. **

For an exception to be considered, please email the information below to sm.oe.foodsafety@usda.gov:

1. Name of employee.
2. Relationship: who they have a relationship with, what relationship, what job does that person have?
3. Official interaction: does employee and other person have official interactions and, if so, what types of interactions?
4. Other overlap: even if no official interaction, what overlap (if any) is there? What potential is there for the FSIS employee to affect the other person's work/job?

The Federal Meat Inspection Act and Gifts from Outside Sources

Under the FMIA, 21 U.S.C. 622, federal meat inspectors and others with duties under the FMIA are prohibited from accepting any gift, money or other thing of value from anyone engaged in commerce (e.g., a plant employee). This is a criminal statute, punishable by a fine of up to $10,000 and imprisonment for up to 3 years.

If you are a federal meat inspector, or someone with duties under the FMIA, then the FMIA supersedes the Gifts from Outside Sources regulation.

As a federal employee, you must not accept gifts from a prohibited source. You must never solicit a gift. All employees authorized to perform duties under the Act are prohibited from receiving anything of value given with the intent to influence their performance of official duties. Examples of circumstances that do not constitute acceptance of a thing of value are covered in FSIS Directive 4735.9 "OFO Assignment Restrictions and Rules on Gifts from Regulated Industry."

There are a few exceptions to both these rules, such as exchanges of low value where no appearance of impropriety and would be awkward to refuse (i.e., cup of coffee). However, please reach out to the Office of Ethics if your job duties involve or affect the person giving you the gift or if you have other questions on this.

Refer to 5 CFR 2635.201-205 regarding gifts from outside sources and 21 U.S.C. 622 of the FMIA.

Gifts Between Employees

You must not (1) give a gift to your supervisor or anyone higher up the chain, or (2) accept a gift from any lesser-paid employee unless you have a personal relationship to justify the gift and neither is in the supervisor chain of the other. There are some exceptions regarding gifts between employees. Contact Ethics-FoodSafety@usda.gov with specific questions.

Refer to 5 CFR 2635.301-304 regarding gifts between employees.

Outside Employment and Activities

An FSIS employee must not engage in any outside employment or activity, regardless of whether you are compensated, if the outside activity creates a substantial conflict with your official duties or creates the appearance of a substantial conflict of interest with your official duties.

All compensated outside positions and certain volunteer positions must be approved by the employee's chain of command and the Office of Ethics. Employees submit form OE-101, Application for Approval to Engage in Non-Federal Employment or Activity to their supervisor within a reasonable time before the employee proposes to begin the employment. More guidance on outside activities and employment, including farming/ranching, is located on the USDA Ethics Website.

Refer to 5 CFR 2635.801-809 regarding outside activities and 5 CFR 8301.104 for the FSIS supplemental ethics regulation.

Seeking Employment

If you are seeking employment with a person or company, or have an arrangement concerning future employment with them, then you cannot participate in any matter involving that person or company as part of your official duties, if their financial interests could be affected by your performance of your duties.

It is important to note that seeking employment is a low threshold and begins when you communicate, respond, or negotiate about possible employment with a potential future employer, regardless of who initiates the contact. Seeking employment ends when either party affirmatively rejects the possibility of employment and all discussions end, or when two months have transpired since you submitted an unsolicited resume and you have not received any indication of interest from a prospective employer.

Refer to 5 CFR 2635.601-606 regarding seeking other employment.

Political Activity

Employees are permitted to engage in political activity, except for specific activities prohibited by law. Federal employees should be aware of the Hatch Act, including when use of social media could violate the Hatch Act. FAQs are located on the Office of Special Counsel website.

Transactions with Regulated Establishments and their Employees

FSIS Directive 4735.9 "OFO Assignment Restrictions and Rules on Gifts from Regulated Industry" states that employees may not accept gifts or engage in business or financial dealings (e.g., buying, selling, or trading) with regulated establishments or their employees. This is intended to prevent transactions that are not "routine consumer transactions."

However, it is acceptable for an employee to use a regulated establishment's retail outlets that are open to the general public. It's important to note that the reason this is acceptable is because the employee is paying fair market value for something available to the general public and has purchased it in the same way as available to the general public.

DOCUMENTING PERSONNEL ISSUES

As a supervisor, you are to promptly report all cases of known, alleged, or suspected misconduct to the next higher-level supervisor and discuss with the assigned Labor and Employee Relations Division (LERD) specialist. Supervisors who fail to report misconduct or take other appropriate action are subject to possible disciplinary or adverse action. FSIS Directive 4735.3 "Employee Responsibilities and Conduct" describes the information a supervisor must include when reporting misconduct, as well as measures that can be imposed for misconduct.

Supervisors may give a verbal or written notice, Caution or Warning, or written instructions to an employee when an aspect with conduct is deficient. These are **informal** measures and not disciplinary action.

Officials authorized to take disciplinary (**formal**) actions may issue a Letter of Reprimand based on delinquency or misconduct. Other disciplinary (and adverse) actions taken by authorized officials include suspension without pay, demotion, and removal. Supervisors should work with their chain of command and the District Office.

Proper documentation is key to sustaining disciplinary actions. LERD supports management to maintain good order and discipline in the workplace. Your LERD specialist can be reached at FSISHR1@usda.gov. For employee performance concerns, the Performance Management team can be reached at PerformanceManagement@usda.gov. You will receive more training on these topics in New Supervisor Training.

REASONABLE ACCOMMODATION

FSIS Directive 4306.2 "Reasonable Accommodation and Accessibility for People with Disabilities" provides information on Reasonable Accommodation (RA), which is defined as:

- A modification or adjustment to a job application process that enables a qualified applicant with a disability to be considered for the position.
- A modification or adjustment to the work environment that enables an employee with a disability to perform the essential functions of that position.
- A modification or adjustment that enables an employee with a disability to enjoy equal benefits and privileges of employment as employees without disabilities.

As a supervisor, you should engage in the interactive RA process and act promptly in response to RA requests. The Reasonable Accommodation team can be reached at

ReasonableAccomodations@usda.gov and additional USDA RA resources can be found on the USDA website. You will receive more training on this topic in New Supervisor Training.

TEAMBUILDING

Depending on your assignment, you may lead a team comprised of food inspectors, consumer safety inspectors (CSIs), and/or supervisory CSIs. As a leader, supervisor, and professional, you are responsible for promoting engagement and collaboration on your team. Utilize Agency resources such as the Supervisor Help Button (e.g., Pathways to Success Desk Guide: Teambuilding), FSIS Mentor/Coaching programs, and AgLearn to assist you as you continue to develop effective communication and teambuilding skills. Ask your direct supervisor and other experienced supervisors for their ideas and best practices to facilitate engaging Work Unit Meetings.

Noncompliance Records

OBJECTIVES

1. Given scenarios in the Slaughter/Kill Floor context, identify situations that warrant a regulatory control action (RCA).
2. For those situations that warrant an RCA, write a supportable noncompliance record (NR) including the correct inspection task and regulatory citations.
3. In a Slaughter/Kill Floor context, demonstrate when and how to associate NRs within the Public Health Information System (PHIS).
4. Demonstrate how to document discussions of noncompliance trends in an MOI.

RESOURCES

FSIS Directive 5000.1 – Verifying an Establishment's Food Safety System
FSIS Directive 13000.1 – Scheduling In-Plant Inspection Tasks in the Public Health Information System
FSIS Directive 13000.3 – Responding in PHIS to Industry Appeal of a Noncompliance Record
NR Writing (AgLearn Course)
PHIS Help: Domestic Tutorials – Document an NR, View/modify an NR, Associate NRs (VPN required)
askFSIS: Should IPP complete an NR every time they initiate an RCA?
askFSIS: Documenting noncompliance for direct product contamination
askFSIS: Does a HACCP or SSOP noncompliance carry more "regulatory weight" than a SPS noncompliance?

INTRODUCTION

IPP ensure establishments meet the regulatory requirements regarding Sanitation, HACCP, and activities relating to other consumer protection. IPP document NRs when they determine that an establishment has failed to meet one or more regulatory requirements. As a supervisor, you are to ensure that IPP are correctly applying inspection methodology, are making informed decisions, are properly documenting findings, and are taking the appropriate enforcement actions as instructed in FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System."

FSIS is responsible for treating all facilities consistently and fairly, ensuring that each facility is afforded due process under the law. The Rules of Practice (ROP) are set out in the regulations in 9 CFR part 500. These regulations identify the conditions under which enforcement actions can be taken by the Agency and include the criteria for when those actions are warranted. These regulations ensure that all establishments are afforded due process.

Section 9 CFR 500.1 defines three types of enforcement actions:

1) Regulatory control action: retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.
2) Withholding action: refusal to allow the marks of inspection to be applied to products; may affect all product in the establishment or product produced by a particular process.
3) Suspension: interruption in the assignment of program employees to all or part of an establishment.

FSIS may take withholding actions and suspensions with or without prior notification (9 CFR 500.3 and 500.4).

REGULATORY CONTROL ACTION

A regulatory control action (RCA) is a limited focus action that is used to address specific problems that IPP come upon while performing their verification activities. RCAs permit IPP to identify regulatory noncompliance and prevent the movement of product involved or use of equipment or facility involved until the noncompliance has been corrected. IPP are not required to give the establishment prior notification that they are about to take an RCA.

Section 9 CFR 500.2 lists the reasons for which IPP may take an RCA. They are:

- Insanitary conditions or practices
- Product adulteration or misbranding
- Conditions that preclude FSIS from determining that product is not adulterated or not misbranded
- Inhumane handling or slaughtering of livestock

FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" provides examples of when an RCA may be warranted. When IPP identify SPS noncompliance, IPP should take an RCA if there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately (even if no product has yet been contaminated or adulterated). When IPP identify Sanitation SOP noncompliance involving product or direct food contact surfaces, IPP should take an RCA on the affected equipment or product. When IPP identify HACCP noncompliance that includes a deviation from a critical limit or an unforeseen hazard, IPP take RCA if they determine that the establishment has failed to identify all the affected product or that the establishment's corrective action will allow adulterated product to enter commerce.

After taking an RCA, IPP will notify the establishment orally and in writing of the action and the basis for it. The written notification is an NR.

NOTE: IPP do not have to issue an NR every time they apply a "U.S. Rejected" or "U.S. Retained" tag. IPP can initiate an RCA as a means to investigate a situation in order to ensure that adulterated or misbranded product does not enter commerce or that an insanitary condition has not been created. If IPP determine that noncompliance does not exist, they can remove the tag without documenting an NR. In that situation, IPP document a Memorandum of Interview (MOI) to explain the circumstances that prompted the RCA.

NONCOMPLIANCE RECORDS

Identifying Noncompliance

When IPP find noncompliance with one or more regulatory requirements, IPP document an NR (FSIS Form 5400-4). When IPP find noncompliance, they are to:

1) Notify the establishment as soon as possible.
2) Document the noncompliance in the Public Health Information System (PHIS), mark the noncompliance as "final," print the NR, and deliver it to the establishment. IPP are to provide the NR as soon as possible and preferably no later than close of business the following business day, or as instructed by supervision.

3) Verify the establishment takes actions to return to compliance with the applicable regulation(s) found noncompliant.
4) Mark the NR and inspection task "complete" when the establishment has returned to compliance with all regulations found noncompliant in the NR.

Documenting Noncompliance

IPP use PHIS to document the NR in the PHIS electronic format following the instructions in FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System." The date, NR number, inspection task, and establishment number are automatically entered by PHIS. IPP enter the following information into PHIS to document the NR:

- Relevant regulations
- Description of noncompliance, including description of any trends
- Affected product information
- Product adulteration information
- Retained/Rejected tag numbers
- Sample form number (if NR is associated with an FSIS sample result)
- Who the NR is addressed to
- Personnel notified
- Signature of IPP

IPP should include a description of each noncompliance in clear, concise terms, including the problem, time of occurrence, location, and effect on the product, if any. The description should clearly explain how IPP's findings support the determination that the establishment did not meet regulatory requirements. IPP should include an explanation of how IPP notified establishment management of the noncompliance.

NOTE: In most cases, it is not necessary to include references to the Acts or to quote the applicable regulation in full in the description of noncompliance. IPP can paraphrase the regulation as a means of explaining how their findings support the determination that the establishment did not meet regulatory requirements.

FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" has more specific information on documenting Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (Sanitation SOPs), and Hazard Analysis and Critical Control Point (HACCP) verification results in Chapter V – Documentation and Enforcement.

Associating Noncompliance

After IPP document a noncompliance, they are to consider whether the noncompliance is associated with previous noncompliances at that establishment. IPP are to associate two or more NRs when they indicate an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system. **Note:** IPP are to notify their supervisors when repetitive noncompliances or systemic problems are documented. As a supervisor, you will engage in discussion with IPP about their findings and any trends or systemic concerns.

IPP should consider several factors in deciding whether to associate NRs, including whether: the noncompliance is part of an ongoing trend; a trend is developing; the establishment's further planned actions were not implemented; the establishment's further planned actions were not effective in

reducing the frequency of noncompliances; and if the establishment finds it necessary to continue to evaluate and implement measures to address recurring noncompliances on an ongoing basis.

IPP are to associate NRs when they determine:

1) One NR indicates that the establishment's corrective actions for a previous NR were not implemented or did not prevent recurrence of the same noncompliance.
2) Two or more NRs demonstrate repetitive failures of the same aspect of the establishment food safety system.

PHIS allows IPP to select a recent similar NR and associate it to the new NR. When there is a developing trend of noncompliance, the number of the associated NR and a description of how the NR is associated is included in the description block. IPP are also to describe any unsuccessful further planned actions taken by the establishment to address the noncompliance.

NOTE: IPP are to discuss a developing trend of noncompliance with establishment management at the weekly meeting and document the discussion in an MOI. Further information on documenting weekly meeting MOIs is found in FSIS Directive 5010.1. "Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management."

APPEALS

An establishment may appeal an RCA and may also appeal NRs. FSIS Directive 13000.3 "Responding in PHIS to Industry Appeal of a Noncompliance Record" provides instructions to supervisors for addressing appeals from establishments. Remember that as a supervisor, you play a key role in ensuring that decisions made by IPP are consistent with Agency policy. See FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" section VIII – Supervisory Responsibilities for more information on your supervisory responsibilities regarding IPP inspection methodology.

Humane Handling/Good Commercial Practices

OBJECTIVES

Scientific:

1. Select acceptable methods for moving conscious, disabled livestock to a different area.
2. Given a scenario, recognize conditions in or around the livestock holding pens in an establishment that might cause injury to animals.
3. Given scenarios, observe an establishment's Good Commercial Practices (GCPs) and evaluate the GCPs according to prescribed standards.

Regulatory/Administrative:

1. Differentiate between situations in which a PHV would document an MOI, e.g., an isolated observation of mistreatment of a single live bird as opposed to other situations demonstrating a loss of process control in which a PHV would document a noncompliance.
2. Given scenarios, explain the actions IPP take upon observing inhumane treatment due to facility deficiency or disrepair, egregious actions by an establishment employee, or improper stunning.
3. Given scenarios, recognize the humane handling responsibilities in the Delivery/Holding context that apply to FSIS, the establishment, or both, and use the Humane Methods of Slaughter Act and 9 CFR 313 to determine whether an establishment's animal handling is compliant.

Note: The following section references the District Veterinary Medical Specialist (DVMS), consistent with FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock." In some assignments, you may work with a District Veterinary Medical Officer (DVMO) instead of or in addition to a DVMS. DVMOs are GS-13 level non-supervisory positions that serve as primary contacts for all veterinary duties associated with food safety, animal welfare, foreign animal disease surveillance, ante-mortem and post-mortem procedures and dispositions, and export certification.

RESOURCES

FSIS Directive 6900.2 – Humane Handling and Slaughter of Livestock
FSIS Directive 6110.1 – Verification of Poultry Good Commercial Practices
FSIS Directive 12,600.1 – Voluntary and Other Reimbursable Inspection Services
Compliance Guide for a Systematic Approach to the Humane Handling of Livestock
70 FR 56624 – Treatment of Live Poultry Before Slaughter
Humane Interactive Knowledge Exchange (HIKE) Scenarios
Humane Methods of Slaughter Act
Humane Handling Basics (AgLearn course)
Humane Handling: Consciousness and Stunning (AgLearn course)

INTRODUCTION

The use of humane methods in the slaughter and handling of livestock prevents needless suffering, results in safer working conditions for packing house workers, improves the quality of meat products, and decreases financial loss to meat packers.

The Humane Methods of Livestock Slaughter Act of 1978 (HMSA) requires that the slaughtering and handling of livestock, including non-ambulatory disabled livestock, be carried out only by humane methods. Two methods of slaughter were determined to be humane. The first method requires that livestock are rendered insensible to pain on the first application of the stunning device before being shackled, hoisted, cast, or cut. This means that the animal must be unconscious and unable to feel pain before it is "stuck" (veins and arteries severed so it bleeds out), before it is shackled and hoisted into the air, or before it is dropped onto a table/floor.

The second method is in accordance with the ritual requirements of any religious faith that prescribes a method of slaughter where the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument. This method is usually called ritual slaughter. In ritual slaughter, the animal's throat is cut from side to side with a sharp knife, deeply enough for the major arteries and veins to be severed. Examples of ritual slaughter include Jewish (Kosher) slaughter and Islamic (Halal) slaughter.

The regulations for humane slaughter are in 9 CFR part 313. FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock" informs IPP of the verification activities and enforcement actions for ensuring that the handling and slaughter of livestock is humane. FSIS Directive 6100.1 "Ante-mortem Livestock Inspection" includes policy requiring that all non-ambulatory disabled cattle, including non-ambulatory disabled veal calves, that are offered for slaughter be condemned and properly disposed of. IPP verify that establishments are meeting regulatory requirements by performing the Humane Activities Tracking System (HATS) task during every livestock slaughter shift. More information and resources regarding humane handling, including additional training, can be found here.

The HMSA of 1978 does not cover poultry. However, welfare practices for poultry are covered by the regulatory requirement for good commercial practices (GCP). The regulations for poultry good commercial practices are in 9 CFR part 381.65(b). FSIS Directive 6110.1 "Verification of Poultry Good Commercial Practices" provides instructions to IPP on verifying GCP.

SYSTEMATIC APPROACH - LIVESTOCK

In 2004, FSIS published a Federal Register Notice, which stated that a systematic approach was beneficial in meeting the regulatory requirements for humane handling and encouraged livestock slaughter establishments to adopt that approach. The Federal Register Notice outlined four steps to the systematic approach, which are:

1. Conduct an initial assessment of where, and under what circumstances, livestock may experience excitement, discomfort, or accidental injury while being handled in connection with slaughter, and of where, and under what circumstances, stunning problems may occur;
2. Design facilities and implement practices that will minimize excitement, discomfort, and accidental injury to livestock;
3. Evaluate periodically the handling methods the establishment employs to ensure that those methods minimize excitement, discomfort, or accidental injury and evaluate those stunning methods periodically to ensure that all livestock are rendered insensible to pain by a single blow; and
4. Respond to the evaluations, as appropriate, by addressing problems immediately and by improving those practices and modifying facilities when necessary to minimize excitement, discomfort, and accidental injury to livestock.

It is important to understand that there is no regulatory requirement for an establishment to have a systematic approach to humane handling. It is also important to understand that an establishment can have and effectively implement a systematic approach that does not incorporate a written program.

Having said that, FSIS has stated that establishments may choose to develop and implement a robust systematic approach that, among other things, includes a written animal handling program with records that are available for review by FSIS using Attachment 3 of FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock." If the establishment has a robust systematic approach, FSIS will take that into consideration when an incident occurs that involves egregious inhumane treatment.

When establishment management states that it believes it has an animal handling program that equates to a robust systematic approach, you are to ask to review the program and any records generated during its implementation. The PHV, DVMS* and District Office (DO) management are to determine whether the information presented by establishment management meets the criteria for a robust systematic approach. If the criteria are met, the inspector-in-charge (IIC) is to inform the establishment that it has a robust systematic approach and the PHV is to document the determination in an MOI under the Livestock Humane Handling Verification task in PHIS. A copy of the MOI is to be emailed to the DVMS, FLS, and Deputy District Manager (DDM) and provided to establishment management.

If the establishment develops and implements what it considers to be a robust systematic approach and IPP have informed the establishment that the Agency agrees, IPP are to verify implementation of the establishment's robust systematic approach as part of performing their daily HATS procedures. While performing these daily HATS procedures, IPP verify that the establishment is following its animal handling program by using the elements found in Attachment 3 of FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock." This would include observing establishment employees during the handling and slaughter of animals, observing the establishment implementing corrective actions, when appropriate, reviewing the establishment's documents that show it evaluated its robust systematic approach (e.g., stunning and handling practices, maintenance logs for facilities and equipment), and reviewing the establishment's response to its evaluations.

The establishment is not required to provide you access to a written humane handling program. However, without access to the written program, you will not be able to verify effective implementation of a robust systematic humane handling program. Because a documented systematic approach is not a regulatory requirement, failure to implement provisions of such a program is not a noncompliance unless such failure to implement results in an identifiable failure to meet specific regulatory requirements.

If an establishment has implemented a robust systematic approach, but you observe that the establishment is not following its written animal handling program, you should follow FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock" to address your findings. This will include discussion and documentation with the establishment, and your FLS and DVMS.

Note: If an establishment is suspended (Notice of Suspension (NOS)) or receives a Notice of Intended Enforcement Action (NOIE) due to an egregious inhumane handling and slaughter event, they will no longer be considered by FSIS to have a robust systematic approach. The establishment will need to proffer corrective actions and preventive measures to the DO in order to develop a verification plan. The establishment may request a review of their system after the suspension has been lifted to determine if their system is again robust.

***Note:** In some assignments, you may work with a DVMO instead of or in addition to a DVMS.

RITUAL SLAUGHTER - LIVESTOCK

As previously mentioned, slaughtering is permitted without a stunning device in accordance with ritual requirements. An example would be kosher slaughter. The animal is fully conscious when the stick or cut takes place. The cut is done by a specially trained shochet (slaughterer) who is chosen from the community and supervised by a rabbi. The cut is made with a razor-sharp knife called a chalef that is honed after each cut.

In halal slaughter, a person of the Islamic faith or a designee performs the ritual cut. A prayer to Allah is recited during the procedure. You may see a lot of variation in how halal slaughter is done. Many religious authorities will accept stunning either before or after the ritual slaughter cut.

Note: For animals that are ritually slaughtered, the ritual slaughter cut will not be evaluated. But for those establishments that are ritually slaughtering, and in addition utilize stunning methods (found in 9 CFR 313), the stun effectiveness will be evaluated.

The ritual slaughter cut and the handling and restraint that immediately precedes that cut is often called the “ritual bubble”. The activities that occur within that “ritual bubble” fall under Section 1906 of the HMSA and are protected as part of the constitutional right of religious freedom. The statutory requirement that livestock are rendered insensible to pain prior to shackling, hoisting, casting, or cutting does not apply to the handling or restraint that is immediately associated with the ritual slaughter cut. This does not mean that Agency personnel are to ignore completely what happens within the “ritual bubble”—what it means is that Agency personnel do not enforce humane handling regulations within that “ritual bubble”. That said, if you see something during the “ritual bubble” that concerns you, contact your immediate supervisor and the DVMS (or DVMO) for guidance on what action can be initiated.

It is important to understand that ritual slaughter establishments are required to meet all the humane handling regulatory requirements except stunning prior to shackling, hoisting, throwing, cutting, or casting. All animals must be unconscious or insensible to pain prior to any dressing procedures such as head skinning, leg removal, ear removal, horn removal, or opening hide patterns.

When you perform your HATS verification activities, you will observe all HATS categories except stunning effectiveness. An exception to this is when stunning methods are an accepted part of that religious slaughter protocol. Therefore, as noted above, if stunning methods are an accepted part of that establishment’s religious slaughter protocol, you will verify that the stunning method is effectively applied. For the other HATS categories, you will verify the availability of water, check the condition of pens and ramps and that there is no excessive prodding in any part of the establishment when moving animals. You will also verify that after the ritual cut (and any additional cuts to facilitate bleeding) no dressing procedure (e.g., head skinning, leg removal, ear removal, horn removal, opening the hide) is performed until the animal is insensible to pain.

TRUCK UNLOADING - LIVESTOCK

Establishment personnel are required to meet the regulatory requirements for humane handling and slaughter of livestock from the time the livestock enter an official slaughter establishment until the point at which the animal becomes a carcass. This includes handling associated with livestock trailers.

Once a vehicle has entered the official establishment premises, it is considered part of the premises and is subject to the FSIS regulations that ensure humane handling. This is an important concept to

understand because it means that your responsibility for verifying humane handling begins when the animals are coming onto the facility, not just once they reach the holding pens. If you observe a humane handling noncompliance during truck unloading, you are to follow the same procedure as when a noncompliance is observed elsewhere in the facility. **Note:** A vehicle carrying livestock that is in line to enter an official establishment's premises is also considered to be part of that establishment's premises. Animals within that vehicle are to be handled in accordance with 9 CFR 313.2.

Truck unloading must be done in a manner that allows animals to be unloaded without injury. This includes proper positioning of the trucks, movement of animals while on the trucks, and the movement of animals off the trucks into the holding pens.

The APHIS Twenty-Eight Hour Law requires transporters to stop at least every 28 hours to provide animals with food, water, and rest, and those who do not are in violation of this law. If livestock arriving on transport vehicles appear exhausted or dehydrated, IPP need to ask establishment management if the truck driver stopped within 28 hours to provide food, water, and rest to the livestock. IPP are to contact the APHIS Area Veterinarian in Charge via their FSIS chain of command if establishment management or the truck driver is unwilling to supply that information, or if IPP believe the condition of the animals could be a result of being deprived of food, water, and rest for more than 28 hours. APHIS can use that information to investigate. IPP should also prepare an MOI to document what was observed and all actions taken. Provide establishment management with a copy of that MOI.

IPP can (on rare occasions and after consultation with FSIS supervision) enter onto transport vehicles to conduct ante-mortem inspection if establishment employees cannot humanely remove disabled livestock from the vehicles. The decision to enter a transport vehicle to conduct ante-mortem inspection or to conduct ante-mortem inspection from outside the vehicle is made by each inspector individually and is voluntary. Inspection personnel may enter onto the transport vehicle or perform ante-mortem inspection from outside the transport vehicle if, in their professional opinion, they can safely and adequately conduct the ante-mortem inspection. When conducting humane handling verification activities, personal safety is paramount. IPP are to conduct this verification from a safe and suitable vantage point, taking into consideration the size and temperament of livestock.

LIVESTOCK PENS, DRIVEWAYS, AND RAMPS (9 CFR 313.1)

Personnel responsible for moving livestock from the livestock trailers onto the unloading ramps, to the holding pens, and from the holding pens to the stunning area must do so with a minimum of excitement and discomfort to the animals. The ramps, driveways, and the floors of pens must be constructed and maintained so that the livestock have good footing. There are many ways to do this, such as using metal mesh and grooves cut or impressed into the cement. Establishments also need to consider the impact that seasonal weather conditions may have on footing. For example, it may be necessary for the establishment to use sand or some other material on the floors during the winter to overcome slick conditions.

Livestock pens and driveways should be constructed so that animals are not driven around many sharp corners. Pens, driveways, and ramps must be maintained in good repair. They must be kept free from sharp or protruding objects that can cause injury. Loose boards, splintered or broken planks, broken pipe rails, broken unloading ramps, and unnecessary openings where the head, feet, or legs of an animal may be injured must be repaired. Pens, alleyways, or fencing in disrepair such that an animal may be injured as a result is a regulatory noncompliance with humane practices required in 9 CFR part 313.

When observing the facilities for compliance, remember to look at the off-loading ramps, inside the holding pens, at the back of solid gates, inside the single file chute, restraint device, and stunning box. You may have to wait until the animals are out of these areas before you can complete your verification activities.

HANDLING OF LIVESTOCK (9 CFR 313.2)

Livestock must not be driven faster than a normal walking speed. That is, the animals must not be forced by the handlers to move more quickly than their normal walking speed. If you see one or a group of animals running, you need to determine what is causing the animal(s) to run before deciding if there is regulatory noncompliance. The key here is whether human actions caused the animal(s) to move faster than a walk.

When moving animals, the use of electric prods, canvas slappers, or any other type of implement must be minimized to prevent injury and excitement. The use of implements such as baseball bats, shovels, sharp prods, whips and the like, which in the opinion of the inspector can or will cause injury, are prohibited. Electric prods wired into AC current must not carry a charge higher than 50 volts.

Livestock must have access to water at all times while in holding pens. If they are held longer than 24 hours, they must also have access to feed. Agency policy is that feed must be appropriate for the age and species of animal being fed. For example, feeding hay to bob veal calves held more than 24 hours may not meet the regulatory requirement for access to feed. If held overnight, livestock must have enough room in the holding pen to lie down, without being forced to lie on top of one another.

Animals that are disabled, non-ambulatory, or designated as U.S. Suspects must be segregated into a separate pen. The pen must protect these animals from adverse weather conditions until you make your ante-mortem disposition because the weakened state of these animals renders them less resistant to even “normal” weather conditions. This means that you need to consider the geographic location of the facility, the season, and the current weather conditions when determining if the covered pen meets regulatory requirements. It also means that the overall level of cover may change, based on the above factors.

Note: When livestock are designated as U.S. Suspect, the establishment is required to handle those animals as U.S. Suspect, per the regulations. Ante-mortem condemned animals are to be euthanized humanely.

The regulations strictly prohibit dragging or pushing a conscious animal that is disabled or unable to walk. Establishment personnel must either stun these non-ambulatory disabled animals before dragging them or move the animals by placing them on a skid, stone boat, bucket lift, or some other type of equipment that is suitable for moving a conscious disabled animal.

All non-ambulatory disabled cattle, including non-ambulatory disabled veal calves, that are offered for slaughter (including those that have passed ante-mortem inspection) must be condemned and properly disposed of in accordance with 9 CFR 309.13.

Note: When the PHV is notified of cattle that have previously passed ante-mortem inspection that have become recumbent (lying down) or non-ambulatory disabled, PHVs are to use sound professional judgement when examining these cattle. The PHV will determine if the animal is ambulatory or if the animal is non-ambulatory disabled. Refer to FSIS Directive 6100.1 “Ante-mortem Livestock Inspection” for more information on this specific situation.

Secondary Entrances

Some establishments may use secondary or alternative entrances to move livestock into the facility. Secondary entrances or pathways are considered potential routes of movement to slaughter that differ from the route followed by the normal livestock population, which are ante-mortem inspected and passed livestock.

There are several concerns with using secondary or alternative pathways (e.g., alleyways, doorways, passageways).

- First, IPP may not be aware that animals are being moved through these secondary pathways, so may not be able to determine whether the animal is eligible for slaughter. Examples of this include bringing in non-ambulatory disabled cattle, dead, or uninspected animals.
- Second, the nature of the entrance may lead to inhumane handling of the animal. For example, the entrance is so small that the animal may be hurt.
- Third, the equipment used, or lack of equipment, may lead to inhumane handling of the animal. For example, ramps may be slippery or missing altogether.

Using alternative entrances is not prohibited. However, establishments using secondary or alternative entrances must ensure that livestock entering the establishment do so under conditions that meet all the relevant statutory and regulatory requirements. While performing HATS Category VIII – Stunning Effectiveness verification, IPP are to look for evidence that animals are being moved through secondary entrances and verify that the situations described above are not occurring at the establishment.

If IPP find evidence that any of the situations described above have occurred, they are to control the condemned livestock and take an RCA by tagging the entrance to prevent its use. If IPP observe that livestock have been inhumanely handled because of the nature of the entrance or equipment used, they are to take an RCA and document a noncompliance record as specified in the "Enforcement" section later in this module.

STUNNING (9 CFR 313.2, 313.5, 313.15, 313.16, 313.30) - LIVESTOCK

To meet the statutory requirements in the HMSA, all animals must be rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut. This requirement includes cattle, calves, horses, mules, sheep, swine, and other livestock.

There are some general principles that apply to all stunning methods:

1. Stunning equipment must be maintained in good repair. Equipment in poor repair can interfere with the rapid and effective application of the stunning blow. This can result in an incomplete or unsuccessful stun.
2. Effective stunning requires effective restraint. If an animal is not effectively restrained, it will be much more difficult to locate the stunning blow with a high degree of accuracy. The stunning area should be designed and constructed to limit the free movement of animals.
3. A well-trained and experienced establishment employee must operate stunning devices. The employee must be able to accurately and consistently position the stunning devices so that the animal is rendered immediately unconscious.
4. Animals need to be delivered to the stunning area with a minimum of excitement or discomfort. It is more difficult to place the stunning device accurately, and the method of stunning may not work as effectively, on an excited or injured animal.

With any stunning method, it is important to observe the amount of time it takes for the establishment to initiate bleeding out ("sticking") of the animal after it has been stunned. Although there is no regulatory requirement for this time period, if the "stun to stick" interval is prolonged, it could result in animals regaining or beginning to regain sensibility on the bleed rail.

It is also important to perform HATS verification at different times of the day. Equipment that may be working well in the morning can malfunction later in the day. Personnel get fatigued, may feel pressure to get a certain number of animals stunned by a particular time, or may be focusing on after work activities. Animals that have been standing around all day can get restless and more difficult to handle quietly and calmly. All these things can contribute to careless handling and/or stunning techniques, resulting in ineffective stuns.

The regulations describe four acceptable methods for producing a state of surgical anesthesia (surgical anesthesia is defined as a state where the animal feels no painful sensations). The four acceptable methods are:

- Chemical (carbon dioxide - CO_2)
- Mechanical (captive bolt)
- Mechanical (gunshot)
- Electrical (electric current)

Carbon Dioxide (9 CFR 313.5)

Carbon dioxide gas (CO_2) is approved for rendering swine, sheep, and calves unconscious. A carbon dioxide gas chamber is designed on the principle that carbon dioxide is heavier than normal atmospheric air. The chamber is open at both ends for the entry and exit of the animals to anesthetizing CO_2 concentrations or can be a pit structure where animals are lowered into the pit then brought out after inducing insensibility to pain. For swine only, CO_2 can be administered to induce death. Once anesthesia has occurred, the animals are removed from the chamber and are ready to be shackled, hoisted, or placed on a table for bleeding.

The gas must be administered in a way that produces surgical anesthesia quickly and calmly, with a minimum of excitement and discomfort to the animals. The establishment must maintain a uniform carbon dioxide concentration in the chamber so that the degree of anesthesia in exposed animals will be constant. The gas concentration and exposure time, also known as the dwell time, must be recorded graphically throughout each day's operation. All gas producing and control equipment must be maintained in good repair and all indicators, instruments, and measuring devices must be available for inspection by FSIS.

Mechanical – Captive Bolt (9 CFR 313.15)

There are two types of mechanical captive bolt stunners—penetrating and non-penetrating—used to produce immediate unconsciousness in cattle, sheep, goats, and swine. Both types have gun-type mechanisms that fire a bolt or shaft out of a muzzle. A measured charge of gunpowder or accurately controlled compressed air propels the stunning bolt. A well-trained and experienced establishment employee must operate both types. The employee must be able to accurately and consistently position the stunning devices so that the bolt hits the skull at the right location to produce immediate unconsciousness. At establishments that handle different slaughter classes (i.e., handles both sheep/goats and cull cows/bulls), the employee must also be able to adjust the air pressure or detonation charge when the sex, the breed, or the size of the animal changes.

Some establishments have adopted a practice of “double knocking”—that is, the animals are stunned with two blows delivered in very rapid succession. The rationale behind this procedure is that the consequences of an animal regaining consciousness are so severe that establishment managers want to make certain that it will not happen. Therefore, there is a second blow as a “security stun” only. The important point to consider here is that to meet the regulatory requirements, the first stun must be effective at rendering the animal insensible to pain.

When fired, the bolt in the penetrating type of captive bolt stunner penetrates the skull and enters the brain. Unconsciousness is caused by physical brain damage, sudden changes in intracranial pressure, and concussion. Penetrating captive bolt devices powered by compressed air must have accurate, constantly operating air pressure gauges. The gauges must be easily read and conveniently located for inspection by FSIS. The brain from animals stunned with penetrating captive bolts may be saved for edible purposes provided the establishment removes the large blood clots, bone splinters, hair, and debris from the brain. **Note:** The brain from cattle 30 months of age and older is a specified risk material (SRM) and is prohibited for use as human food.

9 CFR 313.15(b) prohibits the use of stunning devices that inject air into the cranial cavity of cattle and 9 CFR 310.13(a)(2)(iv)(C) prohibits the use of pneumatic stunning devices that inject compressed air into bovine skulls during stunning. Air-injection stunning is a method of deliberately injecting compressed air into the cranial cavity as a part of the stunning process. This policy ensures portions of the brain are not translocated into the tissues of the carcass (a protection against BSE).

Many establishments will use the non-penetrating type of captive bolt to avoid the time-consuming task of physically removing large blood clots, hair, bone, splinters, and debris from the brain. The non-penetrating (concussion) bolt is similar to the penetrating bolt except that it has a bolt with a flattened circular head (mushroom head). When fired, the mushroom head meets the skull but does not penetrate the brain. The animal becomes insensible from acceleration concussion and sudden changes in intracranial pressure.

Accurate placement of the stunning blow is very important when using a non-penetrating captive bolt stunner. The amount of hair on the animal’s head will also have an impact on the effectiveness of the stunning blow. Because there is no physical destruction of the brain during non-penetrating stunning, close observation and rapid bleed-out are important post-stun to ensure the animal does not regain consciousness.

Mechanical – Gunshot (9 CFR 313.16)

Another type of mechanical device used for stunning is the firearm. It can be used on cattle, calves, sheep, goats, and swine. The caliber of the firearm must be such that a single shot of a bullet or projectile into the animal must produce immediate unconsciousness. If a small-bore firearm is used, the regulations identify the following types of projectiles as acceptable:

- Hollow pointed bullets
- Frangible iron/plastic composition bullets
- Powdered iron missiles

Always consider your safety when observing stunning done with firearms. Ensure that you are out of the way of ricochet and standing away from the direction of fire.

Regardless of the type of projectile, a large percentage of the brain, cheek meat, and head trimmings may contain whole or fragmented bullets. Therefore, 9 CFR 310.18(b) states that after the head is

inspected, the brains, cheek meat, and head trimmings may not be saved for human food. The only portion of the head that can be salvaged for human food is the tongue.

Electrical (9 CFR 313.30)

The final method approved for stunning animals is electric current. Electrical stunning is used for hogs, calves, sheep, and goats. While approved for use in cattle, this is not a common practice. It is most widely used for hogs. The animal is restrained so that the electric current can be applied with a minimum of excitement and discomfort. There are two types of electrical stunning, head only and cardiac arrest. Head only stunning induces a grand mal epileptic seizure, resulting in insensibility to pain. Cardiac arrest stunning will induce a grand mal epileptic seizure and cardiac fibrillation—essentially inducing a heart attack. This means that the head must be stunned first (or simultaneously with the heart) because to stun the chest first would cause pain, not insensibility, which is a violation of the humane handling requirements.

The placement of the electrodes varies from establishment to establishment. It can be across the head only (head only stunning), on the head and thoracic region (cardiac arrest stunning), or across the head only then thoracic region only (two phase stunning). The design of the stunning wand can vary considerably (one or two pieces). Whichever way is used, the current passing through the animal must be enough to ensure surgical anesthesia throughout the bleeding operation. The operator must control the timing, voltage, and current so that each animal is properly stunned. If too much current is applied in the stunning process, hemorrhages or other tissue changes can occur that could interfere with the inspection procedure. Too high an electrical current can damage capillaries, resulting in multiple pinpoint hemorrhages in the muscle tissue. This is commonly referred to as "splashing" or "speckling". If this condition is seen on the post-mortem disposition rail, it is prudent to investigate the stunning process and discuss the findings with establishment managers.

To meet the statutory requirements, animals must be stunned before being shackled, hoisted, thrown, cast, or cut. With head-only stunning, the stun to bleed interval should not exceed 30 seconds. This is not a regulatory requirement and thus, IPP cannot enforce this time limit. However, if the “stun to stick” interval is prolonged, it could result in animals regaining or beginning to regain sensibility on the bleed rail. In cardiac arrest stunning, the stun to stick interval is not as critical because the animal is much less likely to regain sensibility. However, some establishments have had problems with cardiac arrest stunned animals regaining consciousness and stunning effectiveness must be verified on a regular basis.

ASSESSING UNCONSCIOUSNESS - LIVESTOCK

Livestock must remain insensible to pain (unconscious) from the time they are stunned until they are dead. You can use the following signs to verify that animals are insensible to pain (unconscious):

1. The head dangles from a flaccid (limp and flexible) neck. If the animals are suspended from an overhead rail, the head should hang straight down. This can be difficult to see if the animal is lying on its side.
2. The tongue may hang straight down and out of the mouth.
3. The eyelids should be wide open and the pupils fully dilated so, at a distance, the eyes appear black (no eye tracking).
4. There is no vocalization—mooing, bellowing, bleating, or squealing.

You may observe movement of the head and neck. This movement can be because of involuntary reflexes caused by random firing of damaged muscle neurons. It can be associated with movement of equipment. It may also be voluntary movement because the animal is regaining consciousness.

Some of the signs that an animal might be returning to sensibility include:

1. Rhythmic breathing.
2. Eye reflex in response to touch ("menace reflex"). This sign is not used for electrically stunned animals. Also, be very aware of your safety if using this method to check insensibility.
3. Spontaneous natural eye blinks without touching the eye or eye area.
4. Tense and moving tongue or lips.

These signs need to be carefully assessed and interpreted, as they are indications that the animal *may* be returning to consciousness or that the stunning was ineffective. They are not, in and of themselves, a definitive determination that the animal is conscious and able to feel pain.

A previously stunned animal that has regained sensibility (consciousness) may:

1. Vocalize
2. Show a "righting reflex"
3. Stand intentionally after stunning attempt
4. Display eye tracking and/or react to surroundings.

Some properly stunned animals may make some noises such as snoring type breaths or groans due to being relaxed, having stomach gas escape, or the last dying breaths. These noises may be mistaken as vocalizations. The term "righting reflex" is used to describe the physical actions taken by an animal to move itself into a normal lying, sitting, or standing posture. For example, a conscious cow hanging from a bleed rail will show a contracted back, stiff extended neck and rigid extended forelegs as it tries to pull itself into a normal upright position. An animal lying flat on its side may try to lift its head and may try to roll up onto its chest or stand.

On occasion, you may see an animal's neck flex laterally—that is, to one side —after it has been stunned and hoisted/stuck. With some stunning methods, you may often see kicking or paddling of the legs. Do not mistake these findings for a "righting reflex"; make sure you look at the head to determine if the animal is unconscious. Vocalization and the righting reflex are always signs that the animal is conscious and able to feel pain, though ultimately, it is the PHV that is responsible for assessing sensibility.

When assessing unconsciousness, you need to observe the animals at different places along the bleed rail. For example, you could perform verification just after stunning when the animal is in the shackle pit. Then, you could observe animals after they have been hanging on the bleed rail for several minutes. Always be aware of your safety when performing verification of unconsciousness.

If you observe an animal regain consciousness after stunning, you must contact your supervisor immediately, and take the actions described in the "Enforcement" section below.

ENFORCEMENT - LIVESTOCK

If you observe a humane handling noncompliance, you must take immediate action. The specific action that you take will depend on the nature of the noncompliance and the response of the establishment. The first thing to think about when you observe a humane handling violation is whether there is immediate harm done to the animal. If the animal is being harmed, your first duty should be to ensure

that the animal does not continue to be harmed. For example, if you observe an employee driving livestock with an instrument (i.e., the edge of a shovel) that can cause injury, you must stop that action from continuing. Your action or inaction should not result in further or continued inhumane treatment to the animal.

Once that is done, your next step is to decide if the noncompliance is egregious or non-egregious, because the actions you take will be dictated by that determination. An egregious humane handling violation is so serious that it may warrant an immediate suspension of the assignment of inspectors under the authority of the Rules of Practice (9 CFR 500.3(b)).

Non-egregious Noncompliance

When a noncompliance is observed, the regulations specify a progression of enforcement actions, allowing for an escalating response by IPP when the establishment does not comply with the humane slaughter of livestock regulations.

- First, notify establishment managers of the humane handling noncompliance, if you hadn't already done so when addressing the needs of the animal.
- Second, request that establishment managers immediately correct the situation and take the necessary steps to prevent recurrence.
- Third, document the noncompliance on an NR under the Livestock Humane Handling Verification task in PHIS.

If necessary, take an RCA to prevent further injury to the animal or to prevent injuries from occurring to other animals. You will also take the appropriate RCA if you do not receive an adequate response or corrective actions to the NR or if the noncompliance observed continues to occur. The appropriate RCA depends on the nature of the noncompliance. Remember that the goals of applying a tag are to control the situation and prevent further injury or distress to animals.

- If the noncompliance is the result of facility deficiencies, disrepair, or equipment breakdown, but is not immediately causing injury or distress to livestock, attach a U.S. Rejected tag to the noncompliant equipment/pen/etc. Noncompliance examples include holes in pen floors or fences that can trap/injure an animal's legs or feet.
- If the noncompliance is the result of establishment employee actions in the handling or moving of livestock and animals are being injured or treated inhumanely, attach the tag either at a point specific to the location and nature of the noncompliance or to the alleyways leading to the stunning area. Noncompliance examples include animals driven faster than a normal walking speed or animals slipping and falling because of slick floors.

The tag will remain in place until the establishment operator implements appropriate immediate actions and measures to prevent recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to the tagging may be dressed, processed, or prepared under inspection.

Whenever a non-egregious noncompliance of the humane slaughter requirements is observed, IPP must document the incident on an NR under the Livestock Humane Handling Verification task and send a copy to the DVMS at the DO. It is important that it clearly and specifically describes exactly what was observed, including any response by the animal (if the noncompliance involved animal discomfort or injury). Specify the relevant regulations that pertain to the incident. At the top of Block 10 (where the noncompliance is described) on the NR, list the HATS category you were performing when you saw the

noncompliance. If the noncompliance is covered by a second HATS category, note both categories on the NR.

If the establishment continues to have non-egregious humane handling noncompliance that does not result in injury to animals or does not adequately correct previously documented non-egregious humane handling noncompliance that did not result in harm to animals, the IIC is to communicate this to the FLS and DVMS. The IIC will work with the FLS and DVMS to determine if an NOIE should be issued for multiple non-egregious noncompliances.

Egregious Noncompliance

Under the Rules of Practice, 9 CFR 500.3(b), FSIS can suspend assignment of inspectors at an establishment without prior notification for certain humane handling noncompliances. Humane handling noncompliance for which immediate suspension may be warranted are termed egregious.

So, what is an egregious noncompliance? The Webster's Dictionary defines egregious as “conspicuously bad or flagrant”. The Agency defines it as "any act or condition that results in severe harm to animals,” for example:

1. Making cuts on or skinning conscious animals;
2. Excessive beating or prodding of ambulatory or non-ambulatory disabled animals or dragging of conscious animals;
3. Driving animals off semi-trailers over a drop off without providing adequate unloading facilities (animals are falling to the ground);
4. Running equipment over conscious animals;
5. Stunning of animals and then allowing them to regain consciousness;
6. Failing to immediately (or promptly) render an animal unconscious after a failed initial stunning attempt (e.g., no planned corrective actions);
7. Multiple ineffective stun attempts (2 or more) that are due to one or more of the following establishment failures to properly handle or stun the animal:
    a. Failure to immediately (or promptly) apply the corrective actions that demonstrates a blatant disregard for animal discomfort and excitement;
    b. Failure to adequately restrain an animal;
    c. Failure to use adequate stunning methods (e.g., inadequate air pressure, inadequate caliber, insufficient electrical current) for the animal being stunned (e.g., species of animal, size of animal, etc.);
    d. Poorly trained/untrained operator or inexperienced operator; or
    e. Prolonged discomfort and excitement of the animal due to the inability to render it insensible/unconscious after the application of the immediate (or prompt) corrective actions.
8. Dismembering conscious animals, for example, cutting off ears or removing feet;
9. Leaving disabled livestock exposed to adverse climate conditions while awaiting disposition, or
10. Otherwise causing unnecessary pain and suffering to animals, including situations on trucks.

This is a list of some actions that are considered egregious but is not exhaustive. Each incident of inhumane slaughter or handling needs to be assessed individually by IPP.

If you observe a noncompliance that you believe is egregious, your first action is to immediately stop the inhumane handling or slaughter with the appropriate RCA. Your next set of actions will depend on

whether you are the IIC. If you are the IIC, after you place a U.S. Rejected tag at the appropriate place, inform establishment managers that you are communicating with the FLS, DO, and DVMS to discuss the incident and that the District Manager (DM) will determine the enforcement action to be taken in accordance with 9 CFR 500.3(b). If you are not the IIC, after you attach a U.S. Rejected tag at the appropriate place, inform establishment managers that you are taking an RCA and that no more animals can be slaughtered until you contact the IIC. The IIC will initiate the action described in the above paragraph. Whichever action is taken, all livestock slaughtered before the action may be dressed, processed, or prepared under inspection.

After notifying the establishment, the IIC is to contact and correlate with the SPHV, FLS, DO, and the DVMS to receive the DM's determination (suspension with or without prior notification) and instructions for actions. Multiple factors will be considered in the correlation, all of which are found in FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock."

The IIC will also document the facts that serve as the basis of the suspension action on an NR and promptly provide that information electronically to the DO and the DVMS for their use. The NR will form the basis of the NOS documented by the DVMS and DO staff and of the Administrative Enforcement Report.

If the establishment is suspended or is issued an NOIE by the DO, the IIC or SPHV is to inform the establishment that they will need to proffer acceptable corrective actions and preventive measures to the DO. The DO will develop a verification plan to provide IPP a systematic means to verify the establishment effectively implements these measures.

Note: The decision to issue an NOIE is not automatic. The determination of the enforcement action, by the DO, for those establishments with robust systematic humane handling programs will be based on multiple factors as described in FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock."

Delayed Implementation – Egregious Noncompliance

The IIC may also recommend the DO delay implementing the suspension action if immediate action is likely to result in inhumane treatment of additional animals, until they can ensure that animals on-site or in-transit have been handled humanely. An example is a line stoppage that may result in animals having to stay on a truck during an extremely hot day. The IIC should encourage establishment management to redirect as many animals that are enroute as possible and to order the stoppage of further loading of animals onto trucks at the source location. The IIC needs to consider:

- What immediate corrective action is the establishment taking?
- How likely is it, given the establishment's history, that the corrective action will be effective in preventing a recurrence of the root cause of the situation?
- How many animals are on premises or enroute that will need to be slaughtered?
- What conditions threaten the welfare of the animals if they are not promptly slaughtered?

If the IIC determines that an immediate suspension is likely to result in inhumane treatment of additional animals, the IIC should recommend to the DO that the suspension action should be delayed. In this situation, a line inspector trained in humane handling must be moved to an appropriate area to directly observe establishment employees handling or slaughtering animals, which may require a line speed adjustment according to staffing standards in 9 CFR 310.1.

The IIC may allow slaughter to continue at a reduced line speed for a limited time on their own authority. This is not intended for a “kill-out” of animals at the facility; it is only for a “kill-down” to ensure that the number of animals to be held on-site meets the requirements for holding animals overnight. Contact your supervisor if you are concerned about allowing slaughter to continue at reduced line speeds.

When the IIC determines that additional animals will not be subjected to inhumane handling due to the suspension, the suspension must be promptly implemented. IICs are to document their observations and actions in an MOI and submit it to the DO.

EXOTIC SPECIES – LIVESTOCK

Exotic animals specified by 9 CFR 352 include antelope, bison, buffalo, catalo (cattalo), deer and yak. Additionally, exotic animals are defined by 9 CFR 352.1(k) as any reindeer, elk, deer, antelope, water buffalo, bison or yak.

Exotic animals (voluntary inspection) are covered under 9 CFR 352.10. This section includes regulations that address humane handling during ante-mortem inspection and stunning practices to render the animals unconscious. The regulation states, “Humane handling of an exotic animal during ante-mortem inspection shall be in accordance with the provisions contained in 9 CFR 313.2.” This covers unloading procedures, methods of moving exotics through the holding facility, handling of disabled animals, access to water, access to feed if held over 24 hours, and the effective application of stunning methods. 9 CFR part 352.10(a)(5) states that “Stunning to render the animals unconscious shall be in accordance with 313.15 or 313.16,” which are the stunning by captive bolt and by gunshot sections of the humane handling regulations.

If you have questions or concerns about repetitive noncompliances with exotic animal humane handling and slaughter, contact the DVMS. Although we cannot take action under the Rules of Practice, 9 CFR 500.3(b), these issues can be effectively addressed. If IPP observe an egregious humane handling noncompliance, they should immediately take an RCA to prevent continued egregious humane handling and orally notify the establishment management that the district is being contacted. IPP will then work with the DVMS and District Office personnel to document the incident in an MOI, and District Office personnel may initiate a denial of voluntary service action.

CUSTOM EXEMPT OPERATIONS - LIVESTOCK

The FMIA (21 U.S.C. 610(b)) prohibits slaughter or handling of livestock in connection with slaughter in any manner not in accordance with 7 U.S.C. 1901-1906 (HMSA). This applies to all animals on the premises of a federally inspected establishment whether those animals are designated for slaughter under federal inspection or for slaughter under a custom exempt program. (Custom exempt operators slaughter livestock belonging to someone else and process the carcasses for the exclusive use by the owner, members of the owner’s household, non-paying guests, and employees. The product is exempt from routine Federal inspection.)

When IPP are on-site performing assigned official duties related to regulated product, and there is concurrent handling and slaughter of livestock under a custom exempt program, Agency expectations are that if IPP become aware of inhumane handling or slaughter practices of custom exempt livestock, they are to take the following actions:

- Immediately notify establishment management and request that establishment management address the issue;

- Document their findings on an MOI;
- Provide a copy of the MOI by email to their immediate supervisor, and the DVMS or a DDM if the DVMS is not available.
- Provide a copy of the MOI (printed or electronic) to establishment management.

The district management team will take any further actions, consistent with the instructions found in FSIS Directive 8160.1 “Custom Exempt Review Process.”

HUMANE ACTIVITIES TRACKING SYSTEM (HATS) - LIVESTOCK

You will be verifying that establishment facilities and the activities of establishment personnel comply with humane slaughter laws. The amount of time that IPP spend verifying compliance with the humane handling regulations is captured in the HATS tab within the Livestock Humane Handling Verification task in PHIS. IPP must perform the Livestock Humane Handling Verification task each day and shift that livestock slaughter occurs in federally inspected facilities or when animals are on site, even if it is during a processing-only shift. In PHIS, the Livestock Humane Handling Verification task is entered each time it is performed.

To the maximum extent possible, multiple IPP are routinely to conduct HATS related activities. IPP are to accurately and completely report the time that they spend on these activities and to separate that time into nine specific categories. These categories are listed in the HATS database and cover all the regulatory requirements for the humane handling and slaughter of livestock.

Record the total time spent verifying HATS categories, in quarter-hour increments, rounding up to the next quarter-hour. During normal operations, the total maximum time that would be entered across all HATS categories will generally not exceed the total operational hours for that respective shift. A minimum of one-quarter hour is expected to be entered for each slaughter shift in HATS category IV – “Ante-mortem Inspection,” except for very small establishments. In addition, verify one or more HATS categories during each slaughter shift and ensure that, over time, all HATS categories are verified. When deciding which HATS categories to verify, consider previous inspection results, historical observations, and supervisory direction. You may want to repeat some activities if a significant amount of time has passed between ante-mortem inspection and slaughter. It is important to focus on doing complete, quality verifications of each category.

For very small establishments that slaughter one to a few animals per day, there are special procedures for documenting humane handling verification time in HATS. At many very small establishments, the total amount of inspection time spent on HATS procedures during a shift may only total .25 hour. Therefore, because the minimum amount of time that can be recorded for any given HATS activity is .25 hour, the expectation that .25 hour be entered in HATS Category IV - "Ante-mortem Inspection" for each slaughter shift does not apply. Instead, at those very small establishments where, for example, two or more humane handling verification procedures (one of which will always be “Ante-mortem Inspection” for those shifts when slaughter is scheduled) may be performed in .25 hour, IPP are to rotate through the appropriate HATS categories (i.e., those categories actually performed at a particular establishment including “Ante-mortem Inspection”) when entering their HATS time and record .25 hour per day in a different HATS category each slaughter day. In this manner, all HATS activities performed by IPP will be reflected over the course of several slaughter days.

If you are in a multi-IPPS assignment, conduct one or more HATS category verifications whenever you visit an establishment to perform ante-mortem and post-mortem inspection disposition activities. Focus on verifying category VIII “Stunning Effectiveness” and category IX “Conscious Animals on the Rail.”

If the establishment participates in the Agriculture Marketing Service (AMS) National School Lunch Program (NSLP), determine whether the establishment is meeting the AMS Animal Welfare Requirements, including a review of all humane handling records generated in accordance with this program. If you have reason to believe that the establishment is not fully following its AMS NSLP humane handling obligations, notify your immediate supervisor and the DVMS.

As described above in the Systematic Approach section, if the establishment has an identified robust systematic approach, you will verify that the establishment is following its program on an ongoing basis while performing your daily HATS procedures and inform the establishment of any status change in this regard. If the establishment is not following its program, first discuss your observations with establishment management. Document the discussions in an MOI under the Livestock Humane Handling Verification task in PHIS. If the establishment continues to implement its written animal handling program ineffectively, continue to document and discuss as outlined above. Additionally, notify your immediate supervisor and the DVMS or DDM of your observations by email. You, your immediate supervisor, and the District Office (e.g., DVMS) are to hold a discussion about IPP's observations to determine if the establishment is still implementing a robust systematic approach and follow the additional guidance in FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock."

When writing an NR for a noncompliance in a HATS category that was not the selected category for observation, IPP are to record the HATS time for both the category that was being performed and for the category in which the noncompliance occurred.

When you are verifying humane handling, make certain that you are not predictable in how, where, and when you perform your observations. You need to select areas and times randomly such that you observe all areas at different times of the day. In addition, you need to vary the route you take to get to the areas being observed. Establishment personnel should not be able to anticipate when you are going to be observing their humane handling and slaughter methods because you are always in about the same place at about the same time.

HATS Categories

I. Inclement Weather (9 CFR 313.1 and 313.2): Under this category, IPP record their verification of how the establishment adapts its facilities and handling practices to inclement weather to ensure the humane handling of animals. Inclement weather (e.g., rain, heat, snow, ice) can have adverse effects on facilities and animal handling.

   Examples of noncompliance include livestock slipping and falling due to icy floor conditions; or livestock do not have access to water in holding pens due to frozen water in buckets.

   More examples of noncompliance within this HATS category and the following HATS categories are found in FSIS Directive 6900.2 "Humane Handling and Slaughter of Livestock."

   Note: There is no requirement for a dedicated covered pen; this requirement can be met if the establishment can show they can and will provide a covered area when needed.

II. Truck Unloading (9 CFR 313.1 and 313.2): Under this category, IPP record their verification of the establishment's livestock handling and unloading facilities and its humane handling procedures during livestock unloading activities. IPP are to verify that the establishment's livestock handling facilities are in proper repair and positioned properly during livestock unloading activities.

Examples of noncompliance include when the conditions of the facilities (e.g., ramps, chutes, floors, and vehicles) appear likely to injure or are injuring animals; animals are forced to move faster than a normal walking speed or animals are slipping and falling; disabled or U.S. Suspect animals are not separated from normal ambulatory animals; or during unloading and driving, animals are excessively prodded or not driven with a minimum of excitement and discomfort.

Note: "Fatigued" or "slow" hogs will not be able to move at the same normal walking speed as others in the lot and tend to lie down and in some cases may get knocked down by others in the lot. These hogs (though ambulatory and otherwise normal, bright, and alert) may need to be moved in a manner that protects them from other hogs in the group or lot. Therefore, establishments will need to develop a method or protocol for humanely handling these hogs.

III. Water and Feed Availability (9 CFR 313.2): Under this category, IPP record their verification of the establishment's compliance with 9 CFR 313.2(e), which requires that water be available to livestock in all holding pens, and that animals held longer than 24 hours have access to feed.

An example of noncompliance is when water is not accessible to livestock in holding pens.

IV. Ante-mortem Inspection (9 CFR 313.1 and 313.2): Under this category, while IPP are conducting ante-mortem inspection, they are to record the time spent verifying the establishment's facilities and procedures for humanely handling animals during ante-mortem inspection.

Examples of noncompliance include facilities not maintained in good repair; livestock injured because of handling practices; or livestock are moved faster than a normal walking speed.

V. Suspect and Disabled (9 CFR 313.1 and 313.2): Under this category, IPP record their verification of the measures that an establishment takes to ensure that U.S. Suspect and disabled livestock (9 CFR 313.2 (d)) are handled humanely. In establishments that present higher numbers of disabled livestock, IPP would typically spend more time verifying the humane handling of these animals than they would in establishments that present few disabled livestock.

Examples of noncompliance include dragging conscious animals; or U.S. Suspect and disabled livestock are not provided or placed in a covered pen.

VI. Electric Prod/Alternative Object Use (9 CFR 313.2): Under this category, IPP record their verification of the establishment's procedures for humanely and effectively moving livestock without excessive prodding, the use of sharp objects, or the use of other driving implements that do not minimize excitement, discomfort, or injury after ante-mortem inspection has occurred (9 CFR 313.2). IPP are to verify this by direct observation at multiple locations (e.g., pens, alleyways, single-file chutes, and stunning areas) involving animal movement. Establishments are to use implements (e.g., electric prods, canvas slappers) as little as possible to minimize excitement and injury and are not to drive livestock faster than a normal walking speed. Any use of such implements that, in the opinion of the inspector, is excessive is prohibited (9 CFR 313.2(a), (b) & (c), 313.5(a)(2), 313.16(a)(2), and 313.30(a)(2), as applicable).

Examples of noncompliance include livestock being excessively prodded, causing them to vocalize, be overexcited or injured; prods applied to sensitive areas such as the face or genitals; or livestock handled in a manner that does not minimize excitement, discomfort, pain, or injury.

VII. Slips and Falls (9 CFR 313.1 and 313.2): Under this category, IPP record time spent observing whether any animals are slipping and falling as they are handled and moved through the livestock

facilities. “Slips” are when a portion of the leg other than the foot touches the ground or floor, or a foot loses contact with the ground or floor in a non-walking manner. “Falls” are when an animal loses an upright position suddenly, in which a part of the body other than the limbs touches the ground or floor.

An example of noncompliance would be livestock slipping and falling due to inadequate flooring or improper handling practices.

VIII. Stunning Effectiveness (9 CFR 313.5, 313.15, 313.16, and 313.30): Under this category, IPP record their verification of the establishment’s procedures to appropriately and effectively administer stunning methods that produce unconsciousness in the animal before the animal is shackled, hoisted, thrown, cast, or stuck. Livestock are to be rendered insensible to pain (unconscious) by a single blow or gunshot or by an electrical, chemical, or other means that is rapid and effective. The stunning area is to be designed and constructed to limit the free movement of the animals and to allow the stunning blow to have a high degree of accuracy. Ante-mortem condemned animals are to be euthanized humanely, using one of the four stunning methods identified in 9 CFR 313 or other humane methods acceptable to FSIS.

Examples of noncompliance include the establishment not consistently rendering an animal or animals unconscious with a single application of the stunning methodology; or there are no records for carbon dioxide gas concentration.

Note: As mentioned in the Ritual Slaughter section, the ritual slaughter cut will not be evaluated. For those establishments that are ritually slaughtering, and in addition utilize stunning methods (found in 9 CFR 313), the stun effectiveness *will* be evaluated. See FSIS Directive 6900.2 “Humane Handling and Slaughter of Livestock” for more information.

IX. Conscious Animals on the Rail (9 CFR 313.5, 313.15, 313.16, and 313.30): Under this category, IPP (usually a PHV) record their verification that the establishment ensures that animals do not regain consciousness after stunning and throughout shackling, sticking, and bleeding (Section 1902 of the HMSA). This category focuses specifically on the time after stunning and throughout the process of shackling, hoisting, sticking and bleeding of the animal. The following regulations address these requirements:

1. Chemical; Carbon Dioxide – 9 CFR 313.5 (a) (1) & (2);

2. Mechanical; Captive Bolt – 9 CFR 313.15 (a) (1) & (3);

3. Mechanical; Gunshot – 9 CFR 313.16 a (1) & (3); or

4. Electrical; Stunning or Slaughtering with Electrical Current – 9 CFR 313.30 (a) (1) & (4) and 313.2 (f).

Note: According to the HMSA, stunning methods are to render the animal insensible to pain throughout the shackling, hoisting, throwing, casting, and sticking process. They should remain insensible until death.

Examples of noncompliance include if the establishment further processes livestock not rendered unconscious by the method of stunning; or animals regain consciousness after being stunned.

Odd-hour Verification Visits

Performing unannounced humane handling verification at a time when IPP are not on duty is another component of HATS. Contact your immediate supervisor and the DVMS if you think you need to perform humane handling verification when there is no assigned tour of duty for inspection and services.

The IIC, in conjunction with the FLS and DVMS, determines how frequently IPP need to perform odd-hour inspection to observe the livestock facilities and handling practices. This decision is based on establishment history or other observations, such as:

- A significant percentage of animals are unloaded outside normal hours of operation when federal Inspectors are not on duty.
- Animals are frequently held over the weekend and automatic watering devices are not present in pens and/or there is no access to food within 24 hours of their receipt at the facility.
- Animals delivered outside the regular tour of duties are found with injuries during ante-mortem inspection.
- Non-ambulatory disabled animals are being delivered to the establishment outside the regular tour of duty when IPP are not on duty.
- Phone calls have been received from eyewitnesses alleging inhumane handling practices during times when IPP are not on duty.

All time incurred in the performance of odd-hour inspection will be paid as non-reimbursable overtime if the inspector is in overtime status. You will perform a directed Livestock Humane Handling Verification task, selecting “Supervision Instruction” for the reason. You then record the task outcome within PHIS on the Inspection Results page by selecting the verified regulations and checking the appropriate boxes. Document your observations on FSIS Form 8100-1 (Odd-Hour Inspection Report), and record time in PHIS under the appropriate HATS category on the date of inspection. If noncompliance is identified, write the NR on the date of inspection. IPP are to notify establishment management when they become available and send the final NR to their SPHV, FLS, and DVMS.

GOOD COMMERCIAL PRACTICES – POULTRY

As described previously, there is no humane handling statute requiring humane handling in poultry. In the PPIA Section 453(g)(5), a poultry product is adulterated if, among other circumstances, it is in whole, or in part, the product of any poultry that has died otherwise than by slaughter. The regulations require that poultry be slaughtered in accordance with good commercial practices (GCPs), in a manner that will result in thorough bleeding of the poultry carcass and will ensure that breathing has stopped before scalding (9 CFR 381.65 (b)). Poultry that are still breathing on entering the scalder die from drowning, not from slaughter, and therefore are considered adulterated as defined by 21 USC 453(g)(5) and 9 CFR 381.1(b)(v) . These cadavers are condemned on post-mortem inspection per 9 CFR 381.90.

On September 28, 2005, the Agency published a Federal Register (FR) Notice, Docket No. 04-037N, Treatment of Live Poultry Before Slaughter. In that FR notice, humane handling terminology was used for the first time by the Agency when describing the live poultry being handled in a way consistent with GCPs. FSIS went on to describe a systematic approach for industry to use. The Agency defined a “systematic approach” as one in which establishments focus on treating poultry in such a manner as to minimize excitement, discomfort, and accidental injury the entire time that live poultry is held in connection with slaughter. Although this systematic approach is voluntary on the part of industry, it is a reminder that the statutes and regulations both require that live poultry be handled in a manner that is

consistent with GCPs, which means they should be treated humanely. This signals that the Agency took a more assertive approach to the handling of live poultry.

FSIS Directive 6110.1 "Verification of Poultry Good Commercial Practices" provides guidance on performing GCP verification activities. Additional information is available in a Humane Interactive Knowledge Exchange—01-05—addressing the issue of humane handling of poultry.

POULTRY GCP VERIFICATION ACTIVITIES

IPP assigned to poultry slaughter facilities are expected to complete a Poultry Good Commercial Practices Verification task and record the results in PHIS on a daily, per shift basis when the establishment slaughters. You should visit the receiving through pre-scald areas to observe whether establishment employees are mistreating birds or handling them in a way that will cause death or injury, prevent thorough bleeding, or result in excessive bruising. Some things to look for include:

- Establishment employees breaking the birds' legs to hold them in the shackles.
- Birds frozen inside cages or frozen to the cages in cold weather.
- Birds dead from heat exhaustion—you would primarily see heavy panting in poultry suffering from heat stress.
- Establishment employees driving over live birds with equipment or trucks in the unloading or live hang area.

If the poultry are stunned prior to bleeding, check the stunning equipment to ensure it is functioning properly. Poultry that have been effectively stunned will have an arched neck and tucked-in wings posture. **Note:** Stunning is not a requirement in poultry slaughter, but IPP should consider if stunning system malfunction contributes to other process control concerns.

Check in the bleeding area to determine if the bleeding equipment is functioning properly. One way that you might be alerted to problems with the bleeding equipment is if FSIS inspectors report increased numbers or clusters of cadavers at inspection stations or increased numbers of recently bruised wings or legs.

Once a week, select a day at random to review establishment records documenting adherence to GCPs. This review takes the place of observation in the receiving through pre-scald areas. Establishments are not required to maintain written records of GCPs. If the establishment does not keep records, visit the receiving through pre-scald areas as above.

If the establishment keeps such records and makes them available, assess whether there is evidence that the establishment is monitoring its GCPs in the receiving through pre-scald areas. Video surveillance taken by the establishment can be used by the establishment as a form of GCP record. Also, determine if there is enough information in the records to judge whether the establishment is following GCPs. If there is not enough information to make that judgment, visit the receiving through pre-scald areas to verify compliance with the statute and regulations.

GCP ENFORCEMENT – POULTRY

If the establishment is not following GCPs, and birds are dying other than by slaughter, you are to document a noncompliance record citing 9 CFR 381.65(b). Adhering to GCPs is a process control issue. It is not a bird-by-bird performance standard. To document an NR for GCP, you need to demonstrate that the establishment has lost control of its process. Examples of losing process control are:

- A pattern or trend of birds dying other than by slaughter, such as repeatedly entering the scald tank while still breathing;
- Birds are not being appropriately bled out;
- The process the establishment is using is not able to prevent these problems from occurring, or
- Birds are mistreated intentionally and repeatedly by establishment personnel.

Do not quote the HMSA, the National Chicken Council Audit Guidelines, the Federal Register Notice on Treatment of Live Poultry Before Slaughter, or any of the establishment's written poultry handling plans in the NR.

An isolated instance of a live bird entering the scalding tank is not a GCP noncompliance because it does not demonstrate loss of process control. Document an isolated instance of mistreatment in a GCP MOI.

When documenting a GCP NR or MOI, you should consult FSIS Directive 6110.1 "Verification of Poultry Good Commercial Practices" for specific instructions on what to consider and include in the documentation.

The DVMS will review the MOIs and GCP NRs and determine if additional action is warranted. The correlation includes review to determine accuracy and consistency of documentation. In specific situations, after review of mistreatment MOIs, the DVMS may need to notify appropriate state officials following instructions in FSIS Directive 6110.1 "Verification of Poultry Good Commercial Practices."

If you have questions or concerns about what you observe during poultry slaughter, contact the DVMS and your immediate supervisor for guidance.

Ante-mortem Inspection

OBJECTIVES

Scientific:

1. Given a sample context, perform ante-mortem inspection and make supportable ante-mortem dispositions according to 9 CFR part 309 (livestock) and 381.70-381.75 (poultry).
2. Given those scenarios, identify and demonstrate the appropriate regulatory actions, if any.
3. Given scenarios, determine whether given conditions in an establishment are insanitary and unacceptable according to 9 CFR 307.2 for livestock and as per FSIS Directive 6100.3 for poultry.
4. Verify whether an establishment uses compliant methods to dispose of an animal that a PHV has condemned upon ante-mortem inspection.

Regulatory/Administrative:

1. Recognize and access FSIS form 6150-1 for livestock inspection.
2. Given sample scenarios, complete FSIS form 6150-1 for livestock inspection.
3. Given those scenarios, complete a pen card.
4. Identify accountable items used during ante-mortem inspection.

RESOURCES

FSIS Directive 6100.1 – Ante-Mortem Livestock Inspection
FSIS Directive 6100.3 – Ante-Mortem and Post-Mortem Poultry Inspection
FSIS Directive 6000.1 – Responsibilities Related to FAD and Reportable Conditions
FSIS Directive 6020.1 – Enhanced Inspection of Poultry in Response to a Notification of HPAI Outbreak
FSIS Directive 6240.1 – Inspection, Sampling, and Disposition of Animals for Tuberculosis (TB)
FSIS Directive 6170.1 – Ratite Ante-Mortem and Post-Mortem Inspection
FSIS Directive 9530.1 – Importation of Live Canadian Cattle, Sheep, and Goats into the U.S.
FSIS Directive 6100.8 – Instructions for Verification of Immunologically Castrated Hogs During Ante-Mortem Inspection
IPP Help: Multi-Species Disposition Basics for PHVs – Livestock Ante-Mortem (VPN required)

INTRODUCTION

The term ante-mortem means “before death.” Ante-mortem inspection is the inspection of live animals and birds prior to being slaughtered. All livestock presented for slaughter by the establishment to which you are assigned must receive ante-mortem inspection. Ante-mortem inspection of poultry is performed on the day of slaughter. Ante-mortem inspection is performed either by an FSIS veterinarian or other IPP (CSI or Food Inspector) under veterinary supervision. However, if a CSI or a Food Inspector performs ante-mortem inspection, the PHV must be notified of disease conditions that are observed.

The Agency’s authority for conducting ante-mortem inspection in livestock is found in 21 USC, Chapter 12, Section 603, of the FMIA. The authority for conducting ante-mortem inspection in poultry is found in 21 USC, Chapter 10, Section 455(a), of the PPIA. The statutes establish our authority to examine and inspect livestock and birds prior to slaughter. Under the statues, we are to accept for slaughter only those animals and birds which are capable of producing products that are acceptable for use as human

food. With this goal in mind, the purpose of ante-mortem inspection is to accept only those animals and birds that are healthy, free from harmful chemical and drug residues, and capable of being converted into wholesome product for the consumer. Inspection of live animals and birds is a screening process to remove obviously diseased animals from the food supply prior to slaughter and to identify animals that require a more extensive post-mortem examination by an FSIS veterinarian. It is the first line of defense in protecting the public from potentially harmful meat and poultry products. Those animals and birds that exhibit abnormal signs must be withheld from normal slaughter and segregated for closer examination.

The regulations covering ante-mortem inspection of livestock are found in 9 CFR 307.2 (addresses the requirements for facilities for inspection); 9 CFR 309 (covers ante-mortem inspection); and 9 CFR 313 (addresses the requirement for humane slaughter of livestock). The regulations covering ante-mortem inspection of poultry are found in 9 CFR 381.36(b) (addresses the facilities for inspection of ratites) and 9 CFR 381.70 through 381.75 (covers ante-mortem inspection).

Establishments are required to handle livestock humanely. When you are performing your ante-mortem duties, you will also make observations and document any noncompliance with the humane handling requirements. The requirements for humane handling are covered more extensively in the Humane Handling/GCP portion of this training.

Note: On ante-mortem inspection, IPP must also consider livestock and poultry suspected of having biological residues, as well as livestock and poultry used for research. Information on these topics is covered in the Residue Detection section.

FACILITIES AND CONDITIONS

The regulations identify requirements that the establishment must meet for maintaining facilities where ante-mortem inspection is to be conducted. You are responsible for verifying that the establishment has met the regulatory requirements for maintaining the facilities where ante-mortem inspection is to be conducted. The regulatory requirements for the establishment differ slightly from livestock to poultry.

Livestock

The establishment's responsibilities for maintaining the premises where ante-mortem inspection is to be conducted for livestock are outlined in 9 CFR 307, which covers facilities for inspection, and in 9 CFR 313, the humane handling regulations.

The pens must be satisfactory for conducting ante-mortem inspection and be maintained in a sanitary condition (9 CFR 307.2(a)). Pens must be kept clean and be well drained (9 CFR 307.2(a)). The pens, driveways, and ramps must be maintained in good repair and free from sharp objects that may cause injury or pain to animals (9 CFR 313.1(a)). The floors of pens, driveways, and ramps must be well constructed and maintained and provide good footing for animals (9 CFR 313.1(b)).

The lighting must be sufficient for inspection (9 CFR 307.2(b)). You will need to use your judgment in determining whether the light is adequate or not. The regulations do not specify any measurement or level of light that the establishment is required to provide. Suspect pens and restraining devices require more light because these are places where animals are more closely examined during inspection. The establishment must provide adequate areas for holding animals that are identified by FSIS as U.S. Suspect and U.S. Condemned (9 CFR 307.2(a)). These are typically designated as the suspect and condemned pens. Pens where suspect animals are held must be covered to protect them from adverse weather conditions (9 CFR 313.1(c)). Although it is not required by the regulations, some

establishments may provide a covered area for inspection personnel to use while performing ante-mortem inspection in inclement weather. The establishment may also provide a restraining device such as a chute or squeeze gate for restraining animals and taking temperatures during the examination of animals.

The establishment is required to have an adequate system for the identification of animals presented for slaughter. There is not a uniform method of presenting animals for ante-mortem inspection, but the establishment needs to do so in a manner that will allow IPP to document that ante-mortem inspection has been performed. The most commonly used method for establishments to meet this regulatory requirement is by using establishment identification cards, referred to as "pen cards" or "drive sheets." Although the pen cards themselves are non-regulatory in nature, they must be presented to the inspector before ante-mortem inspection is performed. The pen card or drive sheet should contain space to record the date and time of inspection, pen or lot number, number and slaughter class of animals presented, and IPP signature or initials. In most instances, the establishment will record the information directly on the card for you. However, you should check to see that the information is correct.

The regulations also require that establishments identify the carcass and parts with the animal from which they come, until the post-mortem examination of the carcass and parts has been completed (9 CFR 310.2(a)), and that the establishment maintain records of the buyer and seller of livestock (9 CFR 320.1(b)(1)(iv)). Tags are typically used to maintain the identity of the carcass and its parts. Pen cards may be used to maintain a record of the buyer and seller of the livestock.

IPP are to periodically verify how accurately the establishment records the number of livestock presented for ante-mortem inspection. The frequency of this verification is determined by discussion between the PHV and FLS and is based on the establishment's history of accurately recording the number of livestock on the pen card or drive sheet. You should perform verification after the establishment has identified and presented livestock for ante-mortem inspection and has given the applicable pen card to you. If the count is accurate, the IPP can complete ante-mortem inspection. If the numbers are inaccurate, IPP are to ask management to correct the pen card and cross out the incorrect number. IPP are to initial the change and complete ante-mortem inspection. In rare cases that the establishment refuses to comply, the livestock would be retained and an NR would be documented under the Other Inspection Requirements task, citing 9 CFR 307.2.

It is the responsibility of the establishment to provide adequate, competent employees to move, segregate, restrain, identify and dispose of animals (9 CFR 307.2(a)). Do not allow yourself to become the establishment foreman in the ante-mortem areas. You must closely monitor establishment personnel to ensure that they always use humane animal handling practices. You must also observe safety principles, as large animals can be dangerous.

If the establishment has not met one or more of its responsibilities, you must take action. The action you take will vary from withholding inspection of a single pen of animals until the pen is properly identified, to withholding inspection of all animal pens because the establishment has failed to provide an employee to move and restrain the animals.

Poultry

The establishment responsibilities for facilities and conditions for ante-mortem inspection of poultry are much simpler. The regulatory requirement identified in 9 CFR 381.36 states that a suspect pen is required for adequate ratite inspection.

PERFORMING ANTE-MORTEM: SUPPLIES

The ante-mortem inspection of livestock takes place in the pens. Each animal must be observed. The following equipment and supplies are recommended for performing ante-mortem inspection for livestock: a thermometer, U.S. Suspect and U.S. Condemned tags, tagging pliers and hog rings, a pencil for writing, a pad of paper and a clipboard for taking notes. Many inspectors keep all these items together in a kit that they keep under lock and key in the ante-mortem area or in the government office. Some of the items you will commonly use are:

1. A thermometer- this is supplied by the establishment management. If you do not have one, or if the one you have is broken, request one from establishment management.
2. Pliers- the tagging pliers, commonly called "hog ringers"; the hog rings are used to attach the suspect and condemned tags to the animal's ear.
3. U.S. Suspect (silver) and U.S. Condemned (red) tags.
4. Ante-mortem Card- FSIS Form 6150-1 is used to record and track suspect and condemned animals.
5. FSIS Form 6502-1 (U.S. Rejected/Retained Tag) is attached to areas such as livestock pens to show that they are rejected for use because they didn't meet FSIS requirements and therefore did not pass inspection.

Following ante-mortem inspection, you must record your findings. You will use the FSIS Form 6150-1 (Identification Tag - Ante-mortem) to record your ante-mortem findings. You will also record your findings on the pen card (supplied by the establishment). Remember that the pen card is a part of the procedure used to identify animals as having received ante-mortem inspection.

PERFORMING ANTE-MORTEM: OBSERVATION

Livestock

Part 309 of the regulations covering livestock inspection states that, "*All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of, and before, slaughter.*" A few small-volume establishments are allowed exceptions to this rule, which will be discussed later. Part 309 goes on to say, "*Such ante-mortem inspection shall be made in pens on the premises of the establishment at which the livestock are offered for slaughter.*" Livestock ante-mortem must be done by a PHV or an inspector under the supervision of a PHV.

Ante-mortem inspection consists of two parts:

- Observe animals at rest.
- Observe animals in motion.

It is important to inspect the animals both at rest and in motion because certain abnormal signs, such as labored breathing, are easier to detect while the animals are at rest, while other abnormalities, such as lameness, may not be detected until you observe the animals in motion. Since the regulations do not require in-motion inspection from both sides, PHVs must use their discretion during ante-mortem. The PHV may determine that in-motion inspection from both sides is necessary to determine if the animals are eligible to be passed for regular slaughter. An example of this is in high pathology cattle establishments with a greater incidence of acti, epithelioma, or injection site reactions, which all can be unilateral in nature. FSIS Directive 6100.1 “Ante-mortem Livestock Inspection” states that IPP are to

observe livestock from **both** sides when the slaughter class (e.g., cows and bulls) or the condition of the animals (e.g., diseases, distressed) at the slaughter establishment supports observing from both sides in order to determine whether they are fit to slaughter for human consumption.

When you perform at-rest inspection, position yourself at various locations outside the pen. Observe all the animals and note their general behavior while they're at rest. Determine if any of the animals show abnormal behavior such as excessive excitability or severe depression. Look at the heads, necks, sides, rumps, and legs of as many animals as you can see. Make a note of any abnormalities.

When you perform in-motion inspection of the animals, you should position yourself outside of the pen next to the open gate so that you can easily view the animals as they are driven by you. You should direct the establishment employee to move all the animals slowly and individually out of the pen, while you observe each animal for abnormalities by viewing the head, neck, shoulder, flank, legs, and rump. It cannot be overemphasized to always be alert and think safety. Cattle can be surprisingly fast and agile, particularly when agitated or startled. Never go into a pen of large livestock. This is especially true of a pen with a bull or a cow with a calf. Don't make the mistake of performing in-motion inspection immediately behind a loose, swinging gate. As the animals are driven out of the pen, they could push against the swinging gate and force it against you. Also, never position yourself in a corner or in a place that allows no escape to safety should an animal turn aggressive. Don't climb on high, unstable fences to view the animals during ante-mortem inspection. As in all areas of the establishment, wear your safety helmet during ante-mortem inspection.

IPP are to verify that **only** livestock that have passed ante-mortem inspection are moved to slaughter. IPP are to perform this activity at least once per slaughter shift. IPP can achieve this by verifying that establishment documentation matches the animals driven to slaughter and that the documentation has an IPP signature or initials, and the time ante-mortem was performed. If there is reason to suspect that the animals were slaughtered **without** ante-mortem inspection, then IPP are to retain the carcasses and immediately notify the District Office through supervisory channels for guidance.

VOLUNTARY SEGREGATION, DELAYED, AND EMERGENCY ANTE-MORTEM INSPECTION

There are other ways for performing ante-mortem under certain circumstances. They include voluntary segregation, delayed, and emergency ante-mortem inspection.

Voluntary segregation is the term used to describe the type of inspection that takes place when the establishment voluntarily segregates animals prior to ante-mortem inspection. Many large establishments elect to voluntarily segregate animals. **Voluntary segregation is not permitted for cattle**.

Provided the establishment properly presents animals for ante-mortem inspection and properly follows the HMSA, FSIS permits an establishment to voluntarily segregate animals, to facilitate the establishment's scheduling of swine and sheep (e.g., market hogs and lambs) for slaughter. As per FSIS Directive 6100.1 “Ante-Mortem Livestock Inspection,” FSIS only permits market classes of swine and sheep (i.e., market hogs and lambs), arriving for regular slaughter (i.e., not arriving for slaughter under any APHIS Veterinary Services permit or certificate) to be voluntarily segregated by the establishment prior to FSIS ante-mortem inspection activities provided that:

- Market classes of animals comprise the predominant class slaughtered at the establishment.

- The establishment has documented its segregation procedures in a prerequisite program (PRP).
- All animals are presented to inspection program personnel for examination and inspection prior to slaughter.
- Procedures in the PRP and related records are available to inspection personnel upon request.

Here are the inspection procedures you are to use to verify the establishment's segregation procedures for market swine and lambs prior to FSIS ante-mortem inspection:

1. Verify that the segregation procedures are only for market classes of swine and lambs.
2. Examine all animals found normal by the establishment while the animals are "at rest," (i.e., by randomly moving around in the pens.) (9 CFR 309.1(a)).
3. Select 5 to 10 percent of all animals presented for ante-mortem inspection from several lots and observe them in motion.
4. Instruct the establishment to move abnormal animals that may be condemned under 9 CFR part 311 to the designated suspect pen under 9 CFR 307.2 for final disposition by the PHV.
5. Randomly observe establishment personnel performing segregation procedures (i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals) at least once per month.

If an establishment does not have documented segregation procedures or fails to implement its segregation procedures properly, instruct IPP to not take into consideration the establishment's segregation program.

For livestock classes other than market swine and lambs (such as cattle), establishments may presort animals prior to inspection and move the animals that may be designated U.S. Suspect or U.S. Condemned under 9 CFR part 309 and 311 to the designated suspect pen for final disposition by the PHV. **Note:** Presorting is not the same as voluntary segregation; thus, IPP must observe all presorted animals regardless of where they are placed, at rest and in motion, to complete ante-mortem inspection. The PHV must conduct a careful examination and inspection on all animals in the suspect pen. Inspection program personnel are to conduct an examination and inspection of all remaining animals by observing them both at rest and in motion.

Delayed slaughter is covered in 9 CFR 309.1(a). Delayed slaughter is a method of inspection that allows certain low volume establishments to have ante-mortem inspection completed on the day before the animal is scheduled for slaughter. This type of ante-mortem inspection is performed in the afternoon and is only for facilities that slaughter 1-15 animals per day. Prior approval of the FLS is needed before delayed slaughter can be implemented. **Delayed slaughter is not permitted for cattle** (9 CFR 309.1(a) and 311.27).

Special provisions have been made to allow the emergency slaughter of seriously injured animals during other than normal inspection time. The establishment must attempt to contact FSIS personnel, explain the situation, and arrangements made for inspection to take place. If the establishment is unable to contact FSIS personnel, the emergency slaughter provision allows establishment personnel to slaughter the animals without ante-mortem inspection provided the carcass and all parts, including the viscera, are retained for post-mortem inspection by FSIS. Emergency slaughter is NOT intended to cover the slaughter of sick or dying animals, only those that are seriously injured. Animals that are sick or dying from a disease are not covered by emergency slaughter. **Emergency slaughter is not permitted for cattle.**

Poultry

9 CFR 381.70 describes that poultry ante-mortem inspection must be performed on the day of slaughter (with some exceptions for ratites). It can be performed by either an inspector or PHV. Ante-mortem is performed on a group basis while the birds are in coops or batteries, before or after removal from trucks. IPP follow OFO supervisory instructions as to how often **daily** ante-mortem of poultry is performed (e.g., per lot). When performing ante-mortem inspection, inspection program personnel are to observe the overall condition of the birds, including the head, with attention to the eyes, legs, and the body of the birds; and whether there are any unusual swellings or other abnormalities on the birds.

ANTE-MORTEM DISPOSITIONS

There are three possible outcomes, or dispositions, that follow observation of livestock or birds in ante-mortem inspection:

1. Passed for slaughter
2. Suspect
3. Condemned

The animal or lot of birds can be passed for slaughter. This means that the animals or birds were determined to be fit for human food.

Those animals that clearly exhibit signs of certain diseases and conditions listed in the regulations, which are determined to make the animals unfit for human food, must be condemned. This means that they are not fit for human food, and they must be destroyed and not allowed to enter commerce as human food (see "Condemned and Inedible" for information on verifying the denaturing of carcasses condemned on ante-mortem).

Then there are those animals or birds that may exhibit signs of the diseases or conditions defined in the regulations, but further confirmation during post-mortem inspection is needed before condemning the carcass or a part of the carcass. In each of these three cases, there are certain things that you must do. Let's review each situation for livestock, and then for poultry.

Livestock

Passed for Slaughter

After you complete ante-mortem inspection and properly record the results, you will then take action based on your findings. You will allow the animals that you have determined to be free of the diseases and conditions described in the regulations, and therefore fit for human food, to be released for slaughter. You will certify this to the establishment by signing and dating the time of ante-mortem inspection on the establishment's pen card or drive sheet. Once this is done, ante-mortem inspection is complete, and the livestock may be driven to slaughter. An original or copy of the signed and dated document used by the establishment in presenting animals for ante-mortem inspection is to be collected by IPP daily. Keep this document in the FSIS inspection office for one week following the end of the respective slaughter week.

IPP are responsible for verifying that livestock slaughtered at an establishment have received ante-mortem inspection. IPP do so by:

1) At least once per shift, verify that only livestock that have passed ante-mortem inspection are moved to slaughter by observing livestock handlers driving livestock from the holding pens to the

slaughter area and verify that: the establishment's documentation (e.g., pen card) matches the animals being driven to slaughter; and the documentation has an IPP signature or initial and time that indicates ante-mortem was performed.

2) Periodically, throughout a slaughter shift, verify that the number of livestock slaughtered (during a slaughter shift) is no more than the number of livestock that have passed ante-mortem inspection. The post-mortem location for this verification procedures is determined by the IIC. During post-mortem inspection IPP tally the number of livestock, for a particular lot, that received ante-mortem inspection using the establishment's documentation (e.g., pen card) and compare this number with the establishment's total for the number of livestock slaughtered in that lot.
3) At least once per week, IPP verify that the total number of animals that received and passed ante-mortem inspection are equal to or greater than the total number of animals slaughtered. IPP verify these numbers by determining the number of livestock that were eligible for slaughter by examining and totaling the number of livestock on verified documentation (e.g., pen card); and the completed "Identification Tag Ante-Mortem" forms for that shift; compare this number to the establishment's total number of head slaughtered; and determine whether a discrepancy exists.

If IPP find that there is a discrepancy, they are to discuss with establishment management why the livestock numbers do not agree and determine how to reconcile these figures. If IPP determine that livestock were slaughtered without ante-mortem inspection, IPP are to follow guidance in FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection."

Suspect

Some of the animals may exhibit signs that cause you to question whether the animal is affected by a disease or condition described in the regulations (9 CFR 309.2). You will direct the establishment to place a U.S. Suspect tag in the animal's ear and to segregate those animals with abnormal signs into the suspect pen for further observation after you have completed the ante-mortem inspection. A couple of simple examples of animals that should be tagged as U.S. Suspect and placed in the suspect pen are animals that are seriously crippled and non-ambulatory disabled or those that are non-ambulatory. The exception is non-ambulatory cattle, which must be condemned, including veal calves. Section 9 CFR 309.2(n) states that all animals that are suspect must be set apart and slaughtered separately. When animals are placed in the suspect pen, they must be accompanied by FSIS Form 6150-1 (9 CFR 309.2(o)).

After further examination of an animal in the suspect pen, the PHV may determine that the animal is not fit for human food according to the regulations and that it must be condemned. Alternatively, you may determine that the suspect animal is normal or that the abnormal signs you observed are not severe enough to have the animal suspected or condemned. This animal may be released for slaughter. If the establishment employee moves this animal out of the suspect pen and into a different pen, be sure to make the necessary changes on the pen card. A third possibility is to have the suspect animal continue to be slaughtered separately as a U.S. Suspect, where the veterinarian makes the final disposition during post-mortem inspection.

Section 9 CFR 309.2(p) provides for occasions when the establishment requests and receives permission to hold an animal for treatment to improve the animal's condition to the point that it may become eligible for slaughter (including U.S. Suspect and U.S. Condemned livestock, excluding non-ambulatory disabled cattle). This "on-premises treatment" is a relatively rare occurrence, but, if it does occur, the PHV has certain responsibilities. The identity of the animal must be maintained throughout the treatment period. The animal must be placed in a separate pen identified with a pen card. In

addition, the FSIS Form 6150-1 must be changed. Cross out the word, "slaughter," and write in the phrase "held for treatment" in the appropriate space. Following the treatment, the PHV will examine the animal and make an ante-mortem disposition.

Another possibility is that the establishment may request and receive permission to have an animal treated off-premises, such as at a local veterinary clinic. These animals must also be kept in an identified pen until they are picked up for treatment. The U.S. Suspect or U.S. Condemned tag is removed just before the animal is shipped. The tag can be removed because a different type of identification system will be used to identify the animal after it leaves the establishment premises. IPP are to verify that the establishment has received permission from the appropriate local, state, or federal livestock sanitary official having jurisdiction to move the animals off premises (9 CFR 309.13(d)). **It is not permitted to hold non-ambulatory disabled cattle for treatment, either on or off premises.** Non-ambulatory disabled cattle, including veal calves, are condemned on ante-mortem, and must be promptly humanely euthanized by the establishment.

Condemned

An animal that is condemned during ante-mortem inspection is not eligible for slaughter because it has been identified as having diseases or conditions specified in the regulations that make it unfit for human food. For example, 9 CFR 309.3 indicates that dead, dying, disabled, or diseased livestock are to be condemned. Section 9 CFR 309.13 covers the regulatory requirements for the disposition of condemned livestock. It is your responsibility to identify the animal so that it is neither slaughtered nor used for human food. Any livestock that is condemned must have a U.S. Condemned tag placed in its ear. The FSIS veterinarian must complete the FSIS Form 6150-1 and must ensure that the establishment properly disposes of the condemned animal. The word “Suspect” is crossed out on the form, and the number of the U.S. Condemned tag that was placed in the animal's ear is written in the space provided on the form.

Since the establishment cannot slaughter a condemned animal, the establishment must promptly and humanely euthanize the animal (or hold it for treatment, when permitted) and immediately dispose of the carcass in accordance with 9 CFR 309.13. IPP verify the establishment disposes of the carcass per 9 CFR 309.13 and 314. Establishment disposal of condemned products is covered in the Post-mortem Inspection Overview section.

Here’s an example. As stated earlier, a dead animal may not be used for human food. When you observe an animal that arrives at the establishment dead or subsequently dies in a pen, including the suspect pen, you must make sure that there are adequate controls to prevent the animal from entering the food supply. You must take the following steps:

1. Identify the animal as condemned with a red U.S. Condemned tag.
2. Fill out an FSIS Form 6150-1 and write the words "Dead in Pens" or "Dead on Arrival" in the "Tagged For" space.
3. Ensure the animal is disposed of in accordance with 9 CFR 314.

IPP record appropriate ante-mortem information into the PHIS Animal Disposition Reporting function, including information on condemned livestock.

FSIS Form 6150-1

When you perform the ante-mortem inspection procedure, you observe each animal for abnormal signs. When you find an animal exhibiting signs of the diseases and conditions described in the

regulations, you must record the signs on the FSIS Form 6150-1, Identification Tag Ante-mortem. The form (tag) will identify animals as U.S. Suspect or U.S. Condemned (9 CFR 309.2(o)). The form (tag) is also used for animals identified as TB Reactors by using the reactor tag number instead of the suspect tag number.

For cattle identified as U.S. Condemned during ante-mortem inspection at federally inspected establishments, PHVs are to complete and sign the form. PHVs are to enter the justification for condemnation under the remarks section. Once the form is completed, the form is to be filed in the inspection office. (9 CFR 309.2(o))

The form is divided into two sections:

1. The upper section contains most of the information that identifies the animal, such as the kind of animal, sex of the animal, and the animal approximate weight. You will complete the upper section of the card. When a single Form 6150-1 is used to identify more than one animal, be sure to indicate the number in the section "kind of animal": 3 Herefords, 2 Holsteins, etc. Also record all back tag numbers, ear tag numbers, etc., for each animal.

    Slaughter at establishment - indicate the official establishment number where the animal is to be slaughtered.

    Condemned or suspect tag - if you apply a U.S. Suspect tag, enter the number of the tag and cross out the word "condemned" If the form is used for more than one animal, be sure to enter all suspect tag numbers.

    Kind of animals - terms like Hereford, Jersey, Buffalo, Santa Gertrudis, Hampshire, Yorkshire, Duroc, etc., should be used.

    Sex - use terms like bull, cow, heifer, shoat, ewe, barrow, etc.

    Tagged for - indicate the condition for which you tagged the animal, (e.g., actinobacillosis, epithelioma, non-ambulatory disabled, TB reactor, pneumonia, broken leg, etc.). If you feel it is necessary to add more information, use a phrase like "see back of form" and then write the information on the back of the form.

    Temperature - indicate the temperature in degrees °F. You must take the temperature of (or direct the establishment to take the temperature of) TB reactors and any other livestock you suspect may have an abnormal temperature (i.e., non-ambulatory disabled livestock, mastitis elimination cows, animals exhibiting signs of an abnormal temperature).

    Weight - estimate the animal's weight in pounds.

    Remarks - the PHV will complete the remarks section after determining the ante-mortem disposition and then sign and date the form. Depending on local policy, the optional post-mortem report section may or may not be completed.

2. The lower section is the post-mortem report. This section will be completed by the PHV responsible for post-mortem inspection. The lower half of the form contains the following sections:

    Findings – enter the post-mortem examination findings.

Disposal – enter the disposition of the carcass and parts based on the post-mortem findings.

Inspector and date – the PHV signs and dates the form following final disposition.

Poultry

Condemned

Regulation 9 CFR 381.71 states that birds plainly showing any disease or condition in 9 CFR 381.80 to 381.93 that would cause condemnation of the carcass on post-mortem inspection are condemned on ante-mortem. The specific regulations and conditions for poultry are covered in the Multi-species Disposition Basics section. For now, just remember that you should ante-mortem condemn those poultry that would clearly be condemned on post-mortem inspection.

According to 9 CFR 381.71, condemned poultry are not to be dressed, nor shall they be conveyed into any part of the official establishment where poultry are prepared or held. They must be disposed of appropriately (9 CFR 381.95). We will cover methods of disposal for condemned birds when we discuss post-mortem inspection. They include tanking, incineration, and denaturing. PHVs should ensure that dead-on-arrival (DOA) poultry are identified, counted, and weighed by the establishment, and the number is recorded in the PHIS Animal Disposition Reporting function by IPP.

Suspect

Birds that do not plainly show but are suspected of being affected by any disease or condition in 9 CFR 381.80 to 381.93 that would cause condemnation of the carcass or parts on post-mortem inspection are segregated and held for separate slaughter and examined at post-mortem (9 CFR 381.72). The PHV should verify that the establishment releases birds for treatment under the control of appropriate state or federal officials. PHVs are to notify the DO and follow instructions in FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions" when they suspect a reportable or foreign animal disease. PHVs should also follow instructions in FSIS Directive 6020.1 "Enhanced Inspection of Poultry in Response to a Notification of HPAI Outbreak" when FSIS issues specific instruction via an FSIS user notice. Section 9 CFR 381.73 covers the quarantine of diseased poultry. It states that live poultry affected by a contagious disease transmissible to humans must be segregated and either:

- Slaughtered separately if further handling does not create a health hazard, or
- Released for treatment if practicable (if further handling is a hazard, and in conjunction with state authorities and APHIS), or
- Condemned if treatment is not practicable (when further handling is determined to be hazardous).

SIGNS OF DISEASE AND CONDITIONS DURING ANTE-MORTEM

Livestock

This section covers some general signs that indicate an animal may have a condition or disease referenced in the regulations, making it unwholesome, adulterated, or unfit for human food. Specific diseases and conditions are covered during the Multi-species Disposition Basics portion of this training. In general, these signs include the following:

- Body movement
- Body condition
- Signs on the body's surface

Abnormal Body Movement

Ante-mortem signs that indicate an animal may have a condition or disease referenced in the regulations can be associated with body movement and action, body position, condition, function, surfaces, discharges, and body odor. Some examples of the signs associated with body movement, action and position include:

1. Lameness or limping - sometimes the cause of lameness is rather obvious; sometimes not.
2. Stiffness and pain - lameness may be caused by arthritis in one or more joints.
3. Central nervous system (CNS) diseases - certain diseases such as BSE, rabies and listeriosis can affect the brain and CNS. The animal may appear extremely nervous or restless, excessively anxious or upset, or stagger or circle.
   Note: See FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions" for your responsibilities on **reporting** CNS conditions and FSIS Directive 10400.1 "Sample Collection from Cattle Under the BSE Ongoing Surveillance Program" for information on **collection of brain samples** for the APHIS BSE surveillance program.
4. Certain poisons and toxic residues that the animal has been exposed to may cause abnormal movement and action, such as staggering or circling.
5. A moribund animal may not respond to noises or other stimuli. Animals in a moribund condition are not eligible for slaughter and are ante-mortem condemned.
6. It is possible that an animal that is depressed or fails to respond normally to stimuli could be under the influence of a tranquilizer. Tranquilized animals are not eligible for slaughter. Tranquilizers and other drugs have specific withdrawal periods that must elapse before the animal is eligible for slaughter.
7. An animal may be disoriented and run into things or butt its head against objects.
8. Animals may scratch excessively or rub their hide against objects. Scratching and rubbing associated with hair loss may indicate that the animal has lice or mange infestation. Scabies is a mange condition that is a reportable disease in sheep and goats. The PHV must report this condition to other health agencies. These agencies may want to take skin scrapings from the animal to confirm the diagnosis. In sheep, pruritus and subsequent loss of wool may be a sign of scrapie, which is a reportable disease.
9. Animals may have muscle tremors or shivering, hold their head to one side, or have any number of abnormal gaits.
10. Animals may strain and assume abnormal body positions. For example, urinary or intestinal disorders may cause straining and abnormal positions such as arching of the back, tucking in of the abdomen, and extending the neck and tail.
11. An animal may have difficulty in rising, walking, or be unable to get up at all. 9 CFR 309.2(b) defines non-ambulatory disabled livestock as those that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. The PHV must examine all non-ambulatory disabled livestock, unless the establishment elects to condemn and humanely destroy the non-ambulatory disabled livestock before the PHV inspects and makes a disposition. The PHV may choose to examine non-ambulatory disabled animals

where they are rather than move them to the suspect pen to avoid unnecessary handling and pain or injury to the animal.

All cattle, including veal calves, presented as non-ambulatory disabled on ante-mortem inspection must be condemned. FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection" provides guidance on re-examination by the PHV of bovines that become recumbent or non-ambulatory after passing ante-mortem inspection, including how the PHV is to use sound professional judgement when examining these cattle. All non-ambulatory cattle, including those that have passed ante-mortem inspection, must be condemned and properly disposed of, and the establishment personnel must notify FSIS when cattle become recumbent or non-ambulatory disabled after passing ante-mortem inspection.

Remember that the cattle, including veal calves, must be able to rise from a recumbent position under their own strength and be able to walk under their own power without the use of mechanical devices (such as hobbles or hip hoists).

Abnormal Body Condition

You will also see animals with signs associated with abnormal body condition. Examples of abnormal body condition include:

1. Animals that are extremely thin and weak - you may see animals that are thin and weak due to chronic disease problems such as pericarditis, pneumonia, nephritis, etc. Animals that are in very poor condition and exhibit other signs such as depression, lethargy, respiratory difficulty, etc., should be placed in the suspect pen. Remember, though, that animals can be normally thin, so thinness alone may not be an abnormal sign. For example, some old cows may be very thin, but they may be bright and alert, have a good appetite, and show no other abnormal signs. They should not be placed in the suspect pen.
2. Calves (especially when very young) may be weak, thin, and dehydrated. They may be uncoordinated or barely able to stand. They should be placed in the suspect pen.

Abnormal signs associated with body functions include respiratory distress such as labored or rapid breathing. These signs are commonly seen in animals with lung disorders such as pneumonia. Coughing and sneezing are other signs associated with pneumonia and other respiratory disorders.

You may occasionally see animals in the act of parturition. The regulations prohibit the slaughter of these animals for human food until after they have given birth and passed the placenta (afterbirth) (9 CFR 309.10).

A cow with mastitis may have a hot, hard, swollen, and tender udder. Milk secretion may have partially or entirely stopped. A loss of appetite may be present. In advanced cases, the udder may become hardened throughout.

Animals may exhibit pain. Pain may be manifested by signs such as groaning, grunting, grinding of teeth, or kicking at their sides. You may also see animals that have difficulty drinking and swallowing or appear to be blind. All these signs are abnormal and may be associated with a great variety of diseases.

It is not uncommon during ante-mortem inspection to observe an animal with an eye missing. Any bovine with an eye missing should be handled as a suspect for epithelioma.

The PHV must examine all U.S. Suspect animals.

Abnormal Signs on the Body Surface

There are a great number of abnormal signs associated with body surfaces. Injuries and fractures are included in this group. When observing animals, be on the alert for abnormal growths, swelling, and enlargements such as hernias. Three common conditions you may see are actinomycosis, actinobacillosis, and epithelioma. Actinomycosis (commonly called "acti" or "lumpy jaw") involves the bony structures of the head, particularly the lower jaw (mandible). Actinobacillosis (commonly called “wooden tongue”) involves soft tissues in head, particularly the tongue. Epithelioma (commonly referred to as "cancer eye") is a neoplastic growth involving the eye, eyelids, and the orbital region. The tumor appears to originate in either the cornea, third eyelid, or the eyelids. Herefords are the breed most commonly affected.

Abnormalities of the skin and mucous membranes will be observed while performing ante-mortem inspection. Animals may exhibit a variety of skin lesions including papillomas (warts). They may have a roughened, dry, or dehydrated hair coat or large patches of hair missing. Be on the lookout for superficial ulcers, sores, blisters or vesicles, particularly around the feet or around the mouth. Several diseases may cause these signs, including those that are reportable such as foot-and-mouth disease. If lesions are infested with larvae (maggots), collect samples and send them to the National Veterinary Services Laboratory (Ames, Iowa). The laboratory will examine the larvae to see if they are screwworm larvae. Allied government animal health agencies have been trying for years to control the incidence and spread of screwworm infestations in this country.

The color of exposed membranes of the body, such as the gums or the eyes, may be an indication of a disease condition. The membranes may appear reddened, or very pale, or may have a yellowish color to them.

While observing body surfaces, be on the lookout for injection sites. Abnormal swelling, especially in the round or neck areas, could be an indication that the animal was recently given an injection. Approved drugs have a very specific withdrawal period prior to slaughter that, if not followed, can result in potentially harmful residues in the muscle tissue. If you observe an injection site on an animal, you must make it a suspect so that you can perform tests to determine if residues are present in the tissues.

Animals may also show signs of abnormal body discharges or abnormal odors. Abnormal discharges can include excessive salivation, diarrhea, blood, and pus. In a broad sense, animals with a retained placenta (afterbirth) can be included in this group. Be sure that animals with a retained placenta are placed in the suspect pen as the regulations prohibit the slaughtering of such animals until all the membranes have been passed.

Along with a thorough visual examination of animals, your sense of smell is a very important aspect of performing ante-mortem inspection. For example, an animal may have a prolapsed rectum or uterus that is infected, resulting in a strong, foul odor. At times when looking at a large pen of animals, you may not at first see a wound or prolapse, but you may detect the characteristic odor that will alert you to look more closely at the animals. An epithelioma of the eye that has become infected is another example of an abnormality that may be associated with a very characteristic foul odor.

One of the steps in examining suspect livestock you can conduct is to take the temperature of the animal. The chart below shows the range of normal body temperatures, as well as the condemnation

temperatures, for the various species. The regulations specifically state a certain temperature at which you must condemn the animal.

Normal Animal Temperature Ranges				
	Cattle	Swine	Sheep	Horses
Maximum	102.5	104.0	104.0	100.5
Average	101.5	102.5	102.5	100.0
Minimum	100.0	100.5	102.0	99.0
PHV condemns on ante-mortem if:				
	105.0	106.0	105.0	105.0

Poultry

Just as is true with livestock, there are signs that indicate poultry have a disease or condition outlined in the regulations making them unfit for human food. These diseases and conditions can sometimes be detected through observations of body position, body condition, and body surfaces of poultry.

Symptoms of disease that you may observe on ante-mortem inspection include the following:

- Swelling around the head and eyes
- Edema, cyanosis, or petechial hemorrhages of the wattles
- Gasping and sneezing
- Off-colored diarrhea
- Skin lesions
- Lameness
- Torticollis or wry neck, or ataxia
- Bone or joint enlargement
- Dermatitis
- Emaciation
- Abnormal number of moribund birds

These abnormal signs are covered in more detail in the Multi-species Disposition Basics portion of the training.

BIOLOGICAL RESIDUES

Livestock and Poultry Suspected of having Biological Residues

Section 9 CFR 309.16 covers livestock suspected of having biological residues. This includes livestock that have been exposed to any type of substance that would make the carcass or parts unfit for human food or otherwise adulterated. These livestock are to be identified as U.S. Condemned. The livestock may be held under the custody of FSIS until the animal's metabolic processes have reduced the

residue sufficiently for the carcass or parts to become fit for human food and not adulterated. In these cases, once the holding time has passed, the animal must be re-examined on ante-mortem inspection. It is permitted to allow these animals to be slaughtered for the purpose of collecting tissue to conduct an analysis of the residue. The analysis can include in-plant screening tests (KIS™). If the rapid in-plant antimicrobial residue screening test result is positive, you are to continue to retain the carcass and parts and submit appropriate tissue samples (liver, kidney, and muscle tissue) for further testing at the appropriate FSIS Laboratory.

Regulation 9 CFR 381.74 covers the requirements related to poultry suspected of having biological residues. There are three options. The poultry can be returned to the grower if further holding is likely to result in their not being adulterated from the residue. They can be slaughtered and processed and retained for disposition. They also can be slaughtered and buried or incinerated.

More information regarding residue testing is covered in the Residue Detection section.

APHIS VETERINARY SERVICES

Veterinary Services (VS) is an organizational unit of the Animal and Plant Health Inspection Service (APHIS). APHIS VS works to control or eradicate specified animal diseases in this country. Your role will be to contact VS through your local supervisory chain to the DO when you suspect animals or poultry of having a reportable or foreign animal disease. In most cases, VS will want the livestock or poultry held so they can examine it. For example, in the case of livestock, you will first identify the animal with a reportable disease as condemned and then have the animal placed in a separate pen identified with a pen card. The establishment employees will be notified that the animal is not to be removed from the pen for any reason without the permission of the PHV or some other animal health official. Reportable and foreign animal diseases are covered in the Foreign and Reportable Animal Diseases section.

Requirements to Demonstrate Process Control

OBJECTIVES

1. Given pathogen data from scenarios in a Slaughter/Kill Floor context, interpret the data to determine whether the establishment's process controls and sanitary dressing procedures are in control or trending out of control.
2. Given a scenario depicting a process out of control, identify RCAs that IPP may take.
3. Identify points of potential contamination during the slaughter process.
4. Demonstrate how to evaluate sanitary dressing procedures during the slaughter process.
5. Given details in the Slaughter/Kill Floor context, assess whether an establishment has adequately measured the effectiveness of its sanitary dressing procedures.

RESOURCES

FSIS Directive 5000.1 – Verifying an Establishment's Food Safety System
FSIS Directive 6410.1 – Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age
FSIS Directive 6410.4 – Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens
FSIS Directive 6420.5 – Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens
FSIS Directive 10010.2 – Verification Activities for STEC in Raw Beef Products
FSIS Directive 10010.3 – Traceback Methodology for *E. coli* O157:H7 in Raw Ground Beef Products and Bench Trim
FSIS Meat and Poultry Hazards and Controls Guide
FSIS Industry Guideline for Minimizing the Risk of STEC in Beef (including veal) Slaughter Operations
FSIS Guideline to Control *Salmonella* in Swine Slaughter and Pork Processing Establishments
FSIS Guideline for Controlling *Salmonella* in Raw Poultry

INTRODUCTION

In livestock slaughter establishments, contamination of carcasses and parts from feces, ingesta, and milk are primary avenues for the spread of pathogens. Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal going to slaughter. Edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans.

Per 9 CFR 310.18(a), livestock slaughter establishments are required to handle carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter.

Per 9 CFR 310.18(c), establishments that slaughter swine must develop, implement, and maintain written procedures in their HACCP systems (HACCP plan, Sanitation SOP, or PRP) to prevent contamination of carcasses and parts by enteric pathogens, feces, ingesta, and milk throughout the entire slaughter and dressing operation.

In poultry slaughter establishments, digestive tract contents can be a source of enteric pathogens. 9 CFR 381.65(f) requires poultry (other than ratite) slaughter establishments to develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. 9 CFR 381.65(g) requires poultry (other than ratite) slaughter establishments to develop, implement, and maintain written procedures to prevent contamination with enteric pathogens and feces throughout the slaughter process.

More information about typical steps in livestock and poultry slaughter processes, including the steps where contamination may be likely to occur, can be found in the FSIS Guidelines listed in your Resources above. You may also access HACCP models for these processes at this link.

What is Process Control?

The National Institute of Standards and Technology defines "process control" as "…the active changing of the process based on the results of process monitoring. Once the process monitoring tools have detected an out-of-control situation, the person responsible for the process makes a change to bring the process back into control."

Regarding food production, HACCP is a scientific system for process control. An establishment designs a HACCP system with process control measures in place to adequately prevent, reduce, or eliminate specific hazards. For hazards reasonably likely to occur, critical limits are established to indicate whether control measures are in or out of control. Establishments may support that hazards are not reasonably likely to occur with procedures designed to prevent conditions that make the potential hazards likely to occur.

All processes are subject to variation. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is thus "doing its best." Processes that have not been subjected to analysis are not likely to be in control. Control is attained, often by degrees, by detecting and eliminating special causes of variation, those not present all the time or not affecting all product output. If a process is allowed to go out of control, food safety hazards could become reasonably likely to occur, insanitary conditions could be created, or product may not be eligible for the mark of inspection.

Individual systems will vary, however a simple explanation of what "process controls" may look like includes:

- A written program or procedure that articulates the standard the establishment intends to achieve,
- Points in the operation where the establishment takes measurements, including frequency of those measurements,
- Evaluation criteria (a measurable value) used to determine whether the process is in control or may be trending out of control,
- Corrective actions the establishment plans to take if the above criteria are exceeded, including how the establishment will restore process control and measurements they will take to confirm process control has been restored and
- Records that are generated to document all the above.

For example, a poultry slaughter establishment has a program to produce poultry that meet the definition of "Ready-to-cook". The program is written and includes procedures that clearly describe the establishment's intended outcome. The establishment's program includes points in the process where

measurements are taken, and includes the criteria used for evaluation. For example, they assess feather control at re-hang to verify adequate feather removal at least every 2 hours per line per shift. The program describes a value for the number of feather defects considered acceptable and unacceptable. The program also includes actions the establishment will take if the level of feather defects exceeds the acceptable limits. The program generates records that support the establishment is implementing the program as written, responding to unacceptable results, and maintaining process control.

MICROBIAL TESTING

Livestock and poultry slaughter establishments must conduct microbial testing to verify the effectiveness of their sanitation and process control. Establishments that slaughter livestock (other than swine) or ratites are to test carcasses for *Escherichia coli* Biotype 1 (generic *E. coli*) to meet the requirements of 9 CFR 310.25(a) or 381.94(a), respectively. Establishments that slaughter swine (9 CFR 310.18(c)) or poultry (9 CFR 381.65(g)) are required to determine which microbial organisms will be effective in monitoring process control and to implement sampling plans, specifically to monitor for enteric pathogens and fecal contamination. More information about the livestock and poultry slaughter establishment microbial testing requirements can be found in the Directives listed in your Resources above. Microbial testing for process control is covered in more detail in the Food Microbiology and Microbial Sampling for Process Control section.

VERIFYING PROCESS CONTROL

When you verify an establishment's procedures to maintain process control, you are verifying at multiple steps in the slaughter process. You will be aware of how the establishment has included written programs to prevent contamination and review those programs and associated records. You will determine if the establishment's procedures are regularly or systematically allowing contamination to occur. You will consider your findings in the overall context of the establishment's control of the slaughter process and the effectiveness of the establishment's programs to prevent carcasses and parts from becoming contaminated during slaughter.

As a supervisor, you will also ensure that IPP on your team are correctly applying the inspection methodology, are making informed decisions, are properly documenting findings, and are taking the appropriate enforcement actions. When repeated noncompliance findings are associated and indicative of a systemic problem with the establishment's slaughter HACCP system, such findings must be communicated with your chain-of-command.

Verifying Sanitary Dressing and Process Control in Cattle Slaughter Operations

FSIS Directive 6410.1 "Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age" instructs IPP on how to verify cattle slaughter operations are implementing sanitary dressing and process control procedures, and that the procedures they are implementing prevent contamination of carcasses and ensure that insanitary conditions are not created. It also provides information on how to assess the sanitary dressing and process controls. The directive defines key terms, describes potential contamination points in the slaughter process, and describes how to document noncompliance under the Beef Sanitary Dressing task in PHIS.

Sanitary dressing is defined as the practice of handling carcasses and parts by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, and wholesome meat food product in a sanitary environment. Contamination may occur from

substances not inherent to the species being slaughtered (e.g., rail dust) or substances inherent to the species being slaughtered (e.g., digestive tract contents). Sanitary dressing procedures minimize contamination.

The PHIS Beef Sanitary Dressing task is used to verify compliance with the sanitation performance standards (SPS) requirements in beef slaughter operations. IPP verify establishments slaughter and process cattle in a manner designed to prevent contamination from occurring at any step in the process. IPP will make observations of the slaughter process and review applicable establishment records. IPP focus on all aspects of the establishment's sanitary dressing and process control procedures. Establishments may elect to maintain these procedures as part of their HACCP plan, Sanitation SOP, Good Manufacturing Practices, or other pre-requisite programs.

IPP evaluate the sanitary dressing and process control procedures as a whole. When IPP determine an insanitary condition has been created as the result of ineffective implementation of sanitary dressing procedures, IPP cite noncompliance with 9 CFR 310.18(a) and SPS regulations that are appropriate to the situation in order to address the creation of the insanitary condition. Examples of observations that could indicate that sanitary dressing procedures are not being properly implemented, and where insanitary conditions are being created as a result of the loss of process control include:

- Repeated or ongoing noncompliance related to contamination of carcasses with feces, milk, or ingesta at the final rail (i.e., zero tolerance).
- Repeated or ongoing loss of process control resulting in failure to prevent contamination of carcasses or parts; failure to effectively prevent the contamination of carcasses or parts; or failure to remove such contaminants before final inspection.
- Establishment or FSIS microbial sampling results indicate increasing microbial contamination of carcasses or parts.

Isolated occurrences of contamination observed during verification is not automatic evidence that the establishment has failed to maintain sanitary dressing. IPP are to evaluate incidental occurrences of contamination as they relate to the overall slaughter system to determine whether the establishment has failed to prevent the creation of insanitary conditions, i.e., are the issues "persistent and unattended?" As a supervisor, you are to engage in discussion with IPP about their findings related to the establishment's slaughter HACCP system and any trends or systemic concerns that IPP report.

More examples and information on how to document noncompliance are discussed in FSIS Directive 6410.1 "Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age" and Directive 6420.2 "Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations."

When information suggests that the establishment has lost process control, IPP are to determine whether the establishment has taken measures to bring the process back under control. Examples of types of findings that can indicate a loss of control include:

- Comparison of current and previous reviews indicates there has been an increase in contamination.
- Evidence that contamination events are not being effectively prevented.
- Increase in positive pathogen results from either FSIS or establishment microbial testing.

FSIS Directive 6100.2 "Post-Mortem Livestock Inspection" instructs the IIC to verify whether the establishment's sanitary dressing procedures for controlling contamination are affecting the inspector's

ability to perform proper post-mortem inspection procedures. The PHV (or IIC) is to slow maximum allowed line speeds and document noncompliance when slaughter process control is not maintained because of contamination or sanitary dressing (9 CFR 310.1(b)(1)). IICs are to use the PHIS Beef Sanitary Dressing task to document noncompliance when they determine there is evidence that insanitary conditions have been created resulting in the inability of the on-line inspector to adequately perform the proper post-mortem inspection procedures.

Verifying Swine Slaughter Establishments Maintain Adequate Procedures to Prevent Contamination

FSIS Directive 6410.4 "Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens" instructs IPP on how to verify that establishments effectively prevent contamination of swine carcasses and parts throughout the slaughter and dressing operation (9 CFR 310.18(c)). It also instructs IPP on how to verify the establishments meet the recordkeeping requirements in 9 CFR 310.18(d).

The 9 CFR 310.18(c) requirements to prevent contamination were described in the Introduction and Microbial Testing parts of this section. Establishments may meet these requirements with one written plan or in separate plans in their HACCP system. 9 CFR 310.18(d) requires all swine slaughter establishments to maintain daily records sufficient to document the implementation and monitoring of the procedures required under 9 CFR 310.18(c).

IPP verify an establishment meets the regulatory requirements to prevent contamination of swine carcasses and parts with enteric pathogens, feces, ingesta, and milk throughout the slaughter operation in two ways:

1. IPP conduct the Livestock Zero Tolerance Verification task – to verify that the establishment's HACCP system is preventing carcass contamination with feces, ingesta, and milk.
2. IPP conduct applicable HACCP system verification tasks – either Slaughter HACCP Verification or Operational Sanitation SOP Verification task, depending on the location of the contamination control programs. IPP verify the establishment maintains written plans to effectively prevent contamination of carcass and parts and IPP review the results of the establishment's microbial sampling plan.

IPP observe the swine slaughter operation and review establishment records to verify that the establishment's slaughter process is in control and preventing contamination of swine carcasses and parts. IPP verify that the establishment's procedures are not regularly or systematically allowing contamination with enteric pathogens, feces, ingesta, and milk to occur. IPP are to:

- Observe carcasses at various points on the slaughter line for evidence of frequent or recurring contamination with visible feces, ingesta, or milk.
- Observe the contact surfaces and operation of establishment equipment to verify the equipment appears to be adjusted correctly and is not routinely contributing to contamination of the carcass and parts.
- Observe establishment employees to verify they are consistently preventing contamination of carcasses and that they respond appropriately to remove visible contamination when it does occur.
- Observe establishment employees implementing the procedures for preventing contamination, including any related monitoring, recordkeeping, or sampling activities.

- Verify the establishments use reconditioning, trimming, or antimicrobial intervention treatments effectively.

IPP should consider if recent noncompliance records or problems found during FSIS verification activities or establishment monitoring procedures suggest that increased contamination is occurring at a certain location in the process. IPP should pay particular attention to that location and possible sources of contamination.

IPP are also to verify the establishment's microbial testing for process control. This topic is covered in the Food Microbiology and Microbial Sampling for Process Control section.

IPP document noncompliance following FSIS Directive 6410.4 "Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens" and FSIS Directive 6420.2 "Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations." IPP consider their findings from the verification tasks in the overall context of the establishment's control of the slaughter process and the effectiveness of the establishment's plans to prevent swine carcasses and parts from becoming contaminated with enteric pathogens, feces, ingesta, or milk during slaughter. IPP are to consider whether the overall pattern of inspection findings suggest that the establishment is not maintaining sanitary conditions throughout the slaughter HACCP system. IPP are to discuss such situations with their immediate supervisor to evaluate the need to take an enforcement action. As a supervisor, you are to engage in discussion with IPP about their findings related to the establishment's slaughter HACCP system and any trends or systemic concerns that IPP report.

Verifying Poultry Slaughter Establishments Maintain Adequate Procedures to Prevent Contamination

FSIS Directive 6420.5 "Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens" instructs IPP on how to verify that establishments effectively prevent contamination of poultry carcasses (other than ratite) throughout the slaughter and dressing operation (9 CFR 381.65(f) and (g)).

The 9 CFR 381.65(f) and (g) requirements to prevent contamination were described in the Introduction and Microbial Testing parts of this section. The regulations require poultry slaughter establishments to incorporate written procedures for controlling contamination into their HACCP plan, Sanitation SOP, or other PRP. 9 CFR 381.65(h) requires poultry slaughter establishments to maintain daily records sufficient to document the implementation and monitoring of these procedures.

IPP verify that an establishment meets the requirements to prevent contamination with enteric pathogens and feces throughout the slaughter operation in two main ways:

1. IPP perform the Poultry Zero Tolerance task to verify the establishment's HACCP system is preventing carcasses contaminated with feces from entering the chilling system.
2. IPP verify the establishment implements the written programs to effectively prevent contamination with feces and other sources of enteric pathogens. IPP are also to verify the establishment meets the applicable recordkeeping requirements and review the results of the establishment's microbiological sampling program.

IPP observe the poultry slaughter operation and review establishment records to verify that the establishment's slaughter process is in control and preventing contamination with feces or ingesta. IPP

verify that the establishment's procedures are not regularly or systematically allowing contamination to occur. IPP are to:

- Observe carcasses at various points on the slaughter line for evidence of frequent or recurring contamination with visible ingesta or feces.
- Observe the contact surfaces and operation of establishment equipment (e.g., venter, opener) to verify the equipment appears to be adjusted correctly and is not contributing to fecal and/or ingesta contamination of the poultry carcasses.
- Observe establishment employees to verify that they are consistently preventing contamination of poultry carcasses during dressing tasks and that they respond appropriately to correct visible contamination when it does occur.
- Observe establishment employees implementing the procedures for preventing contamination with enteric pathogens and feces, including any monitoring, recordkeeping, or sampling activities that the establishment uses to document control of contamination during the slaughter process.
- Verify that establishments use reconditioning, reprocessing, or antimicrobial intervention treatments to effectively address any contamination that occurs during the slaughter process.

IPP should consider recent findings during FSIS verification activities or establishment monitoring procedures that might suggest that increased contamination could be occurring in a certain location in the slaughter process and pay particular attention to those possible sources of contamination when observing establishment operations.

IPP are also to verify the establishment's microbial testing for process control. This topic is covered in the Food Microbiology and Microbial Sampling for Process Control section.

IPP document noncompliance following FSIS Directive 6420.5 "Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens." IPP are to consider their verification findings in the overall context of the establishment's control of the slaughter process and the effectiveness of the establishment's programs to prevent poultry carcasses from becoming contaminated with feces or enteric pathogens during slaughter.

IPP are to consider whether the overall pattern of inspection findings suggest that the establishment is not maintaining sanitary conditions throughout the slaughter HACCP system. For example, if an establishment has repetitive associated HACCP or Sanitation SOP noncompliances for multiple aspects of the slaughter system, or if the establishment's corrective actions in response to findings of visible fecal contamination are consistently ineffective, it may indicate that the establishment is slaughtering poultry under insanitary conditions. IPP are to discuss such situations with their immediate supervisor to evaluate the need to take an enforcement action. As a supervisor, you are to engage in discussion with IPP about their findings related to the establishment's slaughter HACCP system and any trends or systemic concerns that IPP report.

VERIFYING SHIGA TOXIN-PRODUCING *E. COLI* RESULTS & HIGH-EVENT PERIODS

Shiga Toxin-Producing *E. coli* (STEC) contamination is a food safety hazard that is reasonably likely to occur during the slaughter and processing of raw intact and raw non-intact beef products. FSIS considers all raw non-intact beef and raw intact beef intended for use in raw non-intact product to be adulterated under the FMIA when it is contaminated with an adulterant, including *E. coli* O157:H7 and

these six non-O157 STEC when the Shiga toxin and Intimin genes are present: O26, O45, O103, O111, O121, and O145.

FSIS requires that establishments perform ongoing verification activities to ensure their food safety system is functioning as intended and support decisions made in their hazard analysis. Establishment verification testing results on trimmings are likely the best available objective information a slaughter establishment can use to determine the ongoing effectiveness of its slaughter/dressing operation.

IPP should also verify and assess the establishment's interventions to reduce *E. coli* O157:H7 and other STECs to below detectable levels. They do so when conducting the Slaughter HACCP Verification task.

If an establishment conducts frequent STEC testing and frequently finds positives, including numerous positives within a day or week, this may indicate the establishment is not maintaining process control.

STEC positives occur on an infrequent basis, (i.e., typically less than 1%). When an establishment conducts frequent testing and never finds a positive, this may indicate problems with the validity of the sampling and testing methodology.

High event periods (HEP) are periods in which slaughter establishments experience a high rate of positive results for STEC in trim samples from production lots containing the same source materials. A HEP may mean that a systemic breakdown of the slaughter dressing operation has occurred and has created an insanitary condition applicable to all parts of the beef carcass. FSIS recommends establishments identify HEP criteria so that they can determine whether they need to withhold product from commerce when a HEP has occurred, because the presence of a HEP may indicate more widespread adulteration of product, beyond the product found positive.

FSIS HEP guidance, found in FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for STEC Organisms or Virulence Markers, applies mainly to beef slaughter/fabrication establishments that manufacture 50,000 pounds or more of trimmings daily. Such establishments are likely to conduct sufficient verification testing on same source materials to determine whether a HEP occurred. Small establishments that test infrequently might decide to develop other criteria for determining whether they have experienced a HEP.

FSIS guidance recommends two distinct HEP situation criteria: one type for a localized out-of-control situation, and a second type for a systemic break-down situation. In both situations, FSIS believes that establishments should be concerned if their sampling of trimmings produce a positive rate statistically significantly greater than 5%. In such cases, the processor should review process control measures and intervention measures used during slaughter, dressing, fabrication, and grinding. When a HEP occurs, the establishment needs to consider whether the negative-tested lots of trimmings are releasable, and whether primal and subprimal product produced from the same source materials as the trimmings may be positive for STEC.

IPP should review the slaughter establishment's STEC test results to determine whether the establishment has experienced a HEP. If establishments have developed their own HEP definition, IPP are to verify that establishments have support for their definition. If the establishment has not developed its own HEP criteria, or its criteria are not supported, IPP are to determine whether the establishment experienced a HEP based upon the following criteria:

- For a local HEP: 3 or more STEC positive results out of 10 consecutive samples from production lots containing the same source materials; that is, the trim was produced from one or

more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift) and

- For a systemic HEP: 7 or more STEC positive results out of 30 consecutive samples from production lots containing same source materials.
- Table 1 in Attachment 3 of FSIS Directive 10010.3 "Traceback Methodology for *E. coli* O157:H7 in Raw Ground Beef Products and Bench Trim" for HEP criteria if an establishment tests more than 60 samples per day or local HEP for 10 consecutive samples.

More information on verification activities for STEC and on how to determine whether an establishment has experienced a HEP can be found in FSIS Directive 10010.2 "Verification Activities for STEC in Raw Beef Products" and 10010.3 "Traceback Methodology for *E. coli* O157:H7 in Raw Ground Beef Products and Bench Trim."

If you or IPP on your team identify concerns with an establishment's STEC sampling and testing (e.g., the establishment conducts frequent testing and never finds a positive, or an establishment conducts frequent testing and frequently finds STEC positives, including numerous positives within a day or week), notify your chain-of-command. The DO may schedule an EIAO to review the establishment's STEC control and verification measures.

Post-mortem Inspection Overview

OBJECTIVES

1. Define the purpose of post-mortem inspection.
2. Identify the statutes that provide FSIS the authority for conducting post-mortem inspection.
3. Identify the regulations that cover post-mortem inspection.
4. List the directives that provide instructions on conducting post-mortem inspection.
5. Identify the establishment responsibilities regarding conducting post-mortem inspection.
6. Describe the process of conducting post-mortem inspection procedures.
7. Given a scenario involving a presentation check at a line inspector station, evaluate the establishment's method of presentation.
8. Define "salvage" and "reprocessing," and describe how IPP assess compliance with these procedures.
9. Define how the establishment must dispose of condemned products.
10. Describe how to complete post-mortem reports.

RESOURCES

FSIS Directive 6100.2 – Post-Mortem Livestock Inspection
FSIS Directive 6100.3 – Ante-Mortem and Post-Mortem Poultry Inspection
FSIS Directive 6240.1 – Inspection, Sampling, and Disposition of Animals for Tuberculosis
FSIS Directive 6170.1 – Ratite Ante-Mortem and Post-Mortem Inspection
FSIS Directive 6210.2 – Inspection of Poultry Feet that are Presented as Eligible to Receive the Mark of Inspection
FSIS Guide for Training Establishment Carcass Sorters in NPIS
FSIS Guide for Training Establishment Sorters under in NSIS
IPP Help: FI Quick Immersion Training (VPN required)
IPP Help: Media Library – Post-Mortem Procedures videos, Slaughter Series videos (VPN required)
PHIS Help: Animal Disposition Reporting (VPN required)

INTRODUCTION

Post-mortem inspection covers the inspection of the carcasses and parts of meat and poultry used for human food. Post-mortem inspection is performed after both slaughter and preparation for presentation are completed by the establishment. Post-mortem inspection ends after IPP/the PHV make a final disposition and complete any post-mortem reinspection, typically just before the step where the carcass is placed into the cooler or chiller. The purpose of post-mortem inspection is to protect the public's health by ensuring that the carcasses and parts that enter commerce are wholesome, not adulterated, and properly marked. This means that any carcasses or parts that are unwholesome or adulterated, and thereby unfit for human food, do not enter commerce.

The FMIA (Section 21 U.S.C. 604) and meat inspection regulations (9 CFR 310.1(a)) mandate that IPP are to conduct post-mortem inspection of all livestock carcasses and parts. IPP are to examine and inspect the livestock carcasses and parts in official establishments in order to determine whether

carcasses are wholesome and not adulterated. Under the PPIA (Section 21 U.S.C. 455), IPP are to perform post-mortem inspection of poultry to prevent the entry into commerce of adulterated products.

Note: Post-mortem inspection procedures for the New Poultry Inspection System (NPIS) are described in FSIS Directive 6500.1 "New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-to-Cook Requirement" and for the New Swine Inspection System (NSIS) are described in FSIS Directive 6600.1. "New Swine Slaughter Inspection System: Ante-Mortem and Post-Mortem Inspection and Verification of Food Safety and Ready-to-Cook Requirements." These procedures are not covered in this training. See the Modernization of Inspection section for more information.

If you are assigned to work in a large establishment, you will be supervising inspectors who perform the post-mortem inspection procedures. However, it may be necessary for you to perform the post-mortem inspection procedures for the inspectors while they take their breaks. If you are assigned to work in a very small establishment, you may be performing some or all of these procedures. Supervisors ensure on-line IPP follow post-mortem procedures according to policy instructions.

POST-MORTEM REGULATIONS

The regulations that cover post-mortem inspection of livestock include:

- 9 CFR 310.2 – 310.6 (covers identification of carcass and parts until inspection is complete; retention for veterinary disposition; U.S. Retained tags; marking as U.S. Condemned; and U.S. Passed for Cooking)
- 9 CFR 310.8 (covers passing and marking carcasses and parts; passed for cooking; and U.S. Retained tags)
- 9 CFR 310.18(a) (covers handling carcasses, organs, and parts in a sanitary manner to prevent contamination)
- 9 CFR 310.21 (covers residues)
- 9 CFR 310.25 (covers process control verification criteria and testing)
- 9 CFR 311, 314, 315 (covers diseased and adulterated carcasses and parts; how establishments must handle condemned and inedible; rendering or other disposal of carcasses and parts; and product passed for cooking)

The regulations that cover post-mortem inspection of poultry include:

- 9 CFR 381.65 (covers sanitary operations, procedures for controlling contamination, and process control verification via microbial sampling and analysis)
- 9 CFR 381.76 – 381.77 (covers post-mortem inspection procedures, including establishment helper and trimmer responsibilities; line speeds; carcasses held for further examination; carcass identity until inspection is complete)
- 9 CFR 381.78 – 381.80 (covers passing and condemnation of carcasses and parts; biological residues)
- 9 CFR 381.81 – 381.93 (covers specific conditions including tuberculosis, septicemia/toxemia, airsacculitis, inflammatory processes, tumors, parasites, bruising, overscald; carcasses having died from causes other than slaughter; reprocessing of contaminated carcasses)
- 9 CFR 381.94 – 381.95 (covers process control verification criteria and testing for ratites; and disposal of condemned products)

See 9 CFR 381 Subpart K and Subpart L.

ESTABLISHMENT RESPONSIBILITIES

The primary responsibility of the establishment is to ensure that its production processes result in the production of safe and wholesome product. In addition, FSIS regulations outline some responsibilities of the establishment that are specifically related to post-mortem inspection, including:

- Sanitary practices in preparing the carcass for post-mortem inspection.
- Presenting the carcasses and parts for inspection in a specified manner (called “presentation”).
- Facility requirements at the inspection stations.

In general, the establishment’s procedures to prepare livestock or poultry for inspection must take place under sanitary conditions and must use sanitary procedures to prevent contamination of the carcasses and parts (9 CFR 310.18, 381.91, and part 416). For example, during livestock slaughter, the establishment must use sanitary dressing procedures to remove and skin the head, de-hide or dehair and eviscerate the carcass, wash the head and carcass, and split and trim the carcass. In poultry slaughter, the establishment must use sanitary procedures to remove feathers and feet, open the carcasses, eviscerate, and shackle the carcasses.

The establishment must also ensure that the carcasses are presented for inspection in a specified manner (9 CFR 307, 381.76). For example, they must be hung on the line in a specified manner and spaced appropriately. The organs must be displayed in a specified order so that the inspector does not have to spend time locating them before they perform inspection procedures. Proper presentation helps to ensure consistent and accurate inspection. There are variations in the ways in which an establishment will present carcasses and parts for inspection. FSIS Directive 6100.2 “Post-Mortem Livestock Inspection” describes possible alternative methods of presentation.

The establishment is also responsible for providing appropriate inspection stations that meet regulatory requirements (9 CFR 307.2, 381.36). The requirements vary depending on the type of equipment used at the establishment and the type of post-mortem inspection system for poultry (9 CFR 381.76). For example, in large livestock slaughter establishments, there may be separate inspection stations for heads, viscera, and carcasses. The following includes conditions that must be provided by the establishment:

- Adequate space for conducting inspection (e.g., the size and height of the on-line inspection station) (9 CFR 307.2(m)(1), 381.36).
- Adequate lighting for conducting inspection (9 CFR 307.2(b), 307.2(m)(2), 381.36).
- Hand rinsing facilities to ensure that sanitary conditions are maintained (9 CFR 307.2(m)(3), 381.36(c)(1)(viii)).
- Condemned containers for disposal of condemned carcasses or parts (9 CFR 307.2(e), 381.36).

In livestock, per 9 CFR 310.2(a), the establishment is required to handle the head, tail, tongue, thymus gland and all viscera of each slaughtered animal in such a manner as to identify them with the rest of the carcass and as being derived from the particular animal involved, until the post-mortem examination of the carcasses and parts has been completed. In poultry, 9 CFR 381.76(a) requires that each carcass, or all parts comprising such carcass, must be examined by an inspector.

These requirements are necessary to ensure that there are adequate provisions to allow for inspection duties to be conducted appropriately.

POST-MORTEM INSPECTION PROCESS

Overview

The purpose of post-mortem inspection is to make a decision about the wholesomeness of each carcass inspected. IPP use organoleptic methods to detect diseases, abnormalities, and contamination of carcasses and parts. These methods include:

- Sight – observing a disease lesion (e.g., abscess, injection site lesion)
- Feel – palpating (e.g., abnormal lump in tissues)
- Smell – smelling (e.g., the urine odor of uremia)

There are three possible outcomes of post-mortem inspection:

1) Passed, and thus eligible to receive the marks of inspection (9 CFR 310.8, 381.79);
2) Retained for veterinary disposition (9 CFR 310.3, 381.77); and
3) U.S. Condemned, which is not eligible to receive the marks of inspection and cannot enter commerce (9 CFR 310.5, 381.78).

Wholesome carcasses, without any localized disease conditions are passed. Carcasses that are wholesome except for a localized condition may be passed after removal of the unwholesome or diseased portions. Carcasses that exhibit abnormal signs or conditions that indicate they are unwholesome are retained for PHV disposition. If abnormal conditions seen on post-mortem inspection do not require veterinary disposition, on-line IPP can condemn localized abnormal or diseased tissue and verify the establishment properly trim the carcass. **Note:** In livestock, the FSIS veterinarian determines if a livestock carcass is condemned. In poultry, inspectors make carcass dispositions under the leadership of an FSIS veterinarian.

From FSIS Directive 6100.2 “Post-Mortem Livestock Inspection,” general conditions or lesions that warrant retention of carcasses for PHV disposition include:

- Carcasses of animals designated as U.S. Suspects at ante-mortem inspection.
- Carcasses of animals that contain lesions consistent with tuberculosis.
- Carcasses that display disease conditions (or other signs) or herd history that warrant residue testing.
- Carcasses that display signs of disease conditions at post-mortem examination that could reasonably result in condemnation or restriction (e.g., pass for cooking).

As the PHV, you may be responsible for making dispositions on carcasses and parts that were U.S. Suspect on ante-mortem inspection or that are retained by on-line IPP for veterinary disposition. Veterinary disposition is where you determine whether to pass or condemn the carcass and parts. The primary guiding principle is whether the carcass, organ, or part is adulterated, or whether it is wholesome and fit for human food. Veterinary disposition is covered in the Multi-species Disposition Basics section.

As a supervisor, you correlate with on-line IPP to ensure appropriate dispositions for carcasses and parts. You may correlate with IPP during work unit meetings and when questions arise to review pathological lesions and explain accurate dispositions that are based on regulatory requirements. For example, you may check the accuracy of inspector poultry dispositions by observing birds upstream or downstream from the inspector or by checking birds and parts in the condemn barrel.

Sanitation

IPP must always maintain proper sanitation and hygiene practices when conducting inspection procedures. In most cases, the establishment will have a set of requirements, such as good manufacturing practices, that are required for establishment employees. Such practices may or may not be incorporated into the establishment's food safety system. These are required by 9 CFR 416.5. For example, they may include requirements for employee hygiene such as hand washing, hair and beard nets, and using foot washes when moving between edible and inedible areas of the establishment. You must meet or exceed those standards (see FSIS Directive 5060.1 "Hygiene and Biosecurity Practices"). In addition, off-line inspectors are responsible for verifying that the establishment is preparing the carcass and parts in a sanitary manner. This includes ensuring that the equipment, utensils, or any other such item used in preparing the carcass and parts are sanitary, and that the conditions in the establishment are sanitary.

Safety

You must maintain safety regarding the use of tools, such as hooks and knives, which are used as part of the inspection process. You will learn the appropriate techniques to maintain safety, such as knife sharpening techniques and how to use hooks, during your in-plant training.

As a supervisor, you are responsible for ensuring a safe work environment for IPP. You ensure that on-line IPP are informed of any necessary safety measures and that on-line IPP are wearing the necessary safety equipment.

General Methods: Livestock

The post-mortem inspection process for livestock involves the following steps:

- Head inspection
- Viscera inspection
- Carcass inspection

No step in the inspection process may be omitted.

In large establishments, inspectors are assigned to cover one of these areas and rotate to different sites according to a rotation pattern. At small or very small establishments, the inspector may perform all of the post-mortem inspection procedures on each animal. The inspection routines differ for each inspection site in each species. The differences reflect variations in anatomy, diseases, and method of dressing that the establishment uses.

In general, when abnormalities are observed while performing inspection, the following actions must take place:

1) If the disease or condition of the head, organ, or carcass is localized, have the establishment trim the affected tissues.
2) If the disease or condition is generalized and affects the majority of the head, organ, or carcass retain it for veterinary disposition.

The specific details for the inspection procedures for each of the livestock species covered by the regulations – cattle, sheep, and swine – differ. However, there are similarities. To perform inspection procedures appropriately, you must be knowledgeable of the step-by-step procedures and familiar with the anatomy of a livestock carcass and its parts. The step-by-step post-mortem inspection procedures

for each species are found in the FSIS Directives 6,000 series: Slaughter Inspection. IPP Help: Media Library contains videos detailing post-mortem inspection procedures for each species. IPP Help: FI Quick Immersion Training has information on livestock anatomy.

Lymph Nodes: Livestock

To detect diseases and contamination, you have to direct your attention to an area where they are likely to be observed. Diseases, abnormalities, and contamination can occur at any place on the carcass or its parts. However, diseases and abnormalities are mostly likely to produce visible or palpable lesions in specific locations. Of primary importance in organoleptic detection of disease is the lymphatic system. The lymphatics consist of vessels throughout all tissues which lead to lymph nodes. Lymph nodes range in size from just visible to 3 to 4 inches across. Their appearance has been variously described as “egg shaped” to “cigar shaped” to “spherical.” All these shapes can be normal. The consistency (firmness) is between that of warm fat and muscle. The color ranges from grey-brown to fat-colored. Some have light and dark markings. The normal range of appearances is wide, depending on the age of the animal, breed, species, and location in the body. The best way to learn what is “normal” is to look at all the lymph nodes you can under the direction of your mentor who will explain what you see.

Lymph nodes function as filters for disease microorganisms and abnormal or toxic chemicals in the tissue fluids of the body. When diseased organisms or toxins begin to spread around the body, the lymph nodes are among the first tissues to become visibly affected. This is the inspector’s signal that something is wrong.

The major lymph nodes are located in specific places and the fluids draining through their filter mechanism comes from specific areas of the body. The FSIS veterinarian examines the carcasses and parts retained by the inspectors. The lymph nodes and tissue responses found during these detailed examinations indicate the location and severity of the condition and whether the disease has begun to spread around the animal’s body. By evaluating these and the ante-mortem findings, plus laboratory results, if necessary, the FSIS veterinarian determines the acceptability of the carcass and parts for human food.

Some lymph nodes and tissues need to be incised so that the internal portions can be observed. The incision technique is critical. First, the cut edges must be smooth, not ragged or torn. Otherwise, the lesions of certain important diseases are difficult to detect. Lymph nodes should be sliced in thin parallel slices to expose the body of the node. Tuberculosis lesions, some abscesses, and other conditions are exposed by incision of lymph nodes. The wrist rolling motion that you will learn from your mentor permits you to observe both sides of the slice.

General Methods: Poultry

Post-mortem inspection for poultry focuses on each carcass, its organs, and parts. The specifics of the procedures will vary depending on which of the six inspection systems – traditional, Streamlined Inspection System (SIS), New Line Speed (NELS), New Turkey Inspection System (NTIS), New Poultry Inspection System (NPIS), or Ratite – is being used at the establishment. You will learn the specifics of the inspection procedures in-plant with your mentor.

Poultry post-mortem inspection procedures are covered step-by-step in FSIS Directive 6100.3 “Ante-Mortem and Post-Mortem Poultry Inspection.” IPP Help: FI Quick Immersion Training has information on poultry anatomy.

Poultry diseases and conditions are listed on FSIS Form 6000-16 (Lot Tally Sheet). On-line IPP make disposition determinations. Supplemental information on poultry diseases and conditions is found in FSIS Directive 6100.3. If on-line IPP are uncertain about a disposition, they consult with the IIC or a PHV.

Salvage: Poultry

The term salvage refers to the actions the establishment takes to trim away any unwholesome or diseased portion of a carcass that is localized. During post-mortem inspection, the FSIS inspector identifies birds that need to be subject to salvage procedures prior to passing post-mortem inspection (9 CFR 381.79). Establishments may have procedures in place to salvage carcasses by ensuring the removal of all affected tissues and exudates in a sanitary manner. Salvaged carcasses are subject to reinspection per 9 CFR 381.76(b)(3)(iii)(c).

The establishment is not necessarily required to have a written procedure for salvage; however, the procedures must be verifiable. Generally, a salvage procedure may be incorporated into a PRP (in support of hazards being NRLTO), a CCP (for hazards RLTO), or be incorporated into the Sanitation SOPs. IPP assess compliance and take necessary regulatory control actions following the instructions in FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System."

Salvage procedures must be conducted under sanitary conditions, with adequate facilities, and personnel must be available to conduct the procedures. There should be continuous product flow without pileup or delay.

Facilities at salvage stations typically include:

- Adequate space located in the eviscerating area.
- A hang back rack designed to prevent cross-contamination.
- A trough or table sloped and properly drained.
- Containers for chilling the product.
- A spray nozzle with proper fittings to clean carcasses.
- A facility for washing hands, tools, etc., such as a gooseneck.
- A vacuum.

When a carcass is designated for knife salvage because of body cavity contamination, most establishments follow a technique similar to the following:

- Remove any remaining viscera.
- Hang the carcass in a designated area on the hang back rack.
- Transfer the carcass to the salvage station and hang it in such a way as to distinguish it from a salvageable airsacculitis carcass. (This varies by establishment. Some establishments choose to hang some types of salvage birds by the neck, whereas others have a specific mark that is placed on the carcass to designate the type of salvage procedure).
- Wash carcass surfaces thoroughly before any cutting.
- Properly trim the carcass without cutting into the body cavity or opening cut surfaces.
- Usually save both wings, both legs, and the breast muscle, including the deep and superficial pectoral muscles if wholesome and without pathology.

Airsacculitis Salvage

Special attention must be given to salvaging carcasses with airsacculitis because of the complexity of the interclavicular air sac and the associated diverticuli. If the visible part of the interclavicular air sac is inflamed, assume all of it is inflamed and salvage the carcass accordingly. Exudates must be removed. The kidneys must be removed if renal pathology is present or if airsacculitis is present specifically in the abdominal air sac membranes making the kidneys an affected tissue, and the posterior part of the carcass is salvaged per 9 CFR 381.84. The viscera must be condemned.

Note: Hepatic or splenic pathology which is determined by IPP to be localized and visibly limited to the affected organ require only the affected visceral organ to be condemned. Localized pathology of the liver or spleen does not require simultaneous condemnation of the kidneys unless the kidneys are also affected by visible pathological changes.

When a carcass is designated for knife salvage because of airsacculitis, most establishments follow a salvage technique similar to the following:

- The salvaged carcass with airsacculitis is usually marked and hung in such a way as to distinguish it from a salvageable contaminated carcass.
- Other steps, such as removing the viscera, transferring the carcass to the salvage station, etc. are also followed for carcasses with airsacculitis.
- The following portions of the carcasses are usually salvageable: the wings (minus the portion containing the humeral bones), the legs, and the breast muscle. The area of the breast muscle around the first wing joint is condemned and the deep pectoral muscle anterior to breastbone bursa is condemned. All the rest is eligible for salvage.

When the interclavicular air sacs are not involved in airsacculitis, knife salvage is not required. The requirement for this type of salvage is removal of all exudates and the kidneys if renal pathology is present or airsacculitis is present specifically in the abdominal air sac membranes making the kidneys an affected tissue, and the posterior part of the carcass is salvaged for airsacculitis per 9 CFR 381.84. This can be accomplished by vacuuming the carcass with a vacuuming device, or by removing all exudates and kidneys by hand. This type of salvage is appropriate when there is involvement of the abdominal and/or thoracic air sacs without involvement of the interclavicular air sacs, because the thoracic and abdominal air sacs do not have diverticuli that extend into bone.

Note: Some establishments do not have airsacculitis salvage programs. At these establishments, the inspector condemns airsacculitis affected carcasses.

Reprocessing: Poultry

Carcasses that have their body cavities contaminated with digestive tract contents may be rendered unadulterated by prompt washing, trimming, and/or vacuuming. The procedure for removing digestive tract content is called reprocessing.

Per 9 CFR 381.91(b)(1), poultry carcasses accidentally contaminated with digestive tract contents may be cleaned by applying an online reprocessing (OLR) antimicrobial intervention to all carcasses while remaining on the line in their individual shackle. If antimicrobial agents are applied to carcasses or parts prior to entering the chiller, parameters of their use are subject to FSIS approval. Establishments must incorporate procedures for the use of any OLR intervention system into their HACCP plans, Sanitation SOPs, or other PRPs.

Establishments may also elect to utilize offline reprocessing (OFLR), 9 CFR 381.91(b)(2), whereby carcasses are removed from the line due to contamination with digestive tract contents and directed to another station for a combination of trimming and antimicrobial treatments. OFLR procedures must be accomplished in a sanitary manner while maintaining product flow. Establishments must incorporate procedures for the use of any offline reprocessing into their HACCP plans, or Sanitation SOPs, or other PRPs.

IPP assess compliance and take necessary RCAs following the instructions in FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System."

The complete listing of OLR and OFLR antimicrobial intervention systems is available in FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" or at this link.

Facilities typically seen at the OFLR station are:

- Adequate space in the eviscerating room or a suitable adjacent area.
- A hang back rack designed to prevent cross-contamination.
- A trough or table that is sloped and properly drained.
- Containers for chilling product.
- A knife rack or stand.
- Conveniently located hand-washing facilities.
- Spray nozzle with proper fitting for cleaning carcasses.
- Water containing 20-50 ppm available chlorine, or another approved antimicrobial substance for rinsing all reprocessed carcasses (9 CFR 381.91(b)(2)).

When a carcass is designated for OFLR because of body cavity (inner surface) contamination, depending on the steps in the written program the establishment typically will:

- Remove the viscera and hang the carcass in a designated area on the hang back rack.
- Transfer the carcass to the reprocessing station and suspend it to prevent contamination during reprocessing.
- Remove the crop.
- Wash the external surface thoroughly removing all visible specks of contamination as required in 9 CFR 381.91(b).
- Remove contaminants by trimming, vacuuming, and/or washing. Any contamination of cut surfaces must be removed by trimming.
- Thoroughly rinse with water containing at least 20 ppm available chlorine (9 CFR 381.91(b)(2)), or other approved antimicrobial treatment.
- Measure and record the chlorine or other antimicrobial concentration at least once a day or at the frequency stated by the manufacturer.
- Monitor reprocessed birds (method will depend on how the establishment incorporates its offline reprocessing procedures into the HACCP plan, Sanitation SOPs, or other PRP).
- Make birds available for reinspection by the FSIS inspector as required by 9 CFR 381.91(b).

If hang back racks at the USDA inspection station or reprocessing station are filled, the IIC should allow the establishments the option of disposing of contaminated carcasses or adjusting the production rate. Carcasses disposed of by the establishment because of reprocessing pile ups should be recorded as "Plant Rejects," because the establishment is choosing not to reprocess those carcasses.

RESTRICTED PRODUCTS

The livestock slaughter regulations outline requirements related to restricted products (9 CFR 311 and 315). A restricted product is defined as any meat or meat food product that has been inspected and passed but cannot be released for human consumption until it has been subjected to a required treatment because it has a disease or condition that might be transmitted to humans if the meat is not treated. There are four types of restricted product treatments. They are:

- Refrigeration (311.23(a)(2))
- Heating (311.23(a)(2))
- Cooking (311.2(d)(f)(g), 311.18(e), 311.24, 311.25)
- Use in comminuted cooked meat food product (311.20(b), 311.35(c), 311.37)

Restricted product may be used for human food after required treatments are complete. For this reason, condemned and inedible products are not examples of restricted product.

The establishment must maintain control over all restricted products. FSIS inspection personnel must verify that the establishment has met the conditions associated with the restrictions before this type of product is allowed to be used as human food. Failure to adequately control certain products may result in product that is unsafe or unwholesome for human consumption.

Control of any restricted product begins at the time the PHV makes a disposition. First, a decision is made to pass the carcass with a restriction. A thorough check is made to see that all visible lesions are removed from the carcass. Then, the carcass is retained. If any additional lesions are discovered later (while the carcass is being boned for example), the PHV will make a new disposition based on the new findings.

Some establishments have adequate facilities for treating restricted product (e.g., cooking, freezing). For establishments that do not have such facilities, the establishment is allowed by regulation to ship restricted product to another official establishment that has the necessary facilities (9 CFR 325.7). To maintain security, the restricted product must be shipped under official government (FSIS) seal.

In certain cases, establishments may elect to bone a restricted carcass prior to the carcass undergoing a specified treatment. For example, the establishment manager may request that, in order to bone a carcass with beef measles passed with a freezing restriction, the establishment be allowed to remove it from the retain cage. An inspector must release the carcass from the retain cage and accompany the establishment employee as he/she takes the carcass to the boning area. Once the carcass is in the boning area, it must be boned in a manner that prevents it from being intermingled with non-restricted product. If the restricted product is to be boned out prior to regular boning operations, all restricted products must be removed, and the entire boning area must be thoroughly cleaned before regular boning commences. This must include employee equipment such as knives, hooks, and scabbards used while boning restricted product. To avoid a complete cleaning of the boning area, the establishment may elect to bone the restricted product after regular boning operations are completed. This is acceptable; however, all non-restricted product must be prevented from contacting, or becoming intermingled with, restricted product. Anytime restricted product is being handled, it must be under the direct control of inspection. For boning, this means under direct visual surveillance or secured in a locked or sealed boning room.

IPP should review any records generated by the establishment or records required by the regulations for the transport of restricted products.

Passed for Refrigeration

Only carcasses that are moderately affected with beef cysticercosis (beef measles) may be passed with a refrigeration restriction (9 CFR 311.23(a)(2)). This actually means the carcass or boned meat must be frozen. Freezing this product destroys any tapeworm cysts that were not identified and removed during inspection.

The regulations list separate and specific time/temperature treatment requirements for carcasses and for boxed boned meat affected with beef measles that have been designated "Passed for Refrigeration" by the PHV. The carcass may be branded with a "U.S. Inspected and Passed" brand prior to placing it in the freezer because it is difficult to apply a legible brand to a frozen carcass. After a successful 10-day treatment period, the establishment is then free to ship the carcass. Carcasses may be boned under control prior to freezing. During boning, the establishment is permitted to place the boned meat from restricted carcasses directly into boxes bearing the mark of inspection. The boxes can then be retained in the freezer for the 20-day period.

Passed for Heating

There are two conditions that may be "Passed for Heating" by the PHV. One is cysticercosis of sheep (sheep measles) and the other is cysticercosis of beef (beef measles) (9 CFR 311.23(a)(2)). Notice that beef measles may be passed for refrigeration or passed for heating. A cattle or sheep carcass, or meat derived from such carcasses passed with a heating restriction, must be heated throughout to a minimum internal temperature of 140°F.

Passed for Cooking

Carcasses with the following diseases or conditions may be "Passed for Cooking":

- Tuberculosis – 311.2
- Caseous lymphadenitis – 311.18(e)
- Swine cysticercosis (pork measles) – 311.24
- Carcasses with parasites not transmissible to humans – 311.25

Carcasses passed for cooking must reach a minimum temperature of 170°F for not less than 30 minutes. These carcasses are marked with a "U.S. Passed for Cooking" stamp by the PHV when they make this disposition.

Rendering the restricted carcass and parts into lard, pork fat, or tallow will accomplish the 170°F for 30 minutes requirement. The cooking and rendering of restricted product must be performed under the control of inspection. Once the restricted product is placed into the rendering tank, the tank must be secured with an official government lock or seal to maintain control and prevent removal of its contents. The inspector removes the seal and releases the product after the time/temperature requirements have been met.

Passed for Use in Comminuted Cooked Product

The fourth group of restricted product consists of those carcasses passed for use in comminuted cooked product. There is a difference between this restricted product category and "Passed for Cooking." Passed for cooking requires subjecting the product to 170°F for not less than 30 minutes. There is not such a time/temperature requirement with product passed for use in comminuted cooked product. The only restriction imposed on these products is that they be used only in comminuted

cooked products. Comminuted cooked food products are those that are finely ground and have a uniform appearance, such as frankfurters and bologna. These products are normally cooked at a temperature near 160°F.

There are two conditions for which carcasses may be passed for use in comminuted cooked product by the PHV. The first is certain carcasses affected with eosinophilic myositis (EM) (9 CFR 311.35(c)). The establishment may ship these carcasses prior to meeting the required restrictions. As with control of other restricted product, carcasses with EM passed for use in comminuted cooked product must be shipped under official seal.

The other product in this restricted category is boar carcasses with less than pronounced sexual odor (311.20(b), 311.37). As in the case with all restricted product, inspection must have positive control over these carcasses. A retained tag is used to identify carcasses passed for use in comminuted cooked product. If boar carcasses or parts with less than pronounced sexual odor are to be shipped elsewhere for boning, rendering, or use in comminuted cooked product, they must be shipped under seal like all other restricted product.

The following chart lists conditions that the PHV may pass with a restriction, including the regulatory reference and the specific restrictions.

Condition	Regulation (9 CFR)	Freezing (15°F) Days: 10-carcass 20-boxed	Cooking 170°F/ 30 minutes	Heating 140°F	Comminuted cooked product
Beef Measles	311.23	X		X	
Sheep Measles	311.25			X	
Pork Measles	311.24		X		
Tuberculosis	311.2		X		
Caseous Lymphadenitis	311.18		X		
Parasites (not transmissible to humans)	311.25		X		
Sexual Odor of Swine	311.20				X
Eosinophilic Myositis (EM)	311.35				X

Note: Trichinosis (not considered as passed with restriction)

Trichinosis is a disease in humans that may be contracted from swine carcasses infested with the parasite *Trichinella spiralis*. Some pork products are treated to destroy trichinae. These pork products, however, are **not considered** as passed with a restriction. Trichinae control in the U.S. relies on consumer education. That is, all pork muscle products are considered potentially contaminated and must be thoroughly cooked before being eaten.

This is quite different from many European countries. They often utilize special techniques to examine carcasses for the presence of trichinae and, therefore, when product from the U.S. is exported to these

countries, an export certificate certifying that products have been treated to destroy trichinae must accompany the shipment. IPP are to follow the guidance in FSIS Directives 9000.1 "Export Certification" and 9000.2 "Inspection and Export Certification of Livestock Intestines or Casings" when certifying such product for export.

The HACCP regulations require establishments to consider food safety hazards in their hazard analysis (including *Trichinella*). Establishments producing ready-to-eat (RTE) and not ready-to-eat (NRTE) pork products must determine in their hazard analysis if *Trichinella* is a hazard reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO) based on their processes. If *Trichinella* is a hazard that is RLTO, then establishments must include control procedures for this parasite in their HACCP plans, including the critical control points (CCPs) designed to control the parasitic hazard (9 CFR 417.2(c)(2)) and the critical limits that must be met at each CCP (9 CFR 417.2(c)(3)). Establishments are also required to maintain supporting documentation to justify the decisions made in their hazard analysis (9 CFR 417.5(a)(1)).

Under HACCP, most establishments may determine that *Trichinella* is NRLTO in fresh raw pork products produced from market swine because those products are customarily well-cooked, and the products bear safe handling instructions (SHIs). Examples of products that are customarily well-cooked include fresh pork (i.e., raw or uncured), fresh unsmoked sausage containing pork muscle tissue, and bacon and jowls.

There are certain other less commonly produced raw and NRTE pork products that are not customarily well-cooked or that present an added risk of infection with *Trichinella.* For these other products, establishments need to prevent or control *Trichinella* through either a PRP or a CCP to support decisions in their hazard analysis. These other products include:

1. Pork products that are prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked. Such pork products include ground meat mixtures including those containing pork and beef as well as pork and other ingredients; poultry products containing pork muscle tissue; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; pork products containing ingredients such as annatto, red wine, paprika, red pepper, etc. that can alter the appearance; cured pork; and cured and smoked pork. For these raw and NRTE products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked; and
2. Feral swine that have an increased risk of infection with *Trichinella*.

FSIS has published a guideline titled FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products. The following table summarizes the options recommended in the guideline:

List of Options used to Prevent and Control *Trichinella* in Pork and Products Containing Pork	
Option 1	Acquire pork products from carcasses or carcass parts found to be free of *Trichinella* by a validated testing method.
Option 2	Obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program.

Option 3	Label NRTE pork products, including all forms of fresh pork, to indicate the products require additional treatment by the consumer.
Option 4	Treat NRTE pork products for the destruction of *Trichinella* that might be eaten rare or without thorough cooking because of the appearance of the finished product using (1) heating, (2) freezing, (3) curing, (4) high pressure processing (HPP), or (5) irradiation.
Option 5	Develop alternative *Trichinella* control procedures not included in Option 4.

Establishments may follow any of the 5 options described in the table above including the option to use special labeling (Option 3) if they produce: 1) pork products that are prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked; or 2) pork products from feral swine. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why or how those procedures are effective. More detailed guidance is available in FSIS Directive 7320.1 "Prevention and Control of Trichinella in Pork Products."

As of September 23, 2021, APHIS considers the U.S. commercial swine herd to be free of trichinae. However, this does not apply to transitional or feral swine as pork products from non-confinement raised swine are at higher risk for *Trichinella*. IPP should consider how the establishment addresses the hazard of trichinae during processing, particularly if the establishment processes pork and other species of product simultaneously. IPP should consider how the establishment address separation of these products during processing. Always be alert for potential cross-contamination and its possible deleterious effects on public health.

CONDEMNED AND INEDIBLE

Condemned is defined as any material that has been determined through inspection to be diseased or in a condition that renders it unfit for human consumption. It is prohibited from entering commerce for use as human food (9 CFR 314, 381.95). **Note:** Establishments may also choose to discard materials that are diseased or in a condition that renders it unfit for human consumption as inedible.

For livestock, inedible is defined as "adulterated, uninspected, or not intended for use as human food" (9 CFR 301.2). For poultry, inedible is defined as "any carcass or any part of a carcass that is either naturally inedible by humans or is rendered unfit for human food by reason of adulteration or denaturing" (9 CFR 381.1).

By regulation (9 CFR 325.19(e)), livestock horns, hooves, and hides in their natural state are inedible. Livestock thyroid glands, laryngeal muscle tissue, lungs, and lactating mammary glands may not be saved for edible purpose (9 CFR 310.15(a), 310.16(a), 310.17(c)). Brains, cheek meat, and head trimmings from livestock stunned by lead, sponge iron, or frangible bullets shall not be saved for use as human food (9 CFR 310.18(b)). Per 9 CFR 381.189(c), the parts of poultry carcasses that are naturally inedible by humans include entrails and feathers in their natural state. For parts considered inherently inedible (e.g., hooves, hides), it is not necessary to require special identification or denaturing, but they must be kept separate from edible product.

Both condemned and inedible materials are not fit for human consumption. Due to the edible appearance of condemned and inedible material, its control is crucial, and the requirements found in

the regulations are very specific. Edible product may have a similar appearance to condemned material and some inedible material. FSIS Directive 6300.1 “Manufacture of Animal Food or Uninspected Articles at Official Establishments” contains information for IPP on how to determine whether inedible products are being properly handled at the establishment.

Separation and Identity

Condemned and inedible materials must be kept separate from edible products. A physical separation of edible and inedible facilities must be maintained to avoid cross-contamination. Contamination of edible products with inedible and condemned materials has potentially grave public health consequences. When verifying whether inedible materials are being properly handled, IPP should consider:

- Does the establishment have adequate facilities to ensure that inedible materials are handled correctly (some have specific regulatory requirements, such as 9 CFR 310.16(c), 314.10, and 314.11)?
- Does the establishment have adequate facilities to ensure inedible materials are prepared in a sanitary manner?
- Are condemned and inedible materials properly identified and separated from edible products? (9 CFR 325.11(d), 381.152, 381.193(b))

The regulations require that each condemned carcass, part, or visceral organ be marked with the "U.S. Inspected and Condemned” brand (9 CFR 312.6(a)(5)). If the condemned material cannot be branded because of its size or texture, it must be placed in a container identified with the words U.S. Condemned (9 CFR 310.5). Per 9 CFR 310.5, all condemned carcasses and parts shall remain in the custody of a Program employee and shall be disposed of as required in the regulations in Part 314 of this subchapter (see 9 CFR 381.95 for poultry).

The regulations allow the use of certain classes of condemned materials for the production of pet animal food (9 CFR 314.11). One example is beef livers condemned for human consumption but allowed for use in pet food. The system used to identify material that is condemned versus product that is allowed for animal food must be consistent (9 CFR 318.12(b)). IPP should also consider, does the establishment have adequate facilities to maintain sanitary conditions if animal food is stored in the edible product department?

The regulations require that receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. These receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses (9 CFR 416.3(c)).

Carcasses of livestock condemned on ante-mortem inspection are not to be brought into or through rooms or compartments in which an edible product is prepared, handled, or stored (9 CFR 314.7). Dead animals, except those that die enroute and are received with other livestock to be slaughtered, may not be brought onto the premises. No animal which has died otherwise than by slaughter shall be brought into any room or compartment in which any edible product is prepared, handled, or stored (9 CFR 314.8). See 9 CFR 381.71 for poultry.

Depending on the establishment facilities, ante-mortem condemned animals may be skinned and slashed or slashed through the skin into major body muscles and the body cavities followed by the application of denaturant to all parts of the carcass. Many states, however, have regulations prohibiting

the transport of opened carcasses, so an alternate method is approved. The denaturant may be injected into major muscles and cavities. This method is approved for carcasses of animals condemned on ante-mortem inspection but not for carcasses condemned on post-mortem inspection.

Disposal

When product is determined to be inedible it must be rendered on site or denatured, as required by 9 CFR part 314 for meat and 9 CFR part 381.95 for poultry. If the slaughter or processing establishment has no tanking facility, such inedible material must be denatured prior to leaving the establishment premises. Establishments may use the list of denaturing agents in the regulations (9 CFR 314.3(a), 325.11(a), 325.13(a)(1) through 325.13(a)(7) and 381.95). A sufficient amount of the agent should be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food. The focus is primarily on whether the method ensures that the condemned or inedible materials are clearly distinguished from human food.

9 CFR 314.3(a) and 9 CFR 381.95 require establishments to denature condemned and inedible meat and poultry materials to prevent them from being diverted into commerce for human consumption. The regulations implement the statutory requirement in the laws (FMIA and PPIA). The PPIA (21 U.S.C. 460) requires that any carcasses or parts or products of poultry, which are not intended for use as human food shall be denatured to deter their use as human food if they are offered for sale or transportation in commerce. No person shall buy, sell, or transport... any poultry carcasses or parts or products thereof, which are not intended for human food, unless they are denatured... or are naturally inedible by humans. The FMIA (21 U.S.C. 641) has similar language. FSIS has allowed alternative methods of disposal (such as, without denaturant) on a case-by-case basis, through the DO. For example, a District may allow an establishment, under FSIS supervision, to send inedible materials to the landfill undenatured if under seal and records are made available documenting the destruction at the landfill (9 CFR 325.11(e)).

Documentation

Inspection actions regarding the control of condemned materials must be properly documented. On ante-mortem, actions might be recorded on FSIS Form 6150-1 (Identification Tag-Ante-mortem) or FSIS Form 6502-1 (MP 35) (U.S. Rejected/Retained Tag). All establishments that ship condemned or inedible materials must have the appropriate permissions from local, state, or federal officials. The documents must be available for FSIS review.

Specimens of condemned or inedible materials for educational, research or other nonfood purposes may be released from the establishment under a permit issued by the IIC. The application is FSIS Form 6700-2 (Application and Permit to Obtain Specimens from Official Establishments). If institutions or individuals wish to obtain specimens on an ongoing basis, the permit must be renewed annually.

LINE SPEED AND PRESENTATION

Line Speed

Maximum line speeds established by FSIS are permitted on the slaughter or eviscerating line when optimum conditions exist. For poultry under FSIS post-mortem inspection, 9 CFR 381.76(b)(3)(ii)(a and b) contains the regulation for line speed based on health of each flock and the manner in which birds are being presented to the inspector. For livestock, 9 CFR 310.1(b)(1) contains maximum line speeds permitted. When there are less than optimum conditions, line speed adjustment is required to ensure that IPP can perform a thorough post-mortem inspection of poultry and livestock carcasses. The IIC is

responsible for directing establishment management to reduce the line speed to permit adequate inspection. IICs are to slow maximum allowed line speeds when slaughter process control is not maintained because of inconsistencies in size, class of animal, health, pathology, contamination, sanitary dressing or presentation of carcasses. When the IIC is satisfied that the situation that necessitated the line speed reduction has been corrected, they will permit increase in the line speed.

Presentation

In addition to identifying abnormal conditions, on-line inspectors also identify improper presentation by the establishment. Some examples if improper presentation include:

- Missing organs or parts necessary for a disposition
- Severe contamination
- Uneviscerated poultry carcasses

Based on the severity and the frequency of the improper presentation, certain actions should be taken by inspection personnel.

1) First, direct the designated establishment personnel to immediately remove the condition of improper presentation and delay inspection procedures until the condition is removed.
2) If action in #1 does not result in proper presentation, direct the designated establishment employee to stop the line and remove the condition if it cannot be removed prior to the carcass leaving the inspection area.
3) If conditions exist to the extent that the line must be stopped repeatedly, delay inspection and ask establishment management to correct the problem.
4) The IIC may require the establishment to reduce the line speed until the conditions are favorable.

Poultry Line Speed & Presentation

PHVs or IICs assigned to poultry slaughter establishments are to perform or assign presentation checks using appropriate presentation forms or otherwise assess presentation line speed process control, and evaluate the health status of the flock, as often as necessary. The factors to assess include the following:

- Poultry class and the size of the birds in the class.
- Presentation errors, such as viscera on the wrong side or not presented in a consistent manner.
- High level of disease incidence in birds.
- Establishment personnel's inability to accomplish eviscerating procedures in a sanitary manner with a minimum of contamination.
- Establishment facilities.

PHVs or IICs are to assess evisceration line speed control when on-line IPP report to them potential problems with presentation, sanitary dressing, contamination, and pathology or disease status of the birds. If conditions do not allow IPP to perform the proper inspection procedures at a given line speed, PHVs or IICs are to:

- Reduce line speeds according to instructions provided on presentation forms (FSIS Form 6510 series) or to a speed at which IPP can perform the proper inspection procedures (see FSIS Directive 6100.3 "Ante-mortem and Post-mortem Poultry Inspection");
- Document the reduction of line speed on a noncompliance record (NR) only when the maximum line speed is exceeded or the allowable number of presentation errors that call for an immediate

reduction in line speed is reached. The NR should describe findings that support the reduction in line speed and cite appropriate regulations (9 CFR 381.76, 381.67, 381.68, and 381.65) under the Other Inspection Requirements task in PHIS.

More information on IIC authority and responsibilities for line speed and presentation is found in FSIS Directive 6100.3 "Ante-mortem and Post-mortem Poultry Inspection."

Poultry Presentation: Example

Per FSIS Directive 6100.3 "Ante-mortem and Post-mortem Poultry Inspection," IPP verify poultry presentation for each type of slaughter system (9 CFR 381.76(b)(3)(iii)(*b*)) as often as necessary. Presentation logs for the various evisceration systems are available as FSIS forms (e.g., FSIS Forms 6510-10, 6510-11, 6510-12). IPP document noncompliance when the allowable number of presentation errors that call for an immediate reduction in line speed is reached.

For example, IPP may use FSIS Form 6510-11 at poultry establishments utilizing the Meyn Maestro evisceration system. IPP observe a ten-bird sample per line for "outside errors" (e.g., poultry not hung by two legs or contamination on the outside of the poultry), "inside errors" (e.g., contamination inside the poultry or mutilation), and "viscera errors" (e.g., contamination on the viscera or no viscera). Each error is associated with a corresponding nonconformance value. IPP calculate the total nonconformance value for the ten-bird sample and compare this value to the values in the "actions & comments" column to determine if the process is under control or if a retest or line speed reduction is warranted. For the Meyn Maestro Evisceration system, a total nonconformance value of greater than or equal to 40 warrants an immediate line reduction of 10% and documentation of an NR under the Other Inspection Requirements task.

Livestock Line Speed & Presentation

PHVs or IICs assigned to livestock slaughter establishments are to perform or assign verifications to determine when the inspection procedures cannot be adequately performed at the current line speed. This could be because of particular deficiencies in carcass preparation and presentation by the establishment at that higher speed or because the health condition of the particular animals indicates a need for a more extensive inspection (9 CFR 310.1(b)(1)). PHVs or IICs should also perform or assign verification activities to determine whether the establishment's slaughter and sanitary dressing procedures are controlling contamination that may impact IPPs' ability to perform proper post-mortem inspection procedures. This should be done in conjunction with specific verifications of slaughter line speed process control.

PHVs or IICs are to assess slaughter line speed control in conjunction with sanitary dressing verifications, as appropriate, when on-line IPP report potential problems with presentation, sanitary dressing, contamination or pathology and health status of the animals.

If conditions do not allow IPP to perform the proper inspection procedures at a given line speed, PHVs or IICs are to:

- Reduce line speed to a speed at which IPP can perform the proper post-mortem inspection procedures (see FSIS Directive 6100.2 "Post-mortem Livestock Inspection").
- Use the Beef Sanitary Dressing task in PHIS to document noncompliance in accordance with FSIS Directive 6410.1 "Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age" when the IIC determines there is evidence that the insanitary

condition created has resulted in the inability of the on-line IPP to adequately perform the proper post-mortem inspection procedures.
- Use the appropriate inspection task to document noncompliance when the IIC observes the establishment's slaughter process is regularly allowing enteric pathogens, feces, ingesta or milk to contaminate carcasses and parts.
- Use the Other Inspection Requirements task in PHIS to document noncompliance only when the maximum line speed has been exceeded or when particular deficiencies in carcass preparation and presentation have resulted in the PHV or IIC slowing the line speed. The NR should describe findings that support the reduction in line speed, citing 9 CFR 310.1(b)(1).

PHVs or IICs are responsible for ensuring that each on-line inspector is aware of their authority. The PHV or IIC also has the responsibility to regularly correlate appropriate Agency standards and monitor performance for each inspector to assure uniformity of inspection procedures and actions.

MARKS OF INSPECTION

Once the carcass and parts have been passed for inspection, the carcass may be washed, branded, and sent to the cooler. Parts may also be washed.

For livestock carcasses, the marks of inspection are applied just prior to the carcass entering the cooler. Each carcass contains at least one mark of inspection on each half before entering the cooler if the carcass is completely split in half. If the sides of the carcass are held together by natural (skin) attachments, one mark of inspection is sufficient. If the carcasses are to be further processed in the same establishment, the establishment is not required to mark carcasses with the inspection legend prior to entering the cooler. The marks of inspection for meat products are shown in 9 CFR 312. The marks of inspection for poultry products are shown in 9 CFR 381.96.

STORAGE AND SHIPPING

IPP may be responsible for officially sealing product being shipped from one official establishment to another. The product may consist of unmarked or restricted inspected and passed product (i.e., passed for cooking, refrigeration, or other restriction) being shipped in a truck or railcar. The truck or railcar is sealed by a program employee with an official seal. FSIS Form 7350-1, *Request and Notice of Shipment of Sealed Meat/Poultry* is required to identify the shipment to the inspector at the receiving establishment.

A vehicle carrying restricted product may be sealed or an alternate method may be used. This method is to pack the product into individual containers, sealing the containers by firmly applying a pressure-sensitive tape around each container in two directions, and then stamping the intersection of the tape with the 2 ½ inch rubber brand. A U.S. Retained tag must be affixed to each container and an FSIS Form 7350-1 used for each shipment.

Returned Products

If an official establishment receives returned products, they must address this activity in their HACCP system (HACCP plan, Sanitation SOPs, or other PRP). The establishment must include returned products in its HACCP flow chart and hazard analysis. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment (9 CFR 417.2(a)(1) and (2)). The establishment is required to maintain records to support its hazard analysis decisions (9 CFR 417.5(a)(1)).

When an establishment accepts returned product, they should support the hazard analysis decisions regarding how they will handle returned product to ensure that these products are wholesome and unadulterated prior to accepting them for human consumption. FSIS verifies that returned products are wholesome and unadulterated. IPP verify how the returned products are addressed in the establishment's hazard analysis as required in 9 CFR 417.2 and examine how the establishment supports their hazard analysis decisions.

In addition to the HACCP requirements, there are other regulations that pertain to returned products.

- 9 CFR 318.2 and 9 CFR 381.145(b) - An official establishment is to allow IPP the opportunity to inspect returned products prior to accepting them for human consumption.
- 9 CFR 318.3 – In livestock, the regulations require that every official establishment shall designate a dock or place at which products and other articles, subject to reinspection shall be received, and such products and articles shall be received only at such dock or place
- 9 CFR 381.145(b) – In poultry, there is no regulatory requirement for a designated dock or receiving place. 9 CFR 381.145(b) applies to poultry establishments and requires that:
    - Meat/poultry products that enter the poultry establishment are identified by the operator of the official establishment at the time of receipt at the establishment.
    - Meat/poultry products which are processed or otherwise handled at the establishment shall be subject to examination by IPP as necessary to assure compliance with the regulations.
    - If product is found to be adulterated, products will be condemned and disposed of per 9 CFR 381.95, unless by reprocessing they may be made not adulterated.
- 9 CFR 318.2 and 381.145 also require establishments to identify products at the time of receipt and to make products available for FSIS inspection.
- 9 CFR 320.1 and 9 CFR 381.175 - The establishment must also comply with the record requirements outlined in these regulations.

Receipt of Adulterated or Misbranded Product

FSIS regulation 9 CFR 418.2 requires establishments to notify the local FSIS DO within 24 hours of learning or determining that they have received or have shipped adulterated or misbranded products that have entered commerce. Receiving establishments may notify the DO or IPP. When establishments notify IPP, IPP will enter data into the PHIS Adulterated Product Monitoring (APM) module. This is a digital mechanism to complete FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product.* Information on when and how to use this system is found in FSIS Directive 8140.1 "Notice of Receipt of Adulterated or Misbranded Product" and PHIS Help: APM. If IPP have questions about when and how to report receipt of adulterated product, they should consult with the FLS and DO.

POST-MORTEM INSPECTION REPORTS

Inspection personnel must also record information about the number of animals or birds slaughtered, the number and types of products condemned, and other details. This information is recorded in the **Animal Disposition Reporting** (ADR) part of PHIS. The data found on the slaughter reports and the poultry post-mortem reports reflects an accurate record of the prevalence of diseases encountered by the food inspectors performing post-mortem inspection.

More information on the types of reports is found in FSIS Directive 6100.2 "Post-Mortem Livestock Inspection" and 6100.3 "Ante-Mortem and Post-Mortem Poultry Inspection." Information on how to complete these reports in PHIS is found in PHIS Help: Animal Disposition Reporting.

Multi-Species Disposition Basics, Diseases of/Not of Public Health Significance

OBJECTIVES

1. Describe the thought process used in making a disposition.
2. Identify the public health significance of diseases and conditions found commonly in the slaughter environment.
3. Describe the difference between public health significance and regulatory disposition requirements.
4. Identify disease and conditions which are required by regulation to result in carcass or parts condemnation.
5. Identify the proper regulatory dispositions in given scenarios using the thought process.

REFERENCES

9 CFR Part 309
9 CFR Part 311
9 CFR Parts 381.76 – 381.94
FSIS Directive 6000.1 - Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions
FSIS Directive 6020.1 - Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak
FSIS Directive 6100.1 - Ante-Mortem Livestock Inspection
FSIS Directive 6100.2 - Post-Mortem Livestock Inspection
FSIS Directive 6100.3 - Ante-Mortem and Post-Mortem Poultry Inspection
FSIS Directive 6100.6 - Post-Mortem Dispositions for Public Health Veterinarians
FSIS Directive 6240.1 - Inspection, Sampling, and Disposition of Animals for Tuberculosis (TB)

INTRODUCTION

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency of the U.S. Department of Agriculture (USDA) responsible for ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. The FSIS Public Health Veterinarian (PHV) is responsible for making dispositions of normal and diseased animals, carcasses and their parts. In poultry, the PHV is responsible for supervising inspectors who make carcass and parts dispositions.

The disposition of animals is directed by criteria that are found in the Meat and Poultry Inspection Regulations. Familiarity with applicable regulations (9 CFR Parts 309, 311, and 381.76 through 381.94) and current written policies (such as FSIS Directive 6100.2, “Post-Mortem Livestock Inspection”, FSIS Directive 6240.1, “Inspection, Sampling, and Disposition of Animals for Tuberculosis”, FSIS Directive 6100.3, “Ante-Mortem and Post-Mortem Poultry Inspection”, and FSIS Directive 6100.6, “Post-mortem Dispositions for Public Health Veterinarians”) will greatly facilitate disposition.

A disposition must always be approached as a professional issue; the PHV is expected to make

decisions with dispatch, confidence, and consistency. While normal slaughter operations should not be delayed because of hesitant diagnosis/disposition procedures, a PHV is not expected to make "snap" decisions either. For example, a PHV should not feel pressured to pass an animal for slaughter as a "U.S. Suspect" when the PHV has reason to believe that the animal should be held for observation before such a decision is made.

While the consumer is always considered first, a disposition should never be so stringent that any unnecessary waste of product results. A PHV should always be able to defend a disposition with the same evidence and reasoning that would be used in a clinical veterinary setting. Never should the impression be given that a disposition was made lightly or without considering all the evidence. Should the establishment disagree with the PHV's disposition, they may submit an appeal following the Office of Field Operation (OFO) chain-of-command.

PUBLIC HEALTH FOCUS OF DISPOSITION CRITERIA

As a public health agency, diseases and conditions that are of public health significance are a priority for FSIS. The focus of this training will be on the diseases of public health significance. The outcome will be to identify animals on ante-mortem and post-mortem inspection with disease conditions that are reasonably likely to pose a threat to public health. Once the animal or carcass with the disease is identified, appropriate steps to address the situation must be taken.

Based on an evaluation by policy, certain diseases and conditions found in the regulations are considered of public health significance. In this evaluation, a disease/condition is deemed of public health significance if it is reasonably likely to present a meat- or poultry-borne (foodborne) hazard or an occupational hazard to the public and/or FSIS inspection personnel. Food safety hazards of public health significance may contain infectious agents (bacterial, viral, rickettsial, fungal, protozoal or helminth organisms) that may cause food to be unsafe for human consumption. Occupational hazards of public health significance may be transmitted to employees in the slaughter/processing work environment.

Diseases that are of public health significance but do not occur in this country are also included. PHVs should be vigilant in watching for and detecting signs of foreign animal disease. In 9 CFR Parts 311 and 381, there are several pathologic conditions listed that are caused by an underlying disease. The underlying disease, not the condition itself, would serve to indicate if the pathologic condition is of public health significance. Septicemia, pyemia, and toxemia are considered food safety hazards by FSIS and are deemed of public health significance because of the probability that the underlying condition, not always determined organoleptically while conducting post-mortem inspection, may be reasonably likely to pose a threat to public health.

Many conditions found in the regulations are not of public health significance. Animal diseases and conditions observable at post-mortem inspection that pose food safety hazards or risks need to be distinguished from diseases and conditions that may adulterate product but are not food safety hazards. When conditions which do not present a food safety hazard are identified, localized lesions are removed, and the unaffected portion of the carcass is passed. Carcasses with generalized conditions would be condemned or treated to render them non-infective.

The regulations outline many diseases and conditions for which removal and/or condemnation is required by law. These diseases and conditions are not always of public health significance but do require removal and/or condemnation under the regulations as adulterants. Focusing on diseases of public health significance should not be seen as changing or detracting from the regulatory requirements to remove other conditions seen as product adulteration. Product adulteration and

condemnation requirements of the acts and the regulations must be followed. The mission of FSIS as a premier public health regulatory agency is to prevent illness from meat, poultry, and egg products. Consistent with that mission is training the PHV to be cognizant of diseases of public health significance and their critical role of ensuring that livestock and poultry disease that are reasonably likely to pose a threat to public health are identified and that affected carcasses are appropriately addressed.

The public health focus will ensure that FSIS regulations and occupational safety guidelines are fully followed to protect public health.

DEFINITIONS OF TERMS USED IN MAKING DISPOSITIONS

There are some terms that are used in the regulations and guidance documents that need to be defined and understood by the PHV.

Terms applicable to neoplasia:

Neoplasm/Neoplasia/Tumor - New and abnormal growth of tissue serving no physiological function; specifically, a growth of tissue where the growth is uncontrolled and progressive.

Neoplastic - Pertaining to or having the characteristics of a neoplasm.

Benign - Term used to assess the behavior of a neoplasm. Benign neoplasms are characterized as being typical of the tissue of origin (well differentiated), noninvasive, purely expansive, circumscribed, and not likely to metastasize.

Malignant - Term used to assess the behavior of a neoplasm. Malignant neoplasms are characterized as being atypical of the tissue of origin (undifferentiated), infiltrative as well as expansive and hence not strictly circumscribed, and frequently metastatic.

Metastasis - The transfer of neoplastic tissue from one organ or part to another organ or part not directly connected with the neoplasm. The process may occur through the transfer of cells via the general circulation, the lymphatic system, or within a body cavity (transcoelomic).

Metastasize - To form new foci of neoplasia in another organ or part not directly connected with the original neoplasm. The capacity to metastasize is a characteristic of all malignant tumors.

Terms that apply to inflammatory lesion descriptions for individual organs or parts:

Note: Grossly, inflammatory lesions are described according to their dominant features and are best classified according to their degree, duration, distribution, and type of exudate. Lesion classification does not translate directly into a disposition. Lesion classification is an aid to understanding the overall disease process in a carcass at the time of slaughter.

Slight/Mild - Small in size, quantity, or number; of no significance; so small or unimportant or of so little consequence as to warrant little or no attention. As applied to certain liver abnormalities, slight means that the lesions are small and few. As applied to tuberculosis lesions in lymph nodes, slight means that the lymph node is of normal size and has more normal than diseased tissue.

Moderate - Avoiding extremes of expression, having an average or less than average quality, limited in scope, tending toward the average amount or dimension.

Marked - Having a distinctive or emphasized character, attracting notice or attention; noticeable, unlikely to escape observation; prominent, stands out from its surroundings or background; conspicuous, is obvious or unavoidable to the sight.

Well-marked - The same as marked but to a higher degree. As applied to tuberculosis lesions in lymph nodes, well-marked means that the lymph node is enlarged, or that the lymph node is of normal size but has more diseased than normal tissue.

Severe - To a great degree; serious, having important possible consequences; intense; having or showing a characteristic to an extreme degree.

Diffuse/Extensive/Generalized - Not definitely limited, concentrated, or localized, widely distributed; having wide or considerable extent; widespread, widely diffused or prevalent; widely extended or spread out. Not restricted to a definite locality; existing in or affecting all or most of a carcass or part. Exceeding the usual, proper, or normal; implies an amount or degree too great to be reasonable or acceptable. As applied to tuberculosis lesions in lymph nodes, extensive means that the lymph node is greatly enlarged, or nearly all the lymph node tissue is affected. As applied to tuberculosis lesions in tissues other than lymph nodes, extensive means that more than half of the organ or tissue surface is affected. Multiple means that there are lesions in more than one organ. Acute, progressive means tissue surrounding caseous lesion is edematous and congested or hyperemic, or that several similar small lesions are occurring around an older focus.

Acute - In general, acute refers to a period lasting from a few to several days. Acute lesions usually have some or most of the features of the classic acute response, that is, hyperemia, edema, and exudate. The components may vary considerably. There may be much edema and cellular exudation with little hyperemia, or there may be much hyperemia with little exudation. In general, the presence of fluid suggests an acute lesion.

Subacute - Subacute lies between acute and chronic in character, though closer to acute; usually between one to three weeks.

Chronic - In general, chronic refers to a period of weeks, months, or years. Some degree of fibrosis and/or organization of exudates usually characterize chronic lesions. Chronic inflammation poses two special problems: (1) a chronic lesion that contains foci of acute inflammation, and (2) chronic inflammation that is actively laying down fibrous tissue.

Associated - Secondary or related in some way as a cause and effect.

Focal - Having an area of disease within a definite locality. Describes a single, solitary lesion in a single organ or part.

Multifocal - Multiple focal lesions within an organ or part. Describes lesion distribution in a single organ or part.

Localized - Not general; restricted to a limited region or to one or more spots.

Systemic - Synonymous with generalized; systemic clinical signs are seen on ante-mortem inspection, systemic lesions on post-mortem inspection.

Serous - Composed primarily of clear fluid. Its presence indicates mild injury. Edema due to injury of vessels could be considered a form of serous exudation. Mild irritation of a serosal or mucosal

surface would increase fluid exudation. The location of serous exudate may be within organs or on surfaces. It is usually acute and reflects vascular injury. Hyperemia may or may not be present.

Catarrhal - Occurs on mucous membranes. The exudate has a gross appearance of clear to cloudy to pink color and has a fluid to mucoid consistency. This is one of the most common exudates and is associated particularly with the mucosal surfaces of all levels of the tubular respiratory, reproductive, and digestive tracts.

Fibrinous - Fibrin is a main feature in the exudate that is an indication of severe acute vascular injury. The exudate will be a yellowish fluid, gel, or solid rubbery mat. It usually occurs on serosal or mucosal surfaces and is prominent on intestinal mucosa, peritoneum, pleura, synovial membranes, and in the lungs.

Purulent - Pus (a thick, opaque, usually yellowish-white liquid inflammation product composed of dead white blood cells and cellular fluids) is the predominant feature of the exudate. Purulent exudates may be acute but are usually chronic.

Granulomatous - The presence of a granuloma (lump) is a predominant feature. This granuloma may be made up of many smaller but somewhat confluent granulomas. The lesion may be a discrete or rather diffuse enlargement. It may be solid on the cut surface or may contain small foci of pus or caseous necrosis throughout.

Terms that apply to pathologic conditions affecting the carcass as a whole:

Bacteremia - The presence of bacteria in the blood. Not always associated with systemic illness but may be associated with a focus of inflammation that provides a continuing supply of organisms.

Septicemia - A syndrome accompanied by fever, hemorrhage, and severe systemic illness associated with the presence and persistence of pathogenic microorganisms or their toxin in the blood. It is nearly always associated with some focus of inflammation that provides a continuing supply of organisms.

Pyemia - A variant of septicemia caused by pus-forming bacteria in which secondary foci of suppuration occur, and multiple abscesses are formed. Marked by fever, chills, sweating, jaundice, and abscesses in various parts of the body.

Sapremia - A variant of septicemia associated with a gangrenous condition in which saprophytic bacteria, ordinarily growing only in dead organic matter, are able to survive in the blood and be disseminated throughout the living body.

Toxemia - A condition in which the blood contains bacterial toxins disseminated from a local source of infection or metabolic toxins resulting from organ failure or other disease.

Septic - Relating to, involving, or characteristic of a condition resulting from the spread of bacteria or their products from a focus or foci of infection.

Suppurative (adjective) - Producing pus or associated with the act of becoming converted into and discharging pus.

Suppuration (noun) - The formation of pus; the act of becoming converted into and discharging pus.

Systemic - Pertaining to or affecting the entire carcass or body, generalized.

Cachexia - A profound and marked state of general ill health and malnutrition; general physical wasting and malnutrition usually associated with chronic disease. Cachexia is a purely ante-mortem descriptive term that indicates a chronic wasting condition.

Degeneration - Change of tissue from a higher to a lower or less functionally active form or state. When there is chemical change of the tissue itself, it is true degeneration; when the change consists of the deposition of abnormal matter in the tissue it is infiltration. Atrophy, fibrosis, and necrosis are examples of degeneration.

Hyperemia - An excess of blood in a part due to local or general relaxation of the arterioles. Under normal circumstances, blood does not flow through all capillaries in a tissue. The amount of blood flow usually corresponds to the amount of work being carried out and will vary in different areas at different times. In hyperemia, all capillaries within an organ would be opened, dilated, and filled with red blood cells. Hyperemia usually occurs in a localized area, because if it occurred all over the body, there would not be sufficient blood in the major vessels to maintain systemic blood pressure and shock would occur.

Congestion - Congestion implies that the flow of blood leaving an area is impeded and that blood therefore accumulates in the venous circulation. It is a passive process and results from impaired blood flow in veins. The physical obstruction of either small or large vessels, or the failure of forward blood flow, as in heart failure, may cause congestion. Blood accumulates in dilated capillaries and venules and the tissue appears blue because of the poorly oxygenated venous blood.

Lipidosis - A general term for disorders of cellular lipid metabolism involving abnormal accumulations of lipids within an organ.

Sawdust - A lay term used to describe pinkish-gray to yellowish-white foci of necrosis within the liver that resemble fine particles of wood made by a saw in cutting.

Steatosis - A muscular dystrophy in which muscle is replaced by an abnormal amount of fat without accompanying inflammatory or degenerative change.

Telangiectasia - A vascular lesion formed by an abnormal dilatation of a group of small capillary vessels and arterioles.

Telangiectasis - A condition of the liver in which purplish-red to bluish-black spots form on the surface and in the parenchyma of the organ. The surface spots have a very slightly depressed appearance.

Tissues -– An aggregation of similarly specialized cells united in the performance of a particular function. Fat, muscle, tendons, and bone of the carcass, as opposed to the tissues of organs.

Organs -– Self-contained group of tissues that performs a specific function. Structures such as liver, heart, lungs, kidneys, etc.

Terms that apply to contamination:

Adulterate - To make impure by the addition of a foreign or inferior substance. Generally, refers to a substance that is incorporated into the organ or part and that cannot be removed by trimming or other means.

Contaminate - To soil, stain, corrupt, or infect by contact or association. Generally, refers to a substance that is on the surface of an organ or part and that can be removed by trimming or other means.

Contaminant - Something that contaminates.

Contamination - Soiling or making inferior by contact or mixture, as by the contact of a carcass or part with fecal material, inflammatory exudates, or ingesta.

DISPOSITION THOUGHT PROCESS – A SYSTEMATIC APPROACH

Basic Components of Disposition Decision-Making

Dispositions require a science-based thought process to determine the eligibility of livestock and poultry carcasses for human food. Four basic components comprise this thought process. They are:

- History
- Examination
- Diagnosis
- Disposition

History

This includes data such as ownership; geographical, herd, or lot origin; animal age; and special handling. Additional information, such as knowledge that livestock are from a producer with a history of residue violations, will have a bearing on the PHV's decisions. When available it is regarded as highly beneficial, though history is often unavailable.

Examination

Routine ante-mortem and post-mortem inspection procedures identify abnormalities in the live animal or the carcass. The affected animal or carcass with significant abnormalities will be separated out for examination by the PHV. The veterinarian must examine all U.S. Suspects identified on ante-mortem and all carcasses retained for veterinary disposition at post-mortem inspection. When such animals may be febrile or when the temperature of such animals may have a bearing on post-mortem disposition, examination should include taking the temperature of that animal. Temperatures must also be taken during the examination of all TB Reactors.

The examination process should utilize the knowledge and skills gained through veterinary education, experience, and training. The post-mortem examination should be thorough and complete, resulting in the PHV being able to arrive at a sound, supportable diagnosis and disposition. In making dispositions, the PHV is to use a consistent, systematic approach for evaluating each carcass. When examining carcasses for the purpose of making a post-mortem disposition, the disposition is to be made as soon as the PHV has gathered enough information to provide adequate support for the disposition. This is to occur as early as possible in the examination process, so normal slaughter operations are not delayed. There is no required “set” of procedures

that must be performed on each carcass. Each PHV is to use their professional judgement, including their knowledge of the herd and establishment, to determine how much information is to be collected to make a supportable disposition. Sometimes laboratory support in the form of histopathology, microbiology, or residue analysis may be required; however, the laboratory report alone should not dictate carcass disposition. PHVs are to consider the laboratory's report within the context of ante-mortem and post-mortem findings to make the most supportable disposition possible.

For carcasses tested for residues, PHVs are to make final dispositions based on the regulations (9 CFR 311.39) and FSIS Directive 10,800.1, "Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat And Poultry Products":

1. Condemn the tissues identified as violative in the test results.

2. For residue results reported as "Not Detected" or "Detected – non-violative," release the carcass and its parts.

3. For residue results reported as "Detected but not Quantified, Violation" or those that have a quantified violation for some part (such as organ tissue) without a quantified muscle result, condemn the carcass and all parts.

Diagnosis

A diagnosis is a definitive summary of all the facts regarding a particular case. As such, a diagnosis may be made either after the PHV's examination at ante-mortem or post-mortem inspection.

As the examination is performed, the PHV should use a logical thought process to support a diagnosis. The following factors are important:

1. Correlate ante-mortem findings with post-mortem lesions.

2. Determine if pathology is acute or chronic.

3. Determine if pathology or condition is localized or generalized.

4. Determine if a condition or disease is associated with any generalized changes.

Disposition

Disposition is the process of enforcing the regulatory requirements. The dispositions for some diagnoses are quite specific. For example, malignant lymphoma is required in 9 CFR 311.11(b) to be condemned regardless of the extent. Another example would be temperatures at ante-mortem which require condemnation in 9 CFR 309.3(c) for the various species (i.e., 105°F for all species except swine, 106°F for swine). For most conditions there is more latitude given for judgment by the PHV. Judgment is referred to in 9 CFR 311.1(a).

Most dispositions require a PHV's professional judgment of the character and distribution of a disease process. For example, acute pneumonia with attendant generalized inflammatory changes present in other organs and structures requires the carcass to be condemned in its entirety. On the other hand, when the abnormality consists only of chronic pneumonia, the lungs are condemned, and the carcass and viscera would be passed for use as human food.

Principles of Disposition

The PHV should consider history, examination, diagnosis, and pertinent regulations in making a disposition determination. In making the determination the PHV should seek answers to the following questions:

1. Is there any **diseased** or **abnormal** tissue? (If so, it must be trimmed & condemned.)
2. Is the disease or condition **localized** or **generalized**?
3. If a disease, is it **acute** or **chronic**?
4. Is there evidence of a **derangement** of body functions?
5. Is the disease or condition one that would be **injurious** to the health of the consumer?
6. Would the condition be **offensive** or **repugnant** to the consumer (aesthetically unacceptable)?

The philosophy of carcass disposition is based on the interpretation of an interrupted disease process. Dispositions are made on carcasses based on the stage of disease development and the resolution of the disease or processes at the time of slaughter. If a disease process exists in the live animal, the pathogenesis of the disease stops at the time of slaughter, but the lesions of the disease will remain. Our responsibility as regulators is to evaluate and interpret the pathological lesions present after the animal is slaughtered and prepared for post-mortem inspection. Consider the following factors at the time of slaughter:

- Is there evidence that the disease process is being resolved?
- Has it developed into an irreversible stage?
- If it is being resolved, it will show evidence of healing (e.g., connective tissue walling off lesions, minimal evidence of inflammation, and a return to functional activity of the tissues).
- If there is systemic involvement, the carcass is unwholesome and shall be condemned.
- If only a part or a localized area of the carcass is affected, remove the affected portion and pass the remainder of the carcass as wholesome.

The Regulations specifically tell us what to do in the case of some disease conditions.

Ante-mortem Disposition Choices

Livestock examined by a veterinarian on ante-mortem inspection will be either:

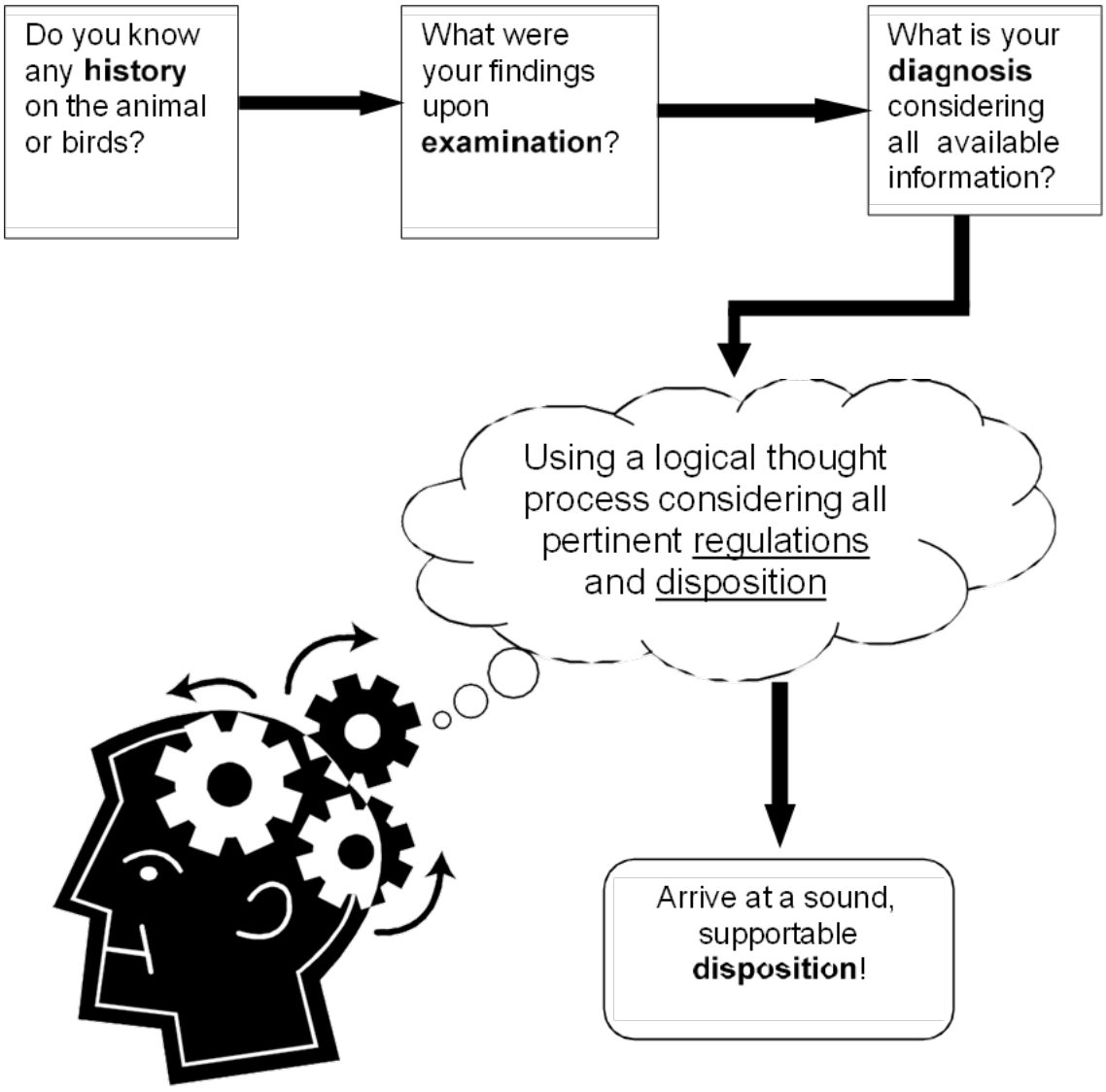
1. Passed for regular slaughter,
2. Passed as a “U.S. Suspect”; or
3. Identified as “U.S. Condemned.”

Post-mortem Disposition Choices

A carcass may be passed for food or condemned, but there are other possibilities that lie between these two extremes. The post-mortem disposition possibilities can be summarized as follows:

1. Pass the carcass for human food ("U.S. Inspected and Passed).
2. Retain the carcass and later pass for human food ("U.S. Inspected and Passed"):
    a. as normal or within the normal range.
    b. after localized lesions are removed and condemned.
3. Condemn the carcass or parts for human food ("U.S. Inspected and Condemned).
    a. Properly denature and render (on or off premises) or incinerate; or
    b. Allow for use as pet food (only in specific cases). Carcasses and parts (unless exempted) require proper denaturation.
4. Retain carcass and parts pending laboratory tests.
5. Pass the carcass and parts with restrictions as follows:
    a. ***Pass for heating:*** Heat thoroughly to an internal temperature of at least 140°F (e.g., certain cases of *Cysticercus bovis* or *Cysticercus ovis*).
    b. ***Pass for refrigeration:*** Carcasses held no higher than 15°F internal temperature continuously for a minimum of 10 days (e.g., certain cases of *Cysticercus bovis*).
    c. ***Pass for use as comminuted cooked product*** (e.g., less than pronounced sexual odor in carcasses of some older hogs or certain cases of eosinophilic myositis).
    d. ***Pass for cooking:*** Heat thoroughly to an internal temperature of at least 170°F and hold at that temperature for at least 30 minutes.

DISPOSITION THOUGHT PROCESS



That's using your HEDD – History, Examination, Diagnosis, Disposition

LIVESTOCK DISEASES AND CONDITIONS OF PUBLIC HEALTH SIGNIFICANCE

Central Nervous System Conditions at Ante-mortem

Various diseases, metabolic disturbances, and syndromes may present with CNS signs. Not all of these are of food safety or zoonotic significance; however, since they are often difficult to differentiate on ante-mortem examination, CNS-related conditions must be considered as having the potential to endanger human health.

Important! All cases of livestock exhibiting clinical signs of central nervous system disorders must be condemned on ante-mortem.

The PHV must keep in mind that condemning an animal on ante-mortem means either that the establishment shall kill the animal as stated in 9 CFR 309.13(a); the livestock may be set apart and held for treatment as stated in 9 CFR 309.13(b) & 309.3(d); or the livestock may be released for treatment (after permission is obtained from local, State, or Federal livestock sanitary officials having jurisdiction) as stated in 9 CFR 309.13(d). The establishment, and not the PHV, exercises the option of holding a condemned animal for treatment or under certain circumstances moving the animal to another premises for treatment.

Some CNS disorders are reportable diseases, such as rabies (any species) and bovine spongiform encephalopathy. The CNS signs observed on ante-mortem from one disorder may be difficult to distinguish from another. If a PHV is uncertain of a diagnosis and the signs are consistent with those of any reportable disease he/she shall contact USDA-APHIS Veterinary Services. Because of the possible threat of adulterating our beef supply with a spongiform agent, it is imperative that any cattle presented for ante-mortem inspection with signs of any central nervous system disorder be condemned and the appropriate APHIS Veterinary Services officials notified immediately.

FSIS has agreed in a memorandum of understanding (MOU) with APHIS “to promptly notify APHIS when signs and/or lesions of foreign animal diseases are noted on livestock or poultry during ante-mortem and/or post-mortem inspection(s).” and that, “FSIS will inform the Area Veterinarian-in-Charge (AVIC) of APHIS prior to processing animals suspected of a foreign animal disease….” 15-9100-1470-MU A.5., page 4.

The PHV must remember local, peripheral, and/or physiological conditions can mimic CNS disorders. Examples of this are lameness, which may be difficult to differentiate from ataxia or paresis; shivering in cold weather, which may be difficult to differentiate from tremors; and water in the external ear canal, which causes a head tilt that may be indistinguishable from a head tilt caused by a CNS disorder. Swine are often sprayed with cool water in ante-mortem pens to keep them from overheating. If the water gets in the external ear canal, the affected pig will tilt its head.

The ante-mortem disposition thought process is similar in all cases with animals presenting with central nervous system disease.

Metabolic Disorders with Central Nervous System Signs

Hypomagnesemic Tetany (Grass Tetany) in Cattle and Sheep

This is a metabolic disorder most common in adult cows and ewes in heavy lactation on lush

pastures, seen especially after winter confinement. This disorder may affect cattle of any age grazing on wheat or other cereal crops. Undernourished cattle exposed to changeable, cold weather may also be affected. Hypomagnesemic tetany may also occur in 2-4 months-old calves fed exclusively milk.

Ante-mortem findings may include the following:

> The acute onset is characterized by bellowing, galloping in a blind and frenzied manner, falling, tetany, and paddling convulsions.
>
> Animals with slow onset may appear ill at ease, irritable, walk stiffly and be hypersensitive to touch and sound. Frequent urination may be observed. The animals with slow onset may take two to three days to progress to the acute convulsive stage and could very well survive shipping to slaughter facilities.

Ante-mortem disposition:

> 9 CFR 309.4(a) requires, "All livestock showing, on ante-mortem inspection, symptoms of...ketosis,… parturient paresis,...grass tetany, transport tetany,...shall be identified as U.S. Condemned and disposed of in accordance with section §309.13." 9 CFR 309.13(b) states, "Any livestock condemned on account of ketosis…grass tetany, transport tetany, parturient paresis...may be set apart and held for treatment under supervision of a Program employee or official designated by the area supervisor. The U.S. Condemned identification tag will be removed by a Program employee following treatment under such supervision if the animal is found to be free from any such disease."
>
> Any cattle presented for ante-mortem inspection with signs of a central nervous system disease or disorder shall be condemned and the appropriate APHIS (Veterinary Services) officials notified by telephone immediately.

Transport Tetany in Ruminants

A metabolic disturbance (possibly hypocalcemia and/or hypomagnesemia), usually seen in pregnant well-fed cows and ewes after transportation and stress.

Ante-mortem findings may include the following:

> Livestock present with restlessness and uncoordinated movements, followed by partial paralysis of the hind legs and staggering, followed by sternal recumbency, progressive paralysis, and death.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Parturient Paresis (Milk Fever) in Cows and Ewes

A metabolic disorder (hypocalcemia) occurring in mature dairy cows following parturition and concomitant with profuse lactation. It also occurs in pregnant and lactating ewes.

Ante-mortem findings may include the following:

Cattle present early with an unsteady gait, quickly followed by collapse to sternal recumbency (often with the head turned into the flank) and dilated pupils. Without treatment, cattle with these signs will become comatose and die. In ewes, early signs are hyperexcitability, muscle tremors, and stilted gait, followed by ataxia, paresis, coma, and death.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Ketosis

This condition is also a metabolic disorder (hypoglycemia, ketonemia, and ketonuria) and is most common in high-producing stall-fed lactating cows. It occurs within a few weeks of calving and is characterized by inappetence, weight loss, decreased milk production, and acetone odor to the breath.

Ante-mortem findings may include the following:

Many cows appear lethargic and depressed, but some may be frenzied or aggressive. Other CNS signs are head pressing, circling, staggering, bellowing, hyperesthesia, and compulsive walking.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Pregnancy Toxemia in Cows

A metabolic disorder (ketonemia, ketonuria, [ketosis] hypoglycemia, proteinuria) occurring in beef cows fed heavily during the first two trimesters of pregnancy and nutritionally stressed the last trimester.

Ante-mortem findings may include the following:

Restlessness and incoordination are the early signs, followed by sternal recumbency, coma, and death.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Pregnancy Toxemia in Sheep (Ovine Ketosis)

A metabolic disorder (hyperketonemia with variable hypo/normo/hyperglycemia) of preparturient (usually undernourished) ewes.

Ante-mortem findings may include the following:

Affected ewes become listless, and show muscle twitching around the head, abnormal postures, grinding of teeth, loss of reflexes, blindness, ataxia, sternal recumbency, coma, and death.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Porcine Stress Syndrome (PSS) or Malignant Hyperthermia, Transport Myopathy, Back Muscle Necrosis, Pale Soft Exudative Pork (PSE)

Porcine stress syndrome is an inherited metabolic disorder of skeletal muscle calcium kinetics. Clinical signs are brought on by stress, transport, handling, exercise, or excitement. The leaner, heavier-muscled pigs are the most susceptible.

Ante-mortem findings may include the following:

> Initially pigs present with muscle tremors of the tail, back, and legs. Tremors progress to rigor and pigs are unable to move. Additionally, there is tachycardia, open-mouthed breathing, pyrexia (temperatures up to 113°F), and death, with rigor mortis developing in minutes.

Ante-mortem disposition:

> The regulations do not specifically address PSS, but they do address transport tetany in 9 CFR 309.4(a) and 9 CFR 309.13(b). These regulations would apply to PSS.
>
> Follow the same disposition process as discussed in hypomagnesemic tetany.

Special Note: Loading, transport, and unloading may cause fatigue or muscle cramps in pigs that should not be confused with PSS. Fatigued pigs will typically recover and walk normally after a period of rest and generally do not have a fever.

Polioencephalomalacia

A nervous system disorder (of nutritional-metabolic origin) in ruminants. Deficiency of thiamine is present in all cases. The deficiency is precipitated by an abrupt change in diet to concentrates and corn silage.

Ante-mortem findings may include the following:

> Clinical signs are depression, medial dorsal strabismus, abnormal gait, moderate opisthotonos, cortical blindness, and preserved pupillary light reflex. Later signs are hyperesthesia, recumbency, severe opisthotonos and convulsions.

Ante-mortem disposition:

> Polioencephalomalacia is not specifically mentioned in 9 CFR 309.4, “Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases”; however, these animals would be condemned due to the CNS signs.
>
> Follow the same disposition process as discussed in hypomagnesemic tetany.

Viral and Prion Diseases with Central Nervous System Signs

Rabies

A viral encephalomyelitis affecting all warm-blooded animals.

Ante-mortem findings may include the following:

> Two classical presentations are seen in animals with rabies, paralytic and furious. Early paralysis of the throat and masseter muscles is usually accompanied by salivation in the paralytic form. In the furious form, cattle attack man and other animals. Affected cattle are alert with eyes and ears following sound and movement. Cattle also have a characteristic bellowing. Horses and mules may roll as if they had colic, bite, and strike.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

> 9 CFR 309.4(a) requires, "All livestock showing, on ante-mortem inspection, symptoms of ...pseudorabies, rabies, scrapie...shall be identified as U.S. Condemned and disposed of in accordance with section §309.13."
>
> Veterinary Services shall be contacted as rabies is a reportable disease. FSIS Directive 6000.1, VII (B) states, "PHVs are to notify the District Office as soon as possible when they suspect that any undiagnosed or unusual disease condition is reportable, foreign or both." District Office personnel will contact the APHIS Area Veterinarian-in-Charge or the State Animal Health Official and will provide the appropriate information. If rabies is suspected, it should be reported to the state or local health department, establishment management, and all people who could have been exposed.

Pseudorabies

Pseudorabies (Aujeszky's Disease, Mad Itch) is a viral (herpesvirus) infection of the central nervous system in pigs. Cattle and smaller ruminants are less commonly involved; however, the disease is invariably fatal in these species.

Ante-mortem findings may include the following:

> Trembling, incoordination, convulsions, and coma are the most common CNS signs in pigs. These CNS signs are seen after the initial signs of coughing, sneezing, anorexia, pruritus, pyrexia, and listlessness. Adult pigs may exhibit reproductive issues, such as abortions, mummified piglets, stillbirths, and small litters.
>
> Cattle and smaller ruminants have a shorter clinical course and progress from excitement, trembling, and anxiety to incoordination, convulsion, coma, and death. Pruritus is more common in non-porcine species and, when present, is accompanied by extreme efforts to relieve itching.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

> 9 CFR 309.4(a) requires, "All livestock showing, on ante-mortem inspection, symptoms of ...pseudorabies, rabies, scrapie...shall be identified as U.S. Condemned and disposed of in accordance with section §309.13."
>
> Veterinary Services shall be contacted as pseudorabies is a reportable disease. FSIS Directive 6000.1, VII (B) states, "PHVs are to notify the District Office as soon as possible when they suspect that any undiagnosed or unusual disease condition is reportable, foreign or both." District Office personnel will contact the APHIS Area Veterinarian-in- Charge or the

State Animal Health Official and provide the appropriate information.

Bovine Spongiform Encephalopathy (BSE)

Bovine spongiform encephalopathy (BSE), also known as Mad Cow Disease, is a chronic progressive degenerative disease affecting the central nervous system of cattle. There is no treatment and affected cattle die. BSE is classified as a transmissible spongiform encephalopathy (TSE). The causative agent for BSE has not been determined. Some believe it is a “slow virus” or a “virino” while others believe it is a “prion” (an aberrant form of a normal protein) that causes the normal protein to conform to its aberrant shape, which leads to a cascade of abnormal proteins accumulating in brain cells. The accumulation of protein plaques causes cell death and leaves holes in the brain giving a “sponge-like” appearance. The etiologic agent is extremely resistant to destruction.

Like BSE, the TSEs in other species produce spongiform changes in the brain. The TSEs in other species are scrapie (sheep and goats); transmissible mink encephalopathy (mink); feline spongiform encephalopathy (cats); chronic wasting disease (deer and elk); and kuru, Creutzfeldt-Jakob Disease (CJD), Gerstmann-Straussler-Scheinker syndrome, and fatal familial insomnia (humans). The TSEs have also been observed in several exotic species, including primates. The TSEs have long incubation periods of one to thirty years depending on the disease and species.

BSE was first officially recognized in the United Kingdom (UK) in November of 1986. The incubation period for BSE in cattle is from 2 to 8 years. Currently, there is no test to detect the disease in live animals.

Ante-mortem findings may include the following:

> Cattle display changes in temperament (including aggressive behavior), abnormal posture, incoordination, stumbling, or difficulty in rising. In addition to the CNS signs, cattle have a loss of body condition (in the face of a continued good appetite) and decreased milk production.

Ante-mortem disposition: Follow the same disposition thought process as previously discussed (i.e., condemn the animal and notify APHIS through supervisory channels).

Scrapie

Scrapie is a progressive neurological disorder of sheep and goats, caused by an abnormally shaped protein called a prion. This is a transmissible spongiform encephalopathy. The disease is most commonly spread to other animals through contact with the placenta and placental fluids and through milk and colostrum. Additionally, while all goats are susceptible, some sheep have a genetic resistance to the disease.

Ante-mortem findings may include the following:

> A characteristic intense pruritus beginning over the rump is accompanied by excitability, fine tremors of the head and neck, and hypermetria of the forelegs when trotting.
>
> The disease progresses with ataxia, emaciation, weakness, and death.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

> 9 CFR 309.4(a) requires, "All livestock showing, on ante-mortem inspection, symptoms of...pseudorabies, rabies, scrapie...shall be identified as U.S. Condemned and disposed of in accordance with section §309.13."
>
> Veterinary Services shall be contacted as scrapie is a reportable disease. FSIS Directive 6000.1, VII (B) states, "PHVs are to notify the District Office as soon as possible when they suspect that any undiagnosed or unusual disease condition is reportable, foreign or both." District Office personnel will contact the APHIS Area Veterinarian-in-Charge or the State Animal Health Official and provide the appropriate information.

Toxicities with Central Nervous System Signs

Animals showing signs of central nervous system disorders or disease related to toxicities should be:

- Condemned for CNS disorders, condemned for dying condition (9 CFR 309.3(a)), or condemned for comatose or semicomatose condition or…any conditions…which would preclude release of the animal for slaughter for human food (9 CFR 309.3(d)), or
- Condemned for toxic encephalomyelitis (9 CFR 309.4(a), 9 CFR 311.10(a)(8)).

Any cattle presented for ante-mortem inspection with signs of a central nervous system disease or disorder shall be condemned and the appropriate APHIS (Veterinary Services) officials notified through supervisory channels.

Arsanilic Acid Poisoning

This poisoning occurs in pigs due to ingestion of excessive amounts of organic arsenical growth promoters. The CNS lesions are myelin and axonal degeneration in the optic and peripheral nerves.

Ante-mortem findings may include the following:

> Affected pigs progress from hindlimb ataxia to tetraparesis.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Lead Poisoning

Lead poisoning occurs in livestock grazing on contaminated forage, paint, batteries, grease, or oil. Clinical signs may be acute or chronic.

Ante-mortem findings may include the following:

> Cattle show a whole host of CNS signs including bellowing, circling, staggering, excitement, ataxia, twitching, grinding the teeth, and leaning and walking into objects as if blind. Convulsions, seizures, and death may occur.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Organochlorine (Chlorinated Hydrocarbons) Poisoning

Poisoning by organochlorines (e.g., aldrin, benzene hydrochloride, chlordane, dieldrin, endrin, heptachlor, lindane, and methoxychlor) causes stimulation of the central nervous system, manifested by colic or neurological signs.

Ante-mortem findings may include the following:

> The CNS signs are hyperexcitability, muscle twitching, hyperesthesia, and head tremors, progressing caudally. Tonic-clinic seizures are accompanied by collapse to lateral recumbency.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Organophosphate (OP) Poisoning

Poisoning by organophosphates (e.g., chlorpyrifos, coumaphos, dermeton, dichlorvos, diazinon, famphur, fenthion, malathion, parathion, ronnel, ruelene and trichlorfon) causes cholinergic overstimulation of the parasympathetic nervous system. Cattle and sheep show depression, unlike small animals, which show convulsions in the latter stages.

Ante-mortem findings may include the following:

> Muscarinic signs are hypersalivation, dyspnea (resulting from bronchoconstriction and bronchial secretions), miosis, diarrhea, and frequent urination.
>
> Nicotinic signs include muscle fasciculations and weakness.
>
> Central effects are apprehension, nervousness, ataxia, and sometimes convulsions.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Paspalum Staggers

Ingestion of paspalum grasses infested by the fungus *Claviceps paspali*. Cattle, sheep, and horses are all susceptible.

Ante-mortem findings may include the following:

> Continuous trembling, jerky and uncoordinated movements, falling, and paralysis.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Nitrate and Nitrite Poisoning

Toxicoses can occur by ingestion of plants containing excess nitrate or accidental ingestion of

fertilizers or chemicals. Ruminants are the most susceptible, but equines and pigs can be affected.

Ante-mortem findings may include the following:

> The CNS signs associated with this condition are anxiety, weakness, muscle tremors, and ataxia. Other signs are rapid difficult breathing, rapid heartbeat, and brown mucous membranes.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Nonprotein Nitrogen Poisoning

Nonprotein nitrogen (NPN) poisoning (ammonia toxicosis) is caused by the ingestion of excess urea or other NPN compounds. Ruminants are most commonly affected.

Ante-mortem findings may include the following:

> The CNS signs include grinding of the teeth and tremors, which progress to weakness and incoordination.
>
> Sheep appear depressed.
>
> Horses may exhibit head pressing.
>
> Cattle appear agitated and become increasingly belligerent and violent.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Petroleum Hydrocarbon Toxicity

Ingestion of gasoline, diesel fuel, or other petroleum hydrocarbon products can cause illness and death. Clinical signs may be respiratory, gastrointestinal, dermatologic, or CNS.

Ante-mortem findings may include the following:

> Visual problems, excitability, incoordination, depression, head tremors, and shivering.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Perennial Ryegrass Staggers

Perennial ryegrass staggers is a neurotoxic condition affecting all livestock ingesting *Lolium perenne* (perennial ryegrass) or hybrid ryegrasses in the summer and fall infected with the fungus *Acremonium loliae*.

Ante-mortem findings may include the following:

The CNS signs are tremors of the head and nodding movements, progressing to incoordination, and jerky movements. Forced running may produce more severe symptoms including collapse, nystagmus, opisthotonos, and flailing of legs.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Salt Poisoning

Salt poisoning of domestic animals is usually caused by water deprivation coupled with increased salt intake, causing toxic levels of sodium chloride to build up.

Ante-mortem findings may include the following:

Pigs show various CNS signs including deafness, blindness, aimless wandering, head-pressing, circling, tonic-clonic seizures, opisthotonos, paddling, and coma.

Cattle CNS signs are blindness, seizures, and partial paralysis.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Selenium Poisoning

Selenium poisoning is caused by the ingestion of toxic levels of selenium, usually in naturally seleniferous forages and grain. Soils high in selenium are found in Mexico and some areas of the western plains of Canada and the United States. Most selenium poisoning in the United States has occurred in Nebraska, South Dakota, Colorado, and Wyoming.

Ante-mortem findings may include the following:

The CNS signs are referred to as “blind staggers.”

Cattle and sheep show signs of impaired vision, wandering, and walking into objects, followed by weak front legs and throat and tongue paralysis.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Senecio Poisoning

Senecio poisoning (seneciosis, ragwort toxicity, pyrrolizidine alkaloidosis) is caused by ingestion of plants containing hepatotoxic alkaloids with a pyrrolizidine base.

Ante-mortem findings may include the following:

The CNS signs are stumbling, head-pressing, weakness, and aggressiveness.

Ante-mortem disposition: Same disposition thought process as hypomagnesemic tetany.

Non-ambulatory Animals

9 CFR 309.2(b) states that non-ambulatory disabled livestock, including cattle, are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions. Also, 9 CFR 309.3(e) states **that non-ambulatory disabled cattle shall be condemned.** Other species of livestock would be examined by the PHV, and either be condemned or passed for slaughter as a U.S. Suspect.

Non-ambulatory disabled cattle are considered unfit for use as human food. This determination is derived from Title 1, Section 1(m)(3) of the Federal Meat Inspection Act. Specifically,

The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

LIVESTOCK DISEASES AND CONDITIONS OF PUBLIC HEALTH SIGNIFIANCE (CONTINUED)

Septicemia

Septicemia is a condition of public health significance caused by the presence of pathogenic microorganisms and their associated toxins in the blood. The liver, spleen, and lymph nodes are usually hyperemic and swollen because these organs remove most of the bacteria from the bloodstream. Certain types of bacteria, fungi, and viruses circulate in the bloodstream (bacteremia, fungemia, viremia) without overt disease being present. Microorganisms continually enter the blood through the mouth, intestinal wall, and lung, but the life of these organisms is usually short. If the organism is pathogenic and overwhelms the animal's defenses, acute disease will result. Septicemia is an acute disease process, caused by an infectious agent and resulting toxic products that produce a variety of clinical findings including changes in body temperature, pulse rate, and responsiveness (i.e., depression, prostration). In later stages of septicemia, toxic signs and lesions may include disseminated intravascular coagulation and shock. At post-mortem, septicemias may result in congestion, hyperemia, petechial to ecchymotic hemorrhages, acute infarction, edema, darkened musculature, acute lymphadenopathy, loss of body condition, dehydration, anemia, and changes in organ appearance. A change in organ size, color (darkening or pallor), and consistency (change of normal texture from almost fluid to very firm) may be observed. All these signs and lesions, of course, might not be present in every animal with septicemia.

The problem of differentiation between septicemia and a localized inflammatory process is often very difficult. One must be aware that generalized enlargement of lymph nodes may occur in disease remission or in chronic disease and does not necessarily indicate an active septicemia.

Many conditions that are not considered to be a food safety hazard can lead to septicemia. For example, pneumonia in its early stages may not represent a public health hazard. However, if the disease progresses and overwhelms the animal’s immune system, pathogens may gain access to carcass tissues and result in septicemia, thus posing a food safety hazard.

Ante-mortem findings may include the following:

Variable temperature—typically would be high but may vary to subnormal (due to thermal regulation failing); must expect to encounter a whole range when considering the possible array of disease conditions and the drastic range of possible ambient temperatures to which such an animal might be exposed. The PHV should independently assess each case.

Evidence of injury or suppuration

Recumbent, non-ambulatory, or physical depression

Hyperemia of skin

Evidence of pain

Muscle tremors Dyspnea

Congestion of mucous membranes

Changes in locomotion

Ante-mortem disposition: (9 CFR 309.2)

Condemn: When it is possible to establish a diagnosis of septicemia based on any combination of significant findings that would give evidence that the carcass would be condemned on post-mortem.

Suspect: All animals that show signs and lesions of septicemia, but not conclusive evidence.

Post-mortem findings may include the following:

Infected wounds or bruises

Generalized, acute lymphadenitis

Degeneration of tissues or organs Acute infarction

Imperfect coagulation of blood

Petechial or ecchymotic hemorrhage (most noticeable in kidneys, epicardium, lungs, and serosal surfaces)

Sero-sanguinous fluid in abdominal and or thoracic cavities

Injection sites (recent)

Edema or other evidence of acute generalized inflammation

Post-mortem disposition: (9 CFR 311.16, 311.17)

Condemn: In cases of generalized disease due to infected wounds or bruises, or when the primary pathology is masked and associated manifestations are present as outlined in the ante-mortem and post-mortem findings.

(1) Generalized, acute lymphadenitis alone is enough for condemnation.

(2) A carcass manifesting septicemia is never passed.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Note: The term septicemia should only be used for disposition purposes when a specific disease cannot be diagnosed.

Toxemia

Toxemia is a condition of public health significance due to the circulation of exotoxins, endotoxins resulting from the death of microorganisms, or toxins generated by the death or dysfunction of the animal's own cells, and the inflammatory process itself. In the latter situations, cytokines, prostanoids, and acute phase reactant proteins may produce systemic effects such as metabolic changes, fever, and necrosis. Changes in endothelial cells produced by such products may also result in pathologic hemorrhage or edema. Toxemia, as a term, is frequently used but technically the phenomenon is closely related to and may be inseparable from the syndrome seen in septicemia. In examples such as septic mastitis, metritis, or arthritis, a septicemia, a toxemia, or both may simultaneously occur. Unless bacterial culture and isolation is performed on various tissues, toxemia may be difficult to recognize grossly as a separate entity from septicemia.

Ante-mortem findings may include the following:

Condition that may be associated with toxemia, e.g., an old injury, or gangrenous mastitis.

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Recumbent, non-ambulatory, or physical depression

Dehydration—dry nose, sunken eyes, loose skin can be made to tent by digital manipulation

Pain—grinding of teeth

May appear confused or have convulsions

Changes in locomotion

Ante-mortem disposition: (9 CFR 309.2, 309.4)

Condemn: Animals showing conclusive signs of toxemia.

Suspect: Animals indicating signs and lesions, but not conclusive evidence, of toxemia.

Post-mortem findings may include the following:

Petechial or ecchymotic hemorrhage (most noticeable in kidneys, epicardium, lungs, and serosal surfaces)

Generalized, acute lymphadenitis

Degeneration of tissues or organs

Presence of areas of tissue necrosis

Post-mortem disposition: (9 CFR Part 311.16, 311.17, 311.37)

Condemn: When lesions and/or clinical findings indicate that a toxemia exists and the primary pathology is masked, the carcass is condemned for toxemia.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Notes:

(1) Chronic lymphadenitis due to a previous infection or condition should not be confused with toxemia.

(2) An enlarged pale liver from a pregnant animal nearing delivery should not be confused with a liver associated with toxemia. Although a form of hepatic lipidosis may be seen in either, the post-mortem array of lesions in one condition should not be confused with the tissue and organ changes in a periparturient carcass.

(3) The term toxemia should only be used for disposition purposes when a specified disease cannot be diagnosed.

Pyemia

Pyemia is a condition of public health significance resulting from the active circulation of pyogenic organisms in the blood. It is typically characterized by the development of acute suppurative lesions throughout the carcass tissues and organs.

Ante-mortem findings may include the following:

Depression or lethargy

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Swollen joints Umbilical abscess

Subcutaneous abscesses

Cachexia

Scirrhous cord (funiculitis)

Ante-mortem disposition: (9 CFR Part 309)

Condemn: Any combination of significant findings giving evidence that the carcass would be condemned on post-mortem, e.g., abscesses, as well as generalized (systemic) signs.

Suspect: Animals showing signs and lesions, but not conclusive evidence, of pyemia.

Post-mortem findings may include the following:

Acute suppuration (developing foci of suppuration) occurring as a result of pyogenic organism's entry into the systemic circulation

Infarcts accompanied by acute suppuration

Pathologic hemorrhage by itself does not indicate pyemia; however, when associated with either or both of the first two findings, it does support a diagnosis of pyemia.

Degeneration of tissues or organs by itself does not indicate pyemia; however, when associated with either or both of the first two findings, it does support a diagnosis of pyemia.

Generalized, acute, reactive, or edematous lymphadenitis.

Special Notes:

(1) Neoplasia having central liquefaction necrosis may appear as a chronic abscess.

(2) Tuberculosis may appear as a purulent event in certain situations.

(3) Although a pyemia may have caused them, multiple, localized, encapsulated abscesses about the body should not be confused with an active pyemia.

Post-mortem disposition: (9 CFR 311.16)

Condemn: All carcasses affected with an active pyemia are condemned, as evidenced by:

(1) Presence of generalized acute suppuration occurring as a result of a pyogenic organism's entry into the systemic circulation

(2) Abscesses associated with lesions of septicemia as outlined in septicemia post-mortem findings.

Pass: Carcasses not meeting the criteria for condemnation for pyemia, after condemnation and removal of any abnormal tissue.

Special Note: The term pyemia should only be used for disposition purposes when a specific disease cannot be diagnosed.

Contamination

Fecal material, ingesta, and milk are vehicles for microbial pathogens in livestock, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process (9 CFR 417.2(a) and (b)). Consequently, HACCP plans must control for microbiological contamination at slaughter, and to meet the slaughter food safety ("zero tolerance") standard. An establishment's controls must (among other things) include limits that ensure that no visible fecal material is present by the point of post-mortem inspection of livestock carcasses. FSIS enforces "zero tolerance" standards for fecal, ingesta, and milk contamination on livestock carcasses through post-mortem inspection activities at establishments that slaughter livestock. The establishment must meet the slaughter food safety tolerance standard for visible contamination at the post-mortem rail inspection station, regardless of the location of the CCP. The CCP for pathogen contamination or visible contaminants may be at other locations as supported by the hazard analysis.

When the on-line inspectors at the rail station find feces, ingesta, or milk, the establishment reexamines and reworks the entire carcass (trimming all contamination).

"Zero tolerance" is covered during a different part of training.

Cysticercosis of Cattle (Beef Measles)

Cysticercosis is a condition caused by the presence of the larval form of the beef tapeworm, *Taenia saginata*, in the carcass tissues. It is of public health significance because it is transmissible to humans through meat products which are not treated in some manner to kill the larva.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Heart muscle with degenerated cysts

Dead and degenerated cysts in musculature

Meat is watery or discolored and the carcass or parts display lesions of cysticercosis.

Any number of cysts whether alive, dead, or degenerated.

Live cysts will appear as a vesicle or small bladder (balloon) filled with fluid. In most cases, the cyst will be dead (degenerated to some extent) and will appear as small intramuscular foci of fibrotic (hard, thick) tissue that may or may not be calcified and gritty in texture. In addition to these lesions, the associated muscle tissue may be watery or discolored.

Special Notes:

(1) The presence of even one cyst, whether viable or not, indicates beef cysticercosis.

(2) Make certain that food inspectors can recognize live or dead and degenerated cysts, as the presence of either indicates beef cysticercosis.

(3) For purposes of discussing the inspection procedure for cysticercosis in cattle, we must define the term “usual inspection sites” as including the following locations:

a. Muscles of mastication

b. Heart

c. Cut surfaces of muscles exposed during usual dressing procedures

d. The diaphragm and its pillars

e. Esophagus

f. Tongue

(4) Certain conditions such as the following could be confused with cysticercosis:

a. Other localized parasitic or calcified conditions

b. Nerve sheath tumors (covered during neoplasm module)

c. Eosinophilic myositis – especially the large EM lesions in which the centers can be expressed

d. Abscesses

e. Fat marbling in musculature

Post-mortem disposition: (9 CFR 311.23)

(1) When cysticercosis is detected during routine post-mortem inspection procedures, the affected carcass and parts must undergo the following further examination by the PHV:

a. Incise thoroughly the lateral and medial masticatory (cheek) muscles, heart, diaphragm, and its pillars. The peritoneum is removed before incising the diaphragm;

b. Observe and palpate the tongue. If cysts are suspected in the muscular part, then the tongue is thoroughly incised and observed; and

c. Carefully examine the esophagus and the cut surfaces of muscles exposed during regular dressing procedures. If one or more lesions are found at only one site in this inspection, then make your disposition based on these findings. However, if lesions are found in two or more of the usual inspection sites (heart, diaphragm and its pillars, cheeks, esophagus, tongue, and muscles exposed during normal dressing operations), continue with (2).

(2) <u>When cysts in the carcass are in two or more of the above sites</u>:

a. Make one incision into each round, exposing the muscles in cross-section, and

b. One transverse incision into each forelimb, commencing two or three inches above the point of the olecranon and extending to the humerus, exposing the triceps brachii, totaling four incisions.

c. Observe the cut surfaces for cysticercosis lesions.

<u>*Condemn:*</u> The carcass and its parts should be condemned when lesions of cysticercosis are present and:

(1) The musculature is edematous or discolored, or

(2) If infestation is extensive. The carcass shall be considered extensively infested if lesions are found in at least two of the "usual inspection" sites (heart, diaphragm and its pillars, cheeks, esophagus, tongue, and muscles exposed during normal dressing operations) and two of the additional exposed sites (incision made into each round exposing the musculature in cross section; and a transverse incision made into each forelimb commencing 2-3 inches above the joint of the olecranon and extending to the humerus exposing the triceps brachii).

<u>*Passed with Processing Restriction:*</u> Any carcass with an infestation that is less than extensive and that does not show edema or discoloration in the musculature may be passed for refrigeration or be passed for heating after removal and condemnation of affected parts. The PHV should verify that the establishment treats the product as indicated below:

(1) Passed for Refrigeration

a. Carcasses – Hold 10 days at not higher than 15°F

b. Boned meat – Hold 20 days at not higher than 15°F

(2) Passed for Heating

a. Product is brought to an internal temperature of at least 140°F throughout.

Special Notes:

(1) The PHV should send tissue samples to the FSIS Eastern laboratory in Athens, Georgia, to confirm the diagnosis, if necessary.

(2) The Assistant Director (AD), APHIS, Veterinary Services, of the state in which the animal originated should be notified when beef cysticercosis is diagnosed, using VS Form 2-11.

(3) The PHV should notify the health department of the state of animal's origin as well.

(4) The PHV should verify that edible viscera and offal are disposed of in the same manner as the rest of the carcass unless lesions of cysticercosis are found in these byproducts, in which case they shall be condemned.

(5) Identify that all affected products are appropriately controlled by U.S. Retained tags. PHVs are to verify removal of the U.S. Retained tags only after the product has met the processing restrictions. IPP will find regulatory information regarding shipment and control of products containing cysticercosis in 9 CFR 325.7.

(6) **Expanded procedures:** When one beef carcass from a producer is found to contain a tapeworm cyst, the PHV is to follow the procedures below on all carcasses from that producer:

a. Make multiple incisions of the interventricular septum and external and internal muscles of mastication. Closely observe the esophagus and cut surfaces of muscles exposed during the dressing operation.

b. Incise, as above, hearts and cheeks from carcasses that had passed inspection prior to finding the infected carcass and identified as part of the potentially affected production.

Cysticercosis of Swine (Pork Measles)

Swine Cysticercosis is a condition caused by the larval form of the swine tapeworm *Taenia solium*. It is of public health significance because it is transmissible to humans.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Muscle is edematous or discolored

Cysts in muscles of heart, tongue, esophagus, or carcass

Grape-like clusters in tissue underneath the tongue or attached to heart cysts may occasionally be found in fat and viscera.

Special Notes:

(1) When swine cysticercosis is encountered it is generally very extensive.

(2) Most frequently the lesions are first observed on the cheeks and in the heart.

(3) Remind inspectors to observe the cut surfaces on the neck and thigh muscles as cysticercosis could be detected there.

(4) The presence of even one cyst, whether viable or not, indicates swine cysticercosis.

Post-mortem disposition:

(1) When cysticercosis is detected during post-mortem inspection, the following procedures are used by the PHV:

a. Examine the cheeks, heart, and esophagus by sight and numerous incisions.

b. Make several deep longitudinal incisions into the tongue.

c. Remove the peritoneum from the diaphragm and examine the muscles of the diaphragm by numerous incisions.

d. Carefully examine the cut surfaces of muscles exposed during regular dressing procedures (ventral muscles of the ham).

e. If only the initial lesions are found in (a) through (d), make your disposition based on these findings. However, if any additional lesions are found, continue to (2).

(2) If additional lesions are found in the procedures outlined above:

a. Make incisions parallel to cuts described in (1);

b. Remove the peritoneum from the abdominal muscles in the flank and paralumbar regions. Examine visually and then make several incisions to aid in the examination.

c. If no additional lesions are found, make your disposition based on these findings. However, if any additional lesions are found, continue to (3).

(3) If additional lesions are found in the secondary procedures listed above:

a. Make bold incisions into the heavily muscled primal parts to determine if various parts of the musculature expose one or more cysts on most of the cut surface.

Condemn: When porcine cysticercosis infestation is excessive (when the lesions are too extensive to be removed by trimming the carcass).

Pass with processing restriction: Any swine carcass affected with *Cysticercus cellulosae* that is less than excessively infested may be passed for cooking (held at 170°F for 30 minutes), after removal and condemnation of all affected areas (9 CFR 311.24).

Special Notes:

(1) Cases of swine cysticercosis should be confirmed by the Pathology Group of the FSIS Eastern Laboratory—Athens, Georgia. PHVs are to retain swine carcasses pending diagnostic results from the laboratory and report the disease as set out in FSIS Directive 6000.1.

(2) After the diagnosis is confirmed:

a. Make a disposition,

b. Then notify the Veterinarian in Charge, APHIS, Veterinary Services, of the state of the animal's origin using VS Form 2-11, and

c. Notify the health department of the state of the animal's origin.

(3) All product that is passed for cooking must be held under strict control until that processing restriction has been accomplished (9 CFR 315.1, 315.2). Remove U.S. Retained tags only after verifying the product has met the processing restrictions in 9 CFR 311.24.

POULTRY DISEASES AND CONDITIONS OF PUBLIC HEALTH SIGNIFICANCE

Septicemia/Toxemia

Septicemia is a disease state caused by pathogenic (disease producing) microorganisms in the blood that have produced systemic change within the bird. Systemic change affects the body in its entirety rather than localized portions of it.

Toxemia is poisoning caused by the absorption of toxins produced by infective organisms and shows signs similar to septicemia. Both conditions typically exist simultaneously, so the overall condition is referred to as septicemia/toxemia, abbreviated as sep/tox.

In septicemia/toxemia, the normal functions of the bird's organ systems are disrupted. The cells of the body deteriorate. This deterioration may be very rapid when highly virulent microorganisms are the cause, or it may be more gradual if less virulent ones are involved.

In some cases, the changes produced by septicemia overwhelm the bird and result in death. In other cases, the bird's immune system overcomes the causative organism before irreversible damage occurs and it recovers.

Septicemia/toxemia is manifested by a group of clinical signs, not all of which will be present in a single carcass. Therefore, judgment plays an important part in correct dispositions for this condemnation category. Septicemic carcasses frequently have:

- petechial (pinpoint) hemorrhages on the heart, liver, kidneys, muscles, and serous membranes
- blood-tinged exudate in the body cavity
- swollen and hyperemic (contain an excess of blood) liver and spleen (removes most of the bacteria from the circulating blood)
- swollen and congested kidneys hyperemic skin
- muscle wasting (some of this is caused by loss of appetite but most skeletal muscle breakdown is the result of changes in muscle metabolism that triggers protein degradation)

Depending upon the cause and duration of septicemia, carcasses might be hyperemic, cyanotic, anemic, dehydrated, edematous, or exhibit a combination of these signs. No single carcass will show all of the signs.

If a carcass shows systemic change, it is condemned. Once a diagnosis of Sep/Tox has been made the carcass must be condemned (9 CFR 381.83).

Contamination

Because fecal material is a vehicle for pathogens, and microbiological contamination can occur in the slaughter production process, poultry slaughter establishments other than those that slaughter ratites must develop and implement written procedures that demonstrate its effectiveness in reducing the occurrence of pathogens, including controls that prevent the fecal contamination of carcasses. FSIS enforces a "zero tolerance" standard for visible fecal material on poultry carcasses and carcass parts through post-mortem inspection and reinspection activities at slaughter establishments. This slaughter food safety standard also is reflected in FSIS's regulatory requirements. FSIS views preventing carcasses with visible fecal contamination from entering the chilling tank as critical to preventing the cross-contamination of other carcasses.

On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection; 79 FR 49565. The rule became effective on October 20, 2014. Several regulations were revised or newly published relevant to contamination:

- 9 CFR 381.65(f) *Procedures for controlling visible fecal contamination.* Official poultry slaughter establishments must develop, implement and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. Establishments must incorporate these procedures into their HACCP plans, SSOPs, or other prerequisite programs.

- 9 CFR 381.65(g) *Procedures for controlling contamination throughout the slaughter and dressing operation.* Official poultry slaughter establishments must develop, implement and maintain written procedures to prevent the contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, SSOPs, or other prerequisite programs. At a minimum these procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements and monitor their ability to maintain process control.

- 9 CFR 381.65(h) *Recordkeeping requirements.* Official poultry establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required in part (g).

With regards to 9 CFR 381.65(f), this is a review from the Inspection Methods Slaughter Food Safety Standard (Zero Tolerance) module. The PHIS Poultry Zero Tolerance Verification task will be performed at a minimum of twice per line per shift, and 10 birds will be collected randomly from the line. Instructions can be found in FSIS Directive 6420.5, “Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens”, and FSIS Directive 6500.1, “New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirement.” During the performance of the Poultry Zero Tolerance Verification task, how we verify corrective actions when there is a positive fecal finding will depend on how the establishment incorporates their written procedures into their food safety system.

If FSIS IPP find visible fecal contamination on one or more of the selected carcasses while conducting the Poultry Zero Tolerance Verification task, cite noncompliance with 9 CFR 381.65(f), for the

establishment's failure to prevent feces from entering the chiller. If the establishment incorporates written procedures into the:

- **HACCP Plan:** conduct a Slaughter HACCP Verification task to verify 9 CFR 417.3(a)
- **SSOP:** conduct an Operational SSOP Review & Observation task to verify 9 CFR 416.15
- **Prerequisite Program:** conduct a Slaughter HACCP Verification task to verify 9 CFR 417.5(a)(1)

9 CFR 381.91(b) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents need not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut must be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone or may be re-processed as provided in subparagraph (b)(1) or (2) of this section.

The subparagraphs of 9 CFR 381.91(b) describe provisions for online reprocessing (OLR) and offline reprocessing (OFLR). Poultry slaughter establishments are permitted to use approved OLR and OFLR antimicrobial intervention systems to clean carcasses accidentally contaminated with digestive tract contents. The establishment needs to incorporate the OLR and OFLR procedures into its HACCP plan, SSOP, or other prerequisite program. IPP are to verify that the establishment is properly implementing its procedures for removing visible digestive tract contamination when using their antimicrobial intervention system by directly observing the establishment's implementation and monitoring of the procedures.

If a carcass is so contaminated it cannot be inspected or if it is contaminated to the extent that it cannot be made wholesome the carcass would be condemned.

LIVESTOCK DISEASES AND CONDITIONS NOT OF PUBLIC HEALTH SIGNIFICANCE

As with most of the conditions presented in this section, localized conditions may not constitute a public health concern, however, as described in Section 1, carcasses that have become septic, toxic, or pyemic from one or more of these conditions are a public health concern.

Abscess

An abscess is a localized, "walled off" area of pus. Pus is "a liquid inflammation product made up of cells and a thin fluid called Liquor puris." (Dorland's Medical Dictionary)

Ante-mortem findings may include the following:

Swellings may be evident in various parts of the animal

Ante-mortem disposition: (9 CFR Part 309)

Condemn: Any combination of significant findings that would give evidence that the carcass would be condemned on post-mortem, e.g., abscesses, as well as generalized (systemic) signs.

Suspect: Animals showing signs and lesions, but not conclusive evidence, of pyemia.

Post-mortem findings may include the following:

Abscesses in various parts of the carcass or organs

Localized, acute or chronic, reactive, or edematous lymphadenitis.

Special Notes:

(1) Neoplasia having central liquefaction necrosis may appear as a chronic abscess.

(2) Tuberculosis may appear as a purulent event in certain situations.

(3) Although a pyemia may have initially caused them, multiple, localized, encapsulated abscesses about the body should not be confused with an active pyemia.

Post-mortem disposition: (9 CFR 311.14, 311.16)

Condemn: Carcasses affected with multiple abscesses to the extent that all of them could not be removed with a high degree of certainty may be condemned.

Pass: Carcasses not meeting the criteria for condemnation after condemnation and removal of any abnormal tissue. **Note:** all purulent exudate resulting from ruptured abscesses must be trimmed.

When PHVs find slight abscesses in cattle and swine heads, they are to:

(1) Pass the head for food after removal of the lymph node when a small, well- encapsulated abscess is in a cervical lymph node; and

(2) Verify removal of all affected lymph nodes, including mandibular and adjacent lymph nodes, when heads with slight abscesses are passed for food.

Arthritis

Arthritis is the inflammation of joint tissues that may be traumatic or infectious in origin.

Ante-mortem findings may include the following:

Enlargement of one or more joints

Abnormal locomotion

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Painful or abnormal stance and movement

Reluctance to move or stand

Depression Cachexia

Infected navel in young animals

Special Note: Livestock with laminitis, transport injury (sore feet), or pigs raised on concrete can exhibit similar signs and must be distinguished from arthritis.

Ante-mortem disposition: (9 CFR Parts 309.2, 309.4, 309.9)

Condemn:

(1) Arthritis with swollen painful joints, fever

(2) Arthritis with swollen painful joints, cachexia

Suspect: We do not suspect all animals with arthritis, only those with other sufficient clinical signs suggesting that after post-mortem examination the carcass may need to be condemned.

Post-mortem findings may include the following:

Enlarged joints

Reactive or congested regional lymph nodes

Degeneration of tissues or organs

Associated lesions of another condition that may have predisposed to arthritis

Character of exudate in joints:

(1) Increased amount of synovial fluid

(2) Blood-tinged synovial fluid

(3) Turbid, sometimes purulent synovial fluid

Special Notes:

(1) Increased amount of synovial fluid is often associated with stress factors, such as being confined on concrete or being hauled long distances to market. Often this fluid is clear.

(2) As far as carcass disposition is concerned, the type of exudate present in the joints is not the primary consideration; whether the condition is generalized (systemic) is of most public health importance.

Post-mortem disposition: (9 CFR 311.7)

Condemn: Arthritis with generalized changes.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Notes:

(1) The tarsal (hock) joints of swine carcasses affected with localized arthritis may be removed on the pork cut if the affected carcasses are segregated and held by the establishment as a group until this is accomplished.

(2) The number of arthritic joints should not be a primary consideration. If the arthritis is localized and can be removed by trimming, the joint should be condemned and removed along with draining lymph nodes and the carcass passed for food.

(3) Arthritic joints must be removed from the carcass before opening the joint capsule. This is done to avoid contamination of edible product with joint exudate. (9 CFR 311.7)

(4) Verify removal of lymph nodes corresponding with affected joints.

Pericarditis

Pericarditis is an inflammatory condition of the pericardium that is usually due to an infectious agent.

Ante-mortem findings may include the following:

Subcutaneous edema of the lower abdomen and chest (brisket edema)

Distension of jugular furrow, showing a retrograde venous pulse

Tucked-up abdomen and shallow, rapid, abdominal breathing

Stiff, stilted gait; reluctance to move; elbows abducted. Front legs placed forward while at standing rest

Weakness, ataxia

Fever—variable, depending upon stage of condition

Pain elicited on palpation of cardiac region

Cachexia with dehydration, sunken eyes, rough hair coat

Ante-mortem disposition: (9 CFR Part 309)

Condemn: When pericarditis with generalized (systemic) involvement can be diagnosed, the animal shall be condemned.

Suspect: When an animal exhibits signs of pericarditis but does not show conclusive signs of a generalized (systemic) effect, it shall be handled as a suspect.

Post-mortem findings may include the following:

Traumatic reticulitis with penetration of the diaphragm and pericardium by a foreign body

Purulent pericarditis with or without traumatic origin

Serofibrinous or fibrinous pericarditis or epicarditis (shaggy heart)

Pericardial adhesions

Edema of body tissues and fluid accumulations (ascites, pleural effusion)

Putrefactive odor of cut-surface of pericardial, abdominal, or thoracic lesion

Post-mortem disposition: (9 CFR 311.16)

Condemn: When there is purulent or septic pericarditis associated with generalized changes

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Note: A large pocket of pus around the heart does not require automatic condemnation.

Pneumonia

Pneumonia is an inflammatory condition of the lungs that may be caused by infectious agents, parasites, physical trauma, or foreign material inhalation.

Ante-mortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

General depression, reluctance to move

Swollen, watery eyes; sunken eyes from dehydration; injected sclera

Discharge from nostrils (serous to mucopurulent discharge)

Moribund

Cachexia

Pulmonary distress

Stands with forelimbs abducted

Ante-mortem disposition: (9 CFR Part 309)

Condemn:

(1) If the animal has a high or subnormal temperature, general depression, and marked pulmonary distress

(2) Pneumonia in a moribund animal

(3) Pneumonia associated with cachexia

Suspect: Any animal showing signs of pneumonia without conclusive signs of a generalized (systemic) effect.

Post-mortem findings may include the following:

Stages of pneumonia:

(1) Hyperemia—increased blood flow in pulmonary vessels

(2) Red hepatization—lung is heavy, firm, and “liver-like” due to hyperemia, hemorrhage, edema, and leukocytes

(3) Gray hepatization—fibroplasia into areas of red hepatization

(4) Consolidation—chronic areas where fibroplasia is being organized

Lungs may be in one or more stages (red and gray hepatization) concurrently

Lymph nodes draining lungs may be swollen and hemorrhagic

Generalized lesions resulting from septic or toxic conditions may be present:

(1) Reactive, hyperemic, or hemorrhagic lymph nodes in addition to those of the lungs

(2) Degeneration of tissues or organs

(3) Petechial or ecchymotic hemorrhages

Foreign substances in the lung, such as medicinal agents; foreign material may be medicinal in nature, and it should be determined that a residue is not present in carcass tissues. Residues will be covered in a different section of the training.

Parasites (e.g., lungworm infection)

Chronic suppurative bronchopneumonia—chronically dilated airways contain exudate, which on cross-section appears as abscesses

Pneumonia with large amounts of fluid

Pneumonia/pleuritis associated with hardware disease

Special Note:

(1) Pleuritis can be associated with pneumonia or be a separate entity.

(2) Examination of the lungs for pneumonia should include incising the lung as well as opening the airways.

The following are examples of generalized conditions that may have an associated pulmonary lesion. However, they should not be confused with pneumonia caused by primary pulmonary pathogens of livestock.

1. Pyemia with pulmonary abscesses

2. Necrobacillosis

3. Tuberculosis
4. Actinobacillosis
5. Parasitism
6. Caseous lymphadenitis
7. Pleuritis
8. Aspiration of scald tank water
9. Neoplasia

Post-mortem dispositions: (9 CFR 311.16)

Condemn:

(1) Acute extensive pneumonia associated with reactive/hyperemic lymph nodes draining lungs. Generalized (systemic) changes may not be observed at this time because the animal's system has not had a chance to react. (In this situation, if there is reason to believe that the product of the carcass may give rise to food poisoning, condemnation of the carcass is required.) (9 CFR 311.16)

(2) Acute extensive pneumonia with acute pleuritis

(3) Pneumonia with associated generalized (systemic) changes

(4) Marked pulmonary necrosis with associated toxemic changes.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Pleuritis

Pleuritis is an inflammatory condition of the pleural lining due primarily to infectious agents.

Ante-mortem findings – same as pneumonia

Ante-mortem disposition: (9 CFR Part 309)

Condemn:

(1) Fever (or subnormal temperature), general depression, and marked pulmonary distress

(2) Pleuritis in a moribund animal

(3) Pleuritis associated with cachexia

Suspect: Any animal showing signs of pleuritis without conclusive signs of a generalized (systemic) effect.

Post-mortem findings may include the following:

Fibrous adhesions between the lungs and pleura

Fibrinous exudates covering the pleura

Fluid in the thoracic cavity

Reactive thoracic lymph nodes

Pericarditis

Special Note: Pleuritis can be associated with pneumonia or be a separate entity.

Post-mortem dispositions: (9 CFR 311.16)

Condemn:

(1) Acute extensive pleuritis and pneumonia associated with reactive/hyperemic lymph nodes draining lungs. Generalized (systemic) changes may not be observed at this time because the animal's system has not had a chance to react. (In this situation, if there is reason to believe that the product of the carcass may give rise to food poisoning, condemnation of the carcass is required.) (9 CFR 311.16)

(2) Acute extensive pneumonia with acute pleuritis

(3) Pleuritis with associated generalized (systemic) changes

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Peritonitis

Peritonitis is a condition marked by inflammatory processes affecting the peritoneal lining which is usually caused by infectious agents although it can be initiated by intraperitoneal medications, ruptured bladder, hardware disease, or other irritants.

Ante-mortem findings may include the following:

Tucked-up abdomen, shallow thoracic breathing

Stiff-stilted gait, reluctance to move

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Congestion of mucous membranes

Loss of body condition, dehydration

Depression

Abdominal wound suggesting perforation of the peritoneal cavity

Recent parturition

Pain indicated by grinding of teeth, or elicited on palpation of abdominal wall

Rumen atony

Ante-mortem disposition: (9 CFR Part 309)

Condemn: When significant findings of peritonitis are present and there is conclusive evidence of a generalized effect.

Suspect: When an animal exhibits signs of peritonitis but does not show signs of a generalized effect.

Post-mortem findings may include the following:

Pathologic hemorrhage

Generalized, acute lymphadenitis

Injection sites

Degeneration of tissues or organs

Accumulation of fluid in abdominal cavity

Trauma of the abdomen (trocar wounds, penetrations of the genital tract, injuries of the abdominal wall and primary reticuloperitonitis)

Special Note: The following are examples of conditions that may be associated with peritonitis, but should not be confused with infectious peritonitis that might occur in livestock:

(1) Tuberculosis of the peritoneum

(2) Injections into abdominal musculature; bruises of or trauma to the abdominal wall

(3) Adhesions

(4) Neoplasia

(5) Free hemorrhage gives peritoneal surfaces a reddish appearance

Post-mortem disposition: (9 CFR 311.16)

Condemn:

(1) When there is an acute diffuse peritonitis without generalized changes

(2) Peritonitis associated with generalized changes.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Gastroenteritis

Gastroenteritis is an inflammation of the stomach and intestinal tract usually caused by an infectious agent or parasite.

Ante-mortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Diarrhea, rectal prolapse, or vomiting

Dehydration, dry nose, sunken eyes; loose skin may be made to "tent" by digital manipulation

Gaunt—tucked-up abdomen

Weakness, ataxia, depression

Stiff, stilted gait, saw-horse stance

Pain—teeth grinding

Ante-mortem disposition: (9 CFR Part 309)

Condemn:

(1) Abnormal temperature with profuse diarrhea or vomiting.

(2) Debilitation, dehydration, or cachexia associated with gastroenteritis.

Suspect: Any animal with diarrhea or vomiting, but inconclusive signs of generalized effect.

Post-mortem findings may include the following:

Inflammation of stomach or intestine

Intussusception, volvulus, torsion, rectal prolapse

Acute generalized (systemic) changes in lymph nodes

Degenerative changes in tissues or organs

Gangrenous stomach or intestine

An acute, extensive hemorrhagic or gangrenous enteritis with or without generalized changes

Post-mortem disposition: (9 CFR 311.16)

Condemn:

(1) When there is an acute, extensive hemorrhagic or gangrenous enteritis

(2) When there is any degree of gastroenteritis with generalized (systemic) changes

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Nephritis

Nephritis is an inflammatory condition of the kidneys. Etiologies may include infectious agents, parasites, or toxins.

Ante-mortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Abnormal physical appearance of urine (purulent material, blood)

Frequent urination or attempts to urinate

Poor condition

Uremic odor of breath

Accumulations of crystals on preputial hair

An animal with acute nephritis usually shows pain (e.g., teeth grinding, kicking at abdomen, tail switching).

Toxic signs of renal impairment (muscle tremors, exopthalmia, abdominal pain, frothy salivation, polyuria, and bruxism), with muscle tremors progressing to incoordination and weakness; pulmonary edema leads to marked salivation, dyspnea, and gasping.

Ante-mortem disposition: (9 CFR Part 309)

Condemn: A specific diagnosis of nephritis is not possible without more specific diagnostic assistance than is available to in-plant PHVs.

Suspect: Animals showing signs of nephritis that may require condemnation of the carcass on post-mortem inspection.

Post-mortem findings may include the following:

Inflammation, enlargement, pathological hemorrhage, or change of color in kidney

Multiple abscesses of entire kidney

Pyelonephritis--an ascending infection resulting in accumulation of pus in the ureters, renal pelvis, medulla and or cortex

Generalized degeneration of tissues, organs, and lymph nodes

Generalized edema from hypoproteinemia

Uremic odor of carcass, indicating uremia

Special Note:

(1) Certain conditions should not be confused with primary nephritis:

(2) Kidney worms in swine

(3) Urinary obstructions (uroliths)

(4) Infarcts

(5) Neoplasms

(6) Renal cysts or polycystic kidneys

(7) Hydronephrosis

(8) Traumatic injuries

(9) Depressed white areas—scars resulting from previous infarcts or nephritis

Post-mortem dispositions: (9 CFR Part 311)

Condemn:

(1) Nephritis (acute or chronic) associated with generalized lesions or disease

(2) Pyelonephritis associated with generalized changes

(3) Uremia associated with any stage or type of nephritis

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Note:

(1) Carcasses with chronic interstitial nephritis—white, firm, depressed, or pitted kidneys—should be passed for food, if there are no generalized changes, after condemnation of and removal of abnormal tissues.

(2) Hydronephrosis and extensively cystic kidneys do not warrant condemnation of the carcass in the absence of uremia when no generalized changes are present. All abnormal tissues should be condemned and removed.

(3) White spotted kidneys of calves are a subacute to chronic nephritis that contain extensive infiltrates of lymphocytes and plasma cells that produce masses that may be difficult to differentiate from lesions of lymphoma. Laboratory assistance may be required.

(4) Specific disease conditions that have an associated nephritis should carry the diagnosis of the specific condition.

Mastitis

Mastitis is an inflammation of the udder tissue usually associated with a bacterial infection.

Ante-mortem findings may include the following:

Traumatic injury to the udder

Swollen udder may range from a slight edema to a hard, feverish, painful enlargement involving the quarter or whole udder

Reluctance to move because of avoidance of pain

Anorexia, dehydration, cachexia, depression

Variable temperature—depending upon stage of disease and ambient temperature. May range from very high to subnormal; the PHV should independently assess each case.

Purulent to serosanguinous exudate

Gangrenous blue-black discolored area may be sloughing

Ante-mortem disposition: (9 CFR Part 309)

Condemn: Any animal with mastitis exhibiting generalized signs.

Suspect: Animals with mastitis and sufficient clinical signs to indicate that the carcass will likely be condemned on post-mortem inspection.

Special Note: There may be conditions affecting the udder that will not require suspecting the animal, such as pendulous udders. Cattle with pendulous udders are, however, prone to mastitis.

Post-mortem findings may include the following:

Hyperemia in the area of udder attachment

Associated metritis

Traumatic injury of the udder

Foul-smelling exudate—abnormal milk, gangrenous tissue

Disease-related hemorrhage

Reactive or edematous lymph nodes

Degenerative changes of organs/tissues

Post-mortem disposition: (9 CFR 311.16)

Condemn:

(1) Acute diffuse mastitis (In this situation, if there is reason to believe that the product of the carcass may give rise to food poisoning, condemnation of the carcass is required.)

(2) When mastitis is associated with generalized (systemic) changes

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Special Note:

(1) Mammary lymph nodes in mature dairy cows are often hyperplastic.

(2) Enlarged, hyperplastic regional lymph nodes alone are not sufficient reason to condemn the carcass if the carcass and viscera are otherwise normal.

(3) An acute lymphadenitis of a mammary lymph node might be significant, particularly if the udder has been removed and discarded during dressing.

Metritis

Metritis is an inflammatory condition of the uterine tract, usually of bacterial origin.

Ante-mortem findings may include the following:

Vaginal discharge with foul odor

Exudate on perineal hair

Remnants of fetal membranes protruding from vulva

Tucked-up abdomen

Temperature—variable, depending on stage of infection, ambient temperature

Depression, cachexia

Tenesmus

Ante-mortem disposition: (9 CFR Part 309)

Condemn: Animals with metritis exhibiting generalized signs

Suspect: Animals with diagnosis of metritis showing inconclusive signs of generalized involvement

Special Note: Any animal with retained fetal membranes should be withheld from slaughter. Upon passage of fetal membranes, if the animal is otherwise normal, pass for regular slaughter (9 CFR 309.10). Any animal treated for retained fetal membranes should meet withdrawal times for any medication used.

Post-mortem findings may include the following:

Thickened, hyperemic or congested uterine wall

Endometritis

Purulent to watery material (often with a foul odor) within uterus

Generalized, acute, reactive, or edematous lymphadenitis

Associated degenerative changes in tissues/organs indicative of generalized involvement

Pyemia

Dead macerated fetus

Special Note: Metritis is not associated with a dry mummified fetus.

Post-mortem disposition: (9 CFR 311.16)

Condemn:

(1) Acute diffuse metritis (In this situation, if there is reason to believe that the product of the carcass may give rise to food poisoning, condemnation of the carcass is required.)

(2) When the metritis is associated with generalized (systemic) changes

Pass: Those carcasses not meeting the criteria for condemnation shall be passed after condemnation and removal of any abnormal tissue.

Special Note: Purulent material in the uterus alone does not indicate generalized (systemic) involvement. The uterus tends to discharge its contents and contain its disease processes relatively well.

Necrobacillosis

Necrobacillosis is a condition resulting from the entry of the organism *Fusobacterium necrophorum* into the tissue or organs.

Ante-mortem findings may include the following:

Foot rot

Cachexia

Dyspnea

Nasal discharge

Pyrexia

Ante-mortem disposition: (9 CFR Part 309)

Condemn: When evidence indicates foot rot is associated with a generalized (systemic) condition.

Suspect: When foot rot is associated with other clinical signs, suggesting that after post-mortem examination the carcass may need to be condemned.

Post-mortem findings may include the following:

Generalized multiple purulent lesions (pyemia) occurring as a result of the entrance of the bacteria *Fusobacterium necrophorum* into the systemic circulation (e.g., acute lesions in the lung after rupture of a hepatic abscess into the vena cava, or pulmonary hemorrhage resulting from the erosive processes of a lung lesion).

Abscesses in liver, lungs, rumen, etc.

Disease-related hemorrhages

Reactive or edematous lymph nodes

Degenerative changes of organs/tissues

Special Note: The number of lesions present in a liver is less significant than the presence of associated generalized toxic changes and bacterial embolism.

Post-mortem disposition: (9 CFR 311.17)

Condemn: When necrobacillosis is associated with generalized lesions.

Pass: Those carcasses not meeting the criteria for condemnation shall be passed after condemnation and removal of any abnormal tissue.

Swine Erysipelas

Erysipelas is a disease of swine caused by the organism *Erysipelothrix rhusiopathiae*.

Ante-mortem findings may include the following:

Fever in acute stages; some variation, but this is a highly febrile disease

Will move about if forced, but squeal in pain

Bright and alert, but are reluctant to move due to painful or swollen joints

Diffuse areas of purple skin (acute) to raised, red, edematous, rhomboid wheals (acute stages) to sloughing of affected dead areas of skin (chronic)

Arthritis, a lesion seen in naturally occurring disease and vaccine-associated disease

Sudden death of affected animals in acute disease is characteristic—especially if animal is excited

Ante-mortem disposition: (9 CFR 309.2)

Condemn: If fever and signs of acute erysipelas are present, indicating the carcass would be condemned on post-mortem

Suspect: If skin lesions and clinical signs indicate erysipelas, but insufficient for condemnation

Special Note:

(1) Transport injury (sore feet): This can result from pigs being raised on concrete and should not be confused with erysipelas.

(2) Trauma from cane or boot marks, rough handling, or animals fighting can be confused with lesions of erysipelas.

Post-mortem findings may include the following:

Arthritis

Vegetative endocarditis

Skin lesions, which may vary from acute to chronic

In acute disease, generalized lymphadenitis

Petechial hemorrhage may be noticeable in lungs, kidneys, heart, or on serosal surfaces

Degeneration of tissues or organs

Post-mortem dispositions: (9 CFR 311.5 and 311.6)

Condemn:

(1) If disease is acute, as evidenced by skin lesions associated with petechial hemorrhages in the kidneys, hemorrhagic and congested lymph nodes, and degeneration of organs

(2) Acute, extensive skin lesions, with generalized, acute, reactive, lymphadenitis with no visible involvement of body organs

(3) Erysipelas resulting in arthritis when associated with acute degeneration of organs and tissues

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue

Special Note: "Diamond skin" is a common name for erysipelas in swine with skin lesions. This condition is often localized to the skin without generalized lesions. The skin, in such cases, is condemned and trimmed, and the carcass may then be passed for human food.

Caseous Lymphadenitis

Caseous Lymphadenitis (CLA) is a disease of sheep and goats caused by the organism *Corynebacterium pseudotuberculosis*.

Ante-mortem findings may include the following:

Weight loss, cachexia, debilitation

Enlargement (suppuration) of superficial lymph nodes

Abscesses in the lungs and associated pneumonia often produce respiratory signs

Fever

Ante-mortem disposition:

Condemn: When obvious CLA is associated with systemic signs

Suspect: When the animal exhibits signs of CLA and has possible, but not conclusive, signs of systemic effects

Special note: The dispositions of sheep and goat carcasses with CLA are based on two criteria: the carcass condition (well-nourished or thin) and the extent and distribution of lesions in the carcass and viscera (slight, well-marked, extensive and numerous). When an affected carcass is allowed to be used as human food (either passed for cooking or passed after trimming), all diseased tissue must be removed and condemned.

Post-mortem findings may include the following:

Enlarged, abscessed lymph nodes with greenish white-yellow caseous exudate, which tends to become dry and granular

In sheep, cross-sections of lesions contain remnants of connective tissue capsules (resembling the concentric rings seen on the cut surface of an onion). This is not characteristic of the infection in goats.

Lesions found in many lymph nodes, especially the subiliac, superficial cervical, deep popliteal, tracheobronchial, and mediastinal, as well as lungs, heart, liver, spleen, and kidneys.

Definition of terms in the caseous lymphadenitis regulation (9 CFR 311.18):

Viscera - A primary compartment; includes organs and associated lymph nodes that may be affected with lesions of caseous lymphadenitis

Skeletal lymph nodes - The other primary compartment; includes the carcass lymph nodes

Slight - Small in size, quantity, or number; of no significance; so small or unimportant or of so little consequence as to warrant little or no attention. As applied to certain liver abnormalities, slight means that the lesions are small and few.

Well-marked - To a higher degree than having a distinctive or emphasized character, attracting notice or attention; noticeable, unlikely to escape observation; prominent, stands out from its surroundings or background; conspicuous, obvious or unavoidable to the sight

Numerous - Consisting of great numbers of units or individuals

Extensive - Not definitely limited, concentrated, or localized; widely distributed; having wide or considerable extent; widespread, widely diffused or prevalent; widely extended or spread out. Not restricted to a definite locality; existing in or affecting all or most of a carcass or part. Exceeding the usual, proper, or normal; implies an amount or degree too great to be reasonable or acceptable.

Well-nourished carcass - having the flesh characteristics of a robust, healthy, immature or mature carcass

Thin carcass - While not emaciated or anemic, this carcass has much less flesh quality than a well-nourished carcass

Post-mortem disposition: (9 CFR 311.18)

Condemn:

(1) A thin carcass having well-marked lesions in the skeletal lymph nodes and viscera

(2) A thin carcass having numerous and extensive lesions in either the skeletal lymph nodes or the viscera

(3) A well-nourished carcass having both numerous and extensive lesions

Pass for cooking:

(1) A thin carcass showing well-marked lesions in either the skeletal lymph nodes or the viscera

(2) A well-nourished carcass showing marked lesions in both the skeletal lymph nodes and the viscera

Special Note: Diseased carcasses with lesions less severe than those requiring condemnation of the carcass but more severe than those allowed to pass after trimming are eligible for use as “Passed for Cooking.” Affected tissues from such carcasses must be condemned and thoroughly trimmed before being designated as “Passed for Cooking.” These carcasses must be held under FSIS control until the product has met the processing restriction “Passed for Cooking” before being allowed for use as human food.

Pass: Those carcasses not meeting the criteria for condemnation or “Passed for Cooking,” after condemnation and removal of any abnormal tissue; this disposition category accounts for the great majority of cases of caseous lymphadenitis in sheep and goats.

Caseous Lymphadenitis Disposition Guide

Any carcass:

- affected with numerous and extensive lesions is *condemned*
- affected with slight lesions only is trimmed and *passed*

A thin carcass:

- affected with well-marked lesions in any one compartment must be *cooked*
- affected with well-marked lesions in both compartments must be *condemned*

A well-nourished carcass:

- affected with well-marked lesions in one compartment is trimmed and *passed*
- affected with well-marked lesions in both compartments must be *cooked* (“carcass” includes edible viscera)

Actinobacillosis and Actinomycosis

Actinobacillosis is due to infection of soft tissues, especially the tongue, by *Actinobacillus lignieresii*, a gram-negative rod. Granulomas caused by this agent may also be present in cervical lymph nodes, muscles, lungs, or other internal organs.

Actinomycosis is due to infection by *Actinomyces bovis*, a gram-positive filamentous rod that causes granulomas, most often in the bone of the mandible or maxilla of cattle, but which may also affect lymph nodes and other soft tissues.

Special Note: “Acti” is the term commonly applied to both conditions. Certain conditions can be confused with "acti" on ante-mortem:

(1) Abscessed teeth

(2) Sinusitis

(3) Injuries

(4) Lymph node metastasis of squamous cell carcinoma

(5) Sialadenitis, sialoliths, cysts

(6) Neoplasms

(7) Food impacted in the jaw (especially in old cows)

Ante-mortem findings may include the following:

Swelling or enlargement of soft tissue (including tongue) or hard tissue of head and neck. There may be draining fistulous tracts.

Draining fistulous tracts on udders of sows

Excessive salivation

Cachexia

Ante-mortem disposition: (9 CFR Part 309)

Condemn: Livestock plainly showing, on ante-mortem inspection, actinobacillosis or actinomycosis to the extent that, under 9 CFR Part 311, it would cause condemnation of the carcasses on post-mortem inspection, shall be identified as U. S. Condemned and disposed of according with 9 CFR 309.13.

Suspect: Any animal having actinobacillosis or actinomycosis to a lesser degree than that requiring condemnation

Post-mortem findings may include the following:

Generalized involvement—as indicated by distribution of active lesions (definition below), made possible only by entry into the systemic circulation, e.g., extensive lesions (definition below) or active lesions beyond the mandibular lymph nodes and the lungs and their lymph nodes

Localized involvement—as indicated by confinement with no indication of generalized (systemic) involvement

Extensive lesions—Not definitely limited, concentrated, or localized; widely distributed; having wide or considerable extent; widespread, widely diffused, or prevalent; widely extended or spread out. Not restricted to a definite locality; existing in or affecting all or most of a carcass or part. Exceeding the usual, proper, or normal; implies an amount or degree too great to be

reasonable or acceptable; involvement indicated by numerous lesions distributed throughout lung, or most of the lung tissue involved with large lesions

Active lesions—Lesions showing acute inflammation and lack of encapsulation

Special Note: The following lesions could be confused on post-mortem with lesions of "acti":

(1) Tuberculosis

(2) Fungal granulomas

(3) Chronic pneumonia with abscess

(4) Granulomas due to foreign bodies (parasites, weed awns) or other agents (coccidioidomycosis, mucormycosis)

(5) Metastatic tumors

Post-mortem disposition: (9 CFR 311.2(a)(1))

Condemn: When active acti lesions are generalized (when the lesions are distributed in a manner that is possible only by entry of the bacilli into the systemic circulation)

Pass: With condemnation and removal of affected parts. (9 CFR 311.9)

(1) Heads (including the tongue) that are affected with either disease shall be condemned except:

a. When the disease of the jaw is slight, strictly localized, without suppuration, without fistulous tracts, and without lymph node involvement, the tongue may be passed for human food if free from disease.

b. When the disease is slight and confined to the lymph nodes, the head and tongue may be passed for human food after the affected lymph nodes are removed and condemned.

(2) When the disease is slight and confined to the tongue, with or without involvement of the corresponding lymph nodes, the head may be passed for food after removal and condemnation of the tongue and corresponding lymph nodes. The “corresponding” lymph nodes include the medial retropharyngeal, lateral retropharyngeal, and the mandibular lymph nodes.

(3) Well-nourished carcass with localized lesions is passed after infected parts are removed and condemned.

Tuberculosis

Tuberculosis is an infectious disease caused by certain pathogenic acid-fast organisms of the genus *Mycobacterium*.

Special Notes:

(1) APHIS TB reactors are tagged and branded (on the left hip) prior to being sent to slaughter. Cattle that have reacted to a tuberculin test administered by an APHIS (or State or accredited) veterinarian are accompanied by APHIS Form VS 1-27 and are tagged as APHIS TB reactors. TB reactors are treated by an FSIS PHV as "U.S. Suspect" for slaughter and inspection purposes.

(2) TB-suspect and TB-exposed cattle are ante-mortem designations based on testing results or the ecological background of cattle. For Veterinary Services Live Animal Categories, Handling Procedures, and Collection of Identification Devices for TB-suspect cattle, TB-exposed cattle, and Mexican (M-branded cattle), refer to FSIS Directive 6240.1, “Inspection, Sampling, and Disposition of Animals for Tuberculosis (TB).” (Also refer to FSIS Directive 6240.1 for information regarding preparation of lesions for submittal and preparation of forms to report lesions.)

(3) Establishment personnel must segregate all APHIS TB reactors, TB suspects, or TB-exposed animals and must identify them to the PHV before ante-mortem inspection is performed (FSIS Directive 6240.1).

(4) The FSIS PHV performs all ante-mortem and post-mortem inspection, diagnosis, and disposition procedures on all TB reactors, Category 1 TB-exposed, and TB-suspect cattle (laboratory assistance for diagnostic purposes).

(5) The term "TB suspect," used to identify animals that reacted inconclusively to the injection of tuberculin, should not be confused with the term "U.S. Suspect" used on animals identified on ante-mortem.

(6) Special references for all species include the Meat and Poultry Inspection Regulations (9 CFR 311.2) and FSIS Directive 6240.1, “Inspection, Sampling, and Disposition of Animals for Tuberculosis.”

(7) Bovine mycobacteriosis is defined as cattle having *Mycobacterium bovis* (FSIS Directive 6240.1). However, many pathologists also refer to Johne’s Disease (*M. paratuberculosis*) in cattle as mycobacteriosis.

Ante-mortem findings may include the following:

Weakness

Weight loss

Cachexia

Low-grade fever

Intermittent, "hacking" cough

Superficial lymph nodes swollen and firm

Ante-mortem disposition: (9 CFR 309.2)

Special note: Bovine TB reactors that die in pens, or that are inspected (ante-mortem) and condemned by a PHV shall receive a complete post-mortem examination that includes the expanded post-mortem inspection procedure detailed in FSIS Guideline No. 4, "Inspection of Tuberculin Reactors." The examination shall occur in an area designated for inedible product or in another area separate from edible product areas and otherwise acceptable to the PHV.

Condemn: If a TB reactor must be condemned on ante-mortem, it shall be given a thorough post-mortem examination using the procedure described in FSIS Directive 6240.1.

Suspect: All reactors are identified U.S. Suspects (using the USDA Reactor tag in lieu of Suspect tag)

Post-mortem findings may include the following:

Definitions that apply to tuberculosis lesions:

Localized - Not extensive; restricted to a limited region or to one or more foci.

Slight - As applied to tuberculosis lesions in lymph nodes, slight means that the lymph node is of normal size and has more normal than diseased tissue.

Well-Marked - As applied to tuberculosis lesions in lymph nodes, well-marked means that the lymph node is enlarged, or that the lymph node is of normal size but has more diseased than normal tissue.

Extensive - As applied to tuberculosis lesions in lymph nodes, extensive means that the lymph node is greatly enlarged, or nearly all the lymph node tissue is affected. As applied to tuberculosis lesions in tissues other than lymph nodes, extensive means that more than half of the organ or tissue surface is affected. Multiple means that there are lesions in more than one organ. Acute, progressive means tissue surrounding caseous lesion is edematous and congested or hyperemic; or that several similar small lesions are occurring around an older focus.

Special Note:

(1) The FSIS PHV performs all post-mortem inspection, diagnostic, and disposition procedures on all TB reactors, Category 1 TB-exposed, and TB- suspect cattle. Category 2 TB-exposed cattle may be inspected in part by non-veterinary IPP.

(2) The PHV should be sure to report all nonreactor cattle and calves with lesions resembling tuberculosis on VS Form 6-35. Send tissue specimens to the National Veterinary Services Laboratory (NVSL) at Ames, IA (FSIS Directive 6240.1).

(3) Cattle identified as TB reactors shall receive an expanded post-mortem examination using the procedures described in FSIS Guideline No. 4, "Inspection of Tuberculin Reactors." Submit tissues for all granulomatous lesions identified, regardless of anatomical site. If no gross lesions are identified during the expanded post-mortem inspection, submit a representative sample of lymph nodes from the head and thorax for histopathological and bacteriologic examination.

(4) Cattle identified as TB-suspect shall receive a modified expanded inspection procedure by incising the supramammary and mesenteric lymph nodes, in addition to the routine inspection procedure.

(5) Cattle identified as TB-exposed may be further categorized by APHIS as:

a. Category 1: Diagnostic Exposed Animals – animals moved from an infected herd before the infection was exposed but after the herd apparently became infected. These cattle shall receive a modified expanded inspection procedure by incising the supramammary and mesenteric lymph nodes, in addition to the routine inspection procedure.

b. Category 2: Animals that are part of a known affected herd. These are test negative or untested animals which may move to slaughter as regular culls or by entire herd. These cattle shall receive the regular post-mortem inspection procedures.

If APHIS has not identified the TB-exposed category as category 1 or 2 on VS Form 1- 27, handle the TB-exposed cattle as category 2 on post-mortem inspection.

(6) When cattle without any special tuberculosis designation, as well as those identified as TB-exposed and TB suspects, are found on post-mortem inspection to have thoracic granulomas or other lesions suspected of being tuberculous, the PHV shall perform the expanded post-mortem inspection procedure as detailed in FSIS Guideline No. 4, "Inspection of Tuberculin Reactors." Submit tissues to NVSL for histopathology if TB is suspected.

(7) The following are examples of conditions that could be confused with tuberculosis on post-mortem:

a. Other granulomas (such as coccidioidomycosis or mucormycosis)

b. Nontuberculous abscesses

c. Caseous lymphadenitis

d. Actinobacillosis or actinomycosis

e. Adrenal gland tumors (often have a "gritty" calcified texture when incised)

f. In situ or metastatic neoplasia

g. Malignant lymphoma

h. Mesothelioma

TB Granulomas

Tuberculosis granulomas vary in morphology because of the organism's unique virulency factors and the host species physiologic response. Such a granuloma consists of two components, an exudative one and the proliferation of a limiting capsule.

(1) Cattle— *M. bovis* and *M. tuberculosis* primarily affect the respiratory system. In cattle, the exudative (caseous-calcareous) component is typically more prominent than the capsule.

a. Lymph nodes of head and lungs; the lungs and pleura are usually affected

b. Lesions involving the lymph nodes of the digestive tract, liver, and peritoneum, also occur.

i. Active (acute) lesions may have edema and congestion or hyperemia in the periphery surrounding the caseous mass.

ii. Chronic lesions typically have caseo-calcareous exudate with heavier capsule proliferation-fibroplasia (organization).

iii. Old, inactive lesions may become very calcareous and heavily encapsulated.

(2) Swine—Mycobacterial infections in swine primarily affect the digestive system and are due to bacteria of the *Mycobacterium avium* group, though infections with *M. bovis* or *M. tuberculosis* may occur.

a. Lesions are most frequently found in the cervical lymph nodes, mesenteric lymph nodes, liver, and spleen. Pulmonary involvement may also occur. In swine, the proliferative component (thick-walled capsule) is more abundant. In incising these lesions, the cut surface demonstrates the production of the capsule with a small focus of caseous exudate, which may be mineralized.

(3) Sheep & Goats— Disease is rare. Lesions (similar in most respects to cattle) most commonly occur in the lymph nodes of the respiratory tract and lungs.

(4) Calves— Prenatal tuberculosis has been reported

a. Peritoneal lesions.

b. Pleural and thoracic lesions.

c. Other visceral lesions (liver, intestine, spleen).

(5) Horses— TB is rare; most infections, when they occur, are of the alimentary tract, chiefly due to *M. bovis*. Lesions most often occur in the retropharyngeal or mesenteric lymph nodes and have

a lepromatous appearance (resembling a sarcoma), occasionally with some caseous exudate (though calcification is unusual).

(6) Cervids— For comparative medicine purposes, tuberculosis occurs both in captive and wild cervids; the appearance of lesions are often that of a suppurative abscess.

Post-mortem disposition: (9 CFR 311.2)

Special Notes:

Laboratory assistance:

(1) For cattle, TB-exposed and TB-suspect specimens, send VS Form 10-4 with the specimen to the USDA/APHIS National Veterinary Services Laboratory (NVSL), Ames, Iowa.

(2) For cattle, a routine post-mortem on nonreactors, send VS Form 6-35 with the specimen to USDA/APHIS National Veterinary Services Laboratory (NVSL), Ames, Iowa.

Histopathology results from NVSL indicating that the lesions are “compatible” with or “suggestive” of mycobacteriosis shall be considered positive for *M. bovis*.

(3) For swine, the PHV is to complete, submit, and print FSIS Form 8000-19 in PHIS, including the questionnaire, and include the form when submitting samples to the USDA/FSIS Eastern Laboratory, Athens, Georgia. However, if lesions of generalized thoracic granulomas are found, samples should be submitted to USDA/APHIS National Veterinary Services Laboratory (NVSL), Ames, Iowa.

Condemn:

(1) The carcass of any species (including organs and parts) (9 CFR 311.2(a)) is condemned for tuberculosis when any of following conditions occur:

a. TB lesions are generalized (when lesion distribution indicates entry of the organism into the systemic circulation).

b. TB occurs in any muscle, intermuscular tissue, bone, joint, or abdominal organ (excluding the gastrointestinal tract), or in any lymph node as a result of draining a muscle, bone, joint, or abdominal organ (excluding the gastrointestinal tract).

c. TB lesions are extensive in the thoracic or abdominal cavity.

d. Active TB lesions associated with fever on ante-mortem.

e. TB lesions are associated with cachexia

f. TB lesions are multiple, acute, and actively progressive.

g. The character of TB lesions is otherwise not indicative of a localized condition.

(2) An organ or part when an organ or part or its corresponding lymph node of swine, cattle, sheep, goat, or equine is affected with a TB lesion and the carcass is otherwise normal, that organ or part or lymph node shall be condemned (9 CFR 311.2(b)).

Pass:

Carcasses (and parts) passed without processing restriction for human food:

(1) Cattle—only nonreactors, TB suspects, or TB-exposed cattle that do not have tuberculosis lesions can be passed for human food without restriction (9 CFR 311.2(c)).

TB Reactors (even those having no lesions) cannot be passed for human food without the "U.S. Passed for Cooking" processing restriction (9 CFR 311.2(d)(1)).

(2) Swine—A swine carcass may be passed without restriction as long as any TB lesions are localized and limited to one primary seat. (Primary seats are defined as the mandibular, mesenteric, and mediastinal lymph nodes (9 CFR 311.2(e)). Affected tissues must be removed and condemned.

(3) Any livestock (excluding TB reactors) that do not have any tuberculosis lesions can be passed for human food without any processing restriction. TB Reactors (with no lesions) cannot be passed for human food without the "U.S. Passed for Cooking" processing restriction. (9 CFR 311.2(g)).

Pass with processing restriction:

Carcasses and parts with a "U.S. Passed for Cooking" processing restriction (170°F internal temperature, for 30 minutes) must remain under FSIS control until the processing restriction is met (9 CFR 315.1).

(1) **Cattle** (9 CFR 311.2(d))

a. TB reactors, TB suspects, TB-exposed carcasses or non-reactors with lesions that are localized and calcified or encapsulated must be passed with the "U.S. Passed for Cooking" restriction before being allowed to be used as human food. To accomplish this, any gross lesions that are present must be:

i. Less extensive than that requiring condemnation of the carcass, and

ii. The lesions are condemned and removed.

b. Carcasses of TB reactors must be "U.S. Passed for Cooking" before being allowed for human food, even if they are free of gross lesions.

(2) **Swine** (CFR 311.2(f))

a. A swine carcass with lesions of tuberculosis that are localized and calcified or encapsulated confined to two primary seats, or

b. To an extent less than that requiring condemnation must be “U.S. Passed for Cooking” before being allowed for human food.

c. Further inspection procedures used for swine to provide data to arrive at a disposition.

i. Abscess/tuberculosis: When a swine carcass has cervical lymph nodes with a slight abscess and mesenteric lymph nodes with a tuberculosis lesion, such carcass shall be retained and examined by the PHV. If the cervical lesion is definitely an abscess, the carcass may be passed without restriction for food.

ii. Further incisions: PHVs should incise and observe all body lymph nodes of carcasses retained for tuberculosis with the following exceptions:

1. Incisions of body lymph nodes may be omitted when lesions are in the lymph nodes of head and mesentery only.

2. Incision of superficial cervical (prescapular) lymph nodes may be omitted when caudal deep cervical lymph nodes (prepectorals) and thoracic pleura have no lesions.

3. Incision of subiliac (prefemoral) lymph nodes may be omitted when scrotal (superficial inguinal), sublumbar, and iliac lymph nodes show no lesions.

(3) **Sheep, Goats, and Equine** (9 CFR 311.2(h)): Any carcass affected with tuberculosis to a lesser extent than that requiring condemnation shall be “U.S. Passed for Cooking”.

Coccidioidal Granuloma

A disease of mammals caused by the organism *Coccidioides immitis*. It usually manifests itself as thoracic granulomas.

Ante-mortem findings and disposition - not detectable on ante-mortem

Special Notes:

(1) Usually, these granulomas are a sequela to a rapidly healing and common pneumonia (up to 20% of cattle may be affected in endemic areas) due to infection by a soilborne fungus (*Coccidioides immitis*) common in the Southwestern U.S.

(2) Endemically seen in man in the same areas that are endemic for cattle

(3) In endemic infection in cattle, lesions are generally confined to the lungs and their lymph nodes.

(4) Infection not easily spread

(5) The real significance of coccidioidal granulomas is that they may be confused with lesions of tuberculosis.

Post-mortem findings may include the following:

Granulomas in the lymph nodes of the lungs. The lesion will commonly make the lymph node appear pear-shaped.

Granulomas in the lungs

Post-mortem disposition: (9 CFR 311.36)

Condemn:

(1) When there is acute diffuse lung disease and lymph node disease due to *Coccidioides immitis*.

(2) When there are generalized (systemic) changes associated with *Coccidioides immitis* infection.

Pass: Carcasses not meeting the criteria for condemnation, after condemnation and removal of any abnormal tissue.

Remember, it is important to consider tuberculosis when dealing with any potential granuloma!

Bruises and Injuries

Ante-mortem findings may include the following:

Impaired function such as non-ambulatory disabled or a lame animal

Fractures, dislocations

Abrasions, wounds, and hematomas.

Generalized (systemic) change or signs of septicemia, toxemia, /or a variable temperature.

Ante-mortem disposition:

Condemn: Bruised or injured animals showing signs of generalized (systemic) effects

Suspect: Those animals showing signs of injury or fracture with no conclusive signs of generalized (systemic) involvement

Special Note: All non-ambulatory disabled cattle must be condemned and disposed of according to 9 CFR 309.3(e).

Post-mortem findings may include the following:

Septic inflammations

Injection lesions

Agonal hemorrhages, especially of the kidney

Localized recent bruises, injury, or fracture with hemorrhage into the tissues

Bruise showing hemorrhagic regional lymph nodes

Extensive bruises of body tissues over practically the whole carcass

Post-mortem disposition: (9 CFR 311.14)

Condemn:

(1) Carcasses showing extensive, generalized bruising that cannot be removed by trimming.

(2) Bruised or injured carcasses showing associated systemic changes of septicemia or toxemia.

Pass: Localized bruised tissues or fractures may be removed from the carcass by trimming and the remaining tissues may be passed for food.

Special Notes:

(1) From an otherwise acceptable carcass, even a small amount of normal tissue may be saved for human food.

(2) The establishment may choose not to trim a bruised/injured carcass; if so, the carcass will be reported on applicable reports as being tanked by the establishment and not as being condemned by the veterinarian.

(3) A carcass condemned for non-septic bruises or injuries is eligible for animal food (pet food) provided:

a. The Frontline Supervisor has granted permission. (9 CFR 314.11)

b. All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Emaciation

Emaciation is a condition that develops because of a low intake of food or an increase in the metabolic rate that causes the animal to deplete its normal body fat and protein reservoir. As this depletion

becomes more pronounced, a typical abnormal physiological change in the fat and muscle tissues occurs. Some causes are poor teeth, poor diet, starvation, or chronic wasting diseases.

Special Note:

(1) Emaciation is purely a post-mortem descriptive term and does not in any way apply to ante-mortem inspection.

(2) A thin animal may be a normal animal with small amounts of body fat.

(3) Cachexia is an ante-mortem descriptive term that indicates a chronic wasting condition.

Ante-mortem findings:

Poor condition, tight skin or wrinkled skin

Weakness, debilitation

Rough hair coat, may be patchy

Sunken eyes

Gauntness

Depression

Ante-mortem disposition:

Condemn: This should not occur; emaciation is a post-mortem descriptive term indicating the condition of a carcass that shows serous infiltration of its fat and muscle tissues.

Suspect: Animals with a primary clinical disorder associated with cachexia that do not justify condemnation on ante-mortem inspection.

Post-mortem findings may include the following:

Serous infiltration and degenerative change of virtually all visceral and body fat

Serous infiltration and degeneration of muscular tissue is observed. The affected muscle usually has a glassy, moist appearance

Disease or abnormal condition associated with emaciation

A pronounced serous infiltration and degeneration might be observed at the head inspection station

In the split carcass of an older normal cow, the fat between the spinal processes will droop, but retain normal fat appearance

In the old, emaciated cow, fat becomes clear and jelly-like or watery and “actually hangs from an intervertebral space.” Fluid from a hanging emaciated carcass will "drip" from the neck.

Special Note: If any appreciable amount of normal fat is found in the carcass, it would be an important factor in deciding to pass the carcass if everything else is normal. A common finding is heart cap fat showing degeneration and the rest of the carcass showing no signs of serous infiltration and degeneration. This is noted especially in bulls after completion of a heavy service period and is also seen in old ewes.

The following conditions could be confused with emaciation, as they can produce some of the same findings:

(1) Generalized edema, dropsy

(2) Leanness

(3) Anemia

(4) Uremia—Sometimes caused by obstructions such as urinary calculi.

Serous infiltration and degeneration of fat precedes the serous infiltration of the muscle.

Standards for condemnation should not change when changing from a young cattle kill to an old cattle kill. Remember, the old cattle will look poor compared to the young cattle but are not necessarily emaciated.

Post-mortem disposition: (9 CFR 311.26)

Condemn: When virtually all visceral and body fat or muscles show serous infiltration and degenerative change. A gelatinous change of the fat of the heart and kidneys of well-nourished carcasses and mere leanness is not to be classified as emaciation.

Pass: All carcasses retained for emaciation, but determined to be wholesome, will be reported as normal.

Special Note: A carcass condemned for emaciation is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Anasarca

When edema is severe and generalized and causes swelling of all tissues, it is called anasarca. Also, anasarca is the name given to a condition that is seen occasionally in cattle, principally in well-fed steers. It is characterized by an edema occurring subcutaneously primarily in the limbs and in the shoulder region, and brisket.

Generalized edema occurs most often in one of two basic mechanisms, either from increased hydrostatic pressure or due to decreased colloid osmotic pressure of plasma proteins (as might be seen in chronic blood loss anemia, chronic renal disease, and starvation). When protein levels in plasma fall below 5%, the potential for edema is present.

Ante-mortem findings may include the following:

- Swelling in areas of legs, brisket, and shoulders
- Swollen areas that pit on pressure and are of a firm, doughy consistency, and even cool to the touch
- No redness or signs of pain
- Normal temperature
- Reluctant to move, depressed, lethargic
- Diarrhea

Ante-mortem disposition:

Condemn: When the condition has progressed to advanced stages and is characterized by an extensive edema

Suspect: When the condition appears on ante-mortem to be localized

Post-mortem findings may include the following:

- Edema in brisket, shoulder, and shanks
- Hydropericardium
- Ascites
- Hydrothorax

Post-mortem disposition: (9 CFR 311.8)

Condemn: When the condition is in an advanced state and is generalized

Pass: When localized, after removal and condemnation of affected tissues

Special Note: A carcass condemned for anasarca is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Miscellaneous Dropsical Conditions

Dropsy denotes the presence of abnormal amounts of body fluid in the tissues or the body cavities and is often associated with chronic disease of the liver, heart, lungs, and kidneys.

Ante-mortem findings may include the following:

Areas of edema that pit on pressure and have a firm, doughy consistency and are sometimes cool to the touch

No redness nor sign of pain

Normal temperature

Dyspnea

Cyanosis

Marked jugular pulse

Reluctant to move, depressed, lethargic

Diarrhea or constipation

Ante-mortem Disposition:

Condemn: When the condition has progressed to advanced stages and is characterized by an extensive edema

Suspect: When the condition appears on ante-mortem to be localized

Post-mortem findings may include the following:

Hydrothorax

Ascites or abdominal edema

Excess fluid in tissues with no active inflammation

Carcass dripping excess fluid

Chronic lesions of liver, heart, or kidneys

Post-mortem disposition: (9 CFR 311.8)

Condemn: When the condition is in advanced state and is generalized

Pass: When localized, after removal and condemnation of affected tissues

Uremia

Uremia is intoxication caused by the accumulation of waste materials in the blood which is normally excreted through the kidneys.

Ante-mortem findings may include the following:

Variable temperature

Urine infiltration of ventral body wall from urethral rupture

Urinary odor to exhaled breath

Special Notes:

(1) Animals showing early signs of a urinary tract blockage, e.g., anxious expression, ear twitching, restlessness, tenesmus, and possibly frequent attempts to urinate.

(2) If an animal has had a urethrotomy with no detectable symptoms of uremia, the animal should be examined to see if the surgical correction was successful and the animal has recovered.

Ante-mortem disposition:

Condemn: When the condition has progressed to the point of generalized involvement (anasarca) or is associated with cachexia

Suspect: When the condition does not require condemnation of the animal

Post-mortem findings may include the following:

Hydrothorax

Ascites or edema in the abdominal cavity

Fluid in all body tissues with lack of inflammatory process

Nephritis or pyelonephritis

Peritonitis

Cystitis

Calculi

Hydronephrosis

Carcass edema and reddening

Uriniferous odor to muscles

Ruptured urinary bladder with peritonitis

Post-mortem disposition: (9 CFR 311.37(b) and (c))

Condemn:

(1) Carcasses that exhibit a urine odor, regardless of the cause

(2) When it is possible to identify the primary cause based on post-mortem findings, the primary cause should be reported as the cause for condemnation.

Pass: When the disease or disorder is localized and there are no indications of a generalized process resulting in carcass adulteration

Special Notes:

(1) If there is evidence of a localized urine odor in tissues, this area should be trimmed and condemned.

(2) It is possible that a ruptured bladder can result from faulty dressing procedures. Such contaminated areas should be thoroughly trimmed and condemned.

Sexual Odor of Swine

This is a condition most commonly found in boars, stags, and cryptorchids in which there is a distinct odor to the tissues.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Any sex odor of carcass or viscera of any swine

Post-mortem disposition: (9 CFR 311.20)

Condemn: Any carcass that exhibits a pronounced odor

Passed with Processing Restriction: Any carcass that exhibits a sexual odor that is less than pronounced may be passed for use as human food after the product meets a specific processing restriction. Carcasses with a sexual odor that is less than pronounced may be passed for use as human food as either cooked comminuted product or for rendering as lard.

Special Notes:

(1) A rule of thumb: a warm carcass should be considered to have a pronounced odor if the odor emanates toward you when you are several inches from the carcass.

(2) If the odor is less than pronounced, you will normally have to get very close to the carcass and search out the odor.

Immaturity

This represents an animal that is too young to have normal muscle development and coordination.

Ante-mortem findings may include the following:

Muscular incoordination

Inability to stand and walk normally

Lack of muscular development

Ante-mortem disposition:

Condemn: Animals showing an inability to stand and walk normally that is a result of lack of muscular development

Suspect: Those animals that show inconclusive signs of immaturity, such as some muscular incoordination or some difficulty in standing or walking

Special Note: Remember to watch for breed differences as beef calves are usually much stronger than dairy calves.

Post-mortem findings may include the following:

Muscle tissues have a water-soaked appearance, with loose, flabby tissue that tears easily and can be perforated with the fingers.

Grayish-red muscle color

Lacking good muscular development, especially noticeable on upper shanks

Post-mortem disposition: (9 CFR 311.28)

Condemn:

(1) If the meat appears water-soaked, is loose, flabby, tears easily, and can be perforated with the fingers

(2) If muscle color is grayish-red

(3) If muscular development is lacking

Pass: Animals with muscular development and otherwise normal tissues

Special Note: A carcass condemned for immaturity is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Eosinophilic Myositis (EM)

Eosinophilic myositis (9 CFR 311.35) is characterized by large numbers of eosinophilic granulocytes associated with myonecrosis. The cause of the condition has not been determined although two theories are *Sarcocystis* spp. and allergic reaction.

Special Notes:

(1) Found primarily in cattle, occasionally in sheep, rarely in swine

(2) EM occurs primarily in highly fattened steers and heifers, one to two years of age, and less often in older cattle. The cause is currently unknown.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

(1) The most common lesions are the irregularly distributed yellowish-green, yellowish- white, and red spindle-shaped foci found in the heart and tongue.

(2) Striking, but less frequently found lesions, are the large, well-defined, bright green to greenish-gray areas found in the more active muscles (e.g., round, shoulder, esophagus, heart, and brisket); they may not be discovered until the carcass is broken into primal parts.

a. **Special Notes:** Some other conditions are noteworthy as possibly being confused with eosinophilic myositis, especially by less experienced inspectors:

i. Cysticercosis—lesions are usually much larger than EM lesions

ii. Steatosis—where normal fat has replaced muscle tissue

iii. Muscle degeneration

iv. True marbling of meat—intramuscular fat appearing as streaks of fat in the cut surface of muscles

(3) Lesions may be localized in one site or any combination of head, tongue, esophagus, heart, diaphragm, and "hanging tender."

(4) The lesions may be found in carcass musculature alone or in combination with the head, esophagus, heart, diaphragm, or “hanging tender.”

(5) The lesions may be slight in the carcass, in which case they might be removed by trimming, or

(6) The distribution of the lesions might make it impractical to remove them.

<u>When lesions of eosinophilic myositis are observed during routine post-mortem inspection, the following procedures should be used</u>:

(1) Thoroughly incise and observe the lateral and medial masticatory muscles and heart

(2) Observe and palpate the esophagus.

(3) Make several deep longitudinal incisions into the tongue.

(4) Thoroughly incise and observe diaphragm and pillars after removal of peritoneum.

(5) Observe cut surfaces of muscles exposed during the dressing operations (ventral muscles of neck, brisket, medial muscles of round).

(6) When lesions are in any of the locations described above, make several parallel incisions to all such cut surfaces. Also, after removing the peritoneum, thoroughly incise and observe the abdominal muscles in the flank and paralumbar region.

(7) If lesions are in any cut surface exposed during the preceding procedures, the affected primal part should be freely slashed and closely examined.

Special Notes:

(1) Eosinophilic myositis is most readily detected in warm carcasses. Chilling causes muscle contraction and reduction in the size and visibility of lesions present. In most cases, active muscles are affected first and more severely than other muscles.

(2) Incisions made transverse to muscle fibers usually give the best exposure of lesions.

(3) When performing the expanded inspection procedures, you should strive to avoid excessive carcass mutilation.

Post-mortem disposition: (9 CFR 311.35)

Condemn the carcass: If muscular lesions (in the carcass) are found to be distributed in such a manner or to be of such character that removal is impractical.

Condemn affected parts: When localized lesions are present and only certain parts are affected (head, tongue, heart, esophagus, diaphragm, and pillars).

Pass for comminuted cooked product: If the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness, or if complete removal is uncertainly accomplished, the carcass or parts may be passed for use in the manufacture of comminuted cooked product after removal and condemnation of the visibly affected portions.

Pass: If the lesions are localized in such a manner and are of such character that the affected tissues can be removed, the nonaffected parts of the carcass may be passed for human food after the removal and condemnation of the affected portion.

Some examples of dispositions based on these regulations are summarized below:

Parts Affected	Disposition
Head or tongue only	Pass carcass – condemn affected head or tongue
Heart only	Pass carcass – condemn heart
Esophagus only	Pass carcass – condemn esophagus
Hanging tender only	Pass carcass – condemn hanging tender
Diaphragm	Pass carcass – condemn diaphragm
Any combination of above	Pass carcass – condemn affected part(s)
Carcass – lesions extensive and removal is impractical	Condemn carcass
Lesions slight or of such character as to be insignificant from a standpoint of wholesomeness	Trim lesions recognized, allow for comminuted cooked product
Lesion removal is practical	Trim and condemn affected product, pass remainder

Special Note: A carcass condemned for eosinophilic myositis is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Skin Conditions

Skin conditions are varied, and many are very nonspecific, including conditions such as dermatitis, erythema, urticaria, and photosensitization.

Ante-mortem findings may include the following:

Erythema

Photosensitization

Burns

Parasites—lice and mites

Pruritis

Alopecia

Ringworm

Ante-mortem disposition:

Condemn:

(1) Severe skin involvement with associated cachexia, such as in extreme parasitism.

(2) Severe skin involvement with associated generalized disease involvement.

Suspect: Those animals with inconclusive signs of generalized disease resulting from the primary skin lesion.

Post-mortem findings may include the following:

Dermatitis

Generalized lymphadenitis

Tissue or organ degeneration

Petechiae or ecchymotic hemorrhages in tissues/organs

Special Notes: There are conditions that might be confused with disease:

(1) Hogs overscalded due to being in the scald vat for too long or at too high a temperature

(2) Erythema and bruising caused by improper ante-mortem handling

Post-mortem dispositions: (9 CFR 311.21 and 311.22)

Condemn: Those animals with extensive skin lesions and associated generalized disease

Suspect: Those animals with extensive skin lesions and inconclusive signs of generalized disease

Asphyxia (Suffocation)

This condition is most often seen in swine when they enter the scalding vat alive and are suffocated by drowning. Usually this is due to a defective stick wound.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Generalized hyperemic appearance to carcass and viscera

Possible absence of stick wound

Water-logged lungs

Post-mortem disposition: (9 CFR 311.30)

Condemn: When there is a generalized hyperemia of carcass and viscera

Special Note: Carcasses like this would be condemned and ineligible for use as animal food because excess blood in the carcass will mask signs of septicemia, toxemia, and other conditions.

Pass: When involvement is to a lesser extent than that requiring condemnation.

Cysticercosis of Sheep

Cysticercus ovis is not transmissible to man; the definitive hosts are wild carnivores.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Cysts, usually calcified, found in heart, esophagus, tongue, diaphragm, and muscles of the diaphragm

Meat is watery or discolored

Cysticercus ovis may be confused with:

(1) Nodular worms--Oesophagostomum species, seen primarily along intestinal tract

(2) Bladder Worm--Cysticercus tenuicollis, seen in peritoneal cavity often in the pelvic viscera and liver

Post-mortem disposition: (9 CFR 311.25(b))

Detailed Examination Procedure: When cysticercosis is detected during routine post-mortem inspection procedures, the affected carcass and parts should undergo the following further examination by the PHV:

(1) Re-examine the heart and esophagus by sight and palpation.

(2) Palpate the muscles of the diaphragm.

(3) Carefully examine the cut surface of muscles exposed during regular dressing procedures (ventral muscles of the neck and brisket and medial muscles of the leg). If only the initial lesions

are found in (1) through (3), make your disposition based on these findings. However, if any additional lesions are found, continue to:

(4) Make incisions parallel to the cuts described in (3). Also remove the peritoneum from the abdominal muscles in the flank and paralumbar regions. Examine visually and then make several incisions to aid in the examination. If no additional lesions are found in (4), make your disposition based on the findings through (4). However, if any additional lesions are found, continue to (5).

(5) Make deep bold incisions into the heavily muscled primal parts to determine if various parts of the musculature expose one or more cysts on most of the cut surfaces.

Condemn: If the infection is to such an extent that complete removal is impractical because of the extent of the infection.

Pass with Processing Restriction: Pass for heating to an internal temperature of 140°F after trimming and condemnation of affected tissue where there are more than five cysts in the tissues, excluding the heart, and the parasites are distributed in such a manner that their removal is practical.

Pass: When five or fewer cysts are found in the tissues, excluding the heart, the carcass may be passed for human food after trimming and condemnation of affected tissues.

Sarcocystosis (Sarcosporidiosis)

This parasitic condition is most frequently seen in older sheep originating from certain geographical areas, especially the Western United States. Sarcocystosis is caused by specific protozoans not considered pathogenic for humans in the United States.

The esophagus is usually the first site at which the lesions are detected; this alerts the inspection team that many sheep in the lot will probably be affected.

Ante-mortem findings— not specific for disease, so cannot correlate disposition to disease

Ante-mortem disposition—disease signs not specific for disease; can't correlate disposition to disease

Post-mortem findings may include the following:

Lesions detected in the esophagus as white, semi-oval, cigar-shaped, or rice grain shaped lesions

Lesions detected in the diaphragm, skin muscles, internal abdominal muscles, or intercostal muscles

Lesions found in skeletal muscles, detected after incision and observation of primal parts

Special Notes:

(1) Lesions can best be observed by making incisions parallel to muscle fibers rather than by making transverse cuts.

(2) Avoid excessive carcass mutilation with the incisions and cuts made for examination purposes.

Post-mortem disposition: (9 CFR 311.25(a))

Detailed Examination Procedure: When sarcocystosis is detected during routine post-mortem inspection procedures, the affected carcass and parts should undergo the following further examination by the PHV:

(1) Re-examine the esophagus, superficial and cut surfaces of muscles, diaphragm, and internal abdominal and intercostal muscles. If lesions are found in locations other than the esophagus, proceed to (2).

(2) Incise the muscles of shoulder, round, and back to expose the deep muscle tissues.

Condemn: When the infestation is excessive—if the lesions are found to be distributed in such a way that their removal is impracticable, no part of the carcass shall be saved for human food

Pass with Processing Restriction: When an infestation is moderate, the carcass may be passed for cooking (held at 170°F for 30 minutes) after removal and condemnation of affected tissues

Pass: When the lesions can be completely removed and condemned, the unaffected portions of the carcass can be passed for human food.

Special Note: A carcass condemned for sarcocystosis is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Stephanuriasis (Swine Kidney Worm)

A parasitic condition due to the presence of *Stephanurus dentatus* in the carcass tissues.

Ante-mortem findings—not specific for disease, so can't correlate disposition to disease

Ante-mortem disposition—signs not specific for disease, so cannot correlate disposition to disease

Post-mortem findings may include the following:

Adult kidney worms

Lesions:

(1) Pelvic inlet, pelvic and femoral canal

(2) Abdominal lining

(3) Muscle-primarily loin and ham muscles

(4) Organs-primarily kidney, liver, pancreas, spleen, and lungs

(5) Brownish-lemon color of skin and fat

Special Notes:

(1) The larvae migrate to perirenal tissues, form cysts and abscesses, and develop to adulthood. The perirenal area often appears reddish-brown, and the cysts contain a creamy to reddish-brown colored substance. It is even possible to palpate cord-like masses in the perirenal fat, which are tracts made during migration.

(2) In the liver, there are sometimes multiple extensive orange-tan hemorrhagic areas, with the liver parenchyma later taking on a mahogany color. Usually, abscessation occurs where the larvae have been trapped. Also, severe scarring results where abscessation has occurred.

Post-mortem disposition: (9 CFR 311.25(a))

Detailed Examination Procedure: When a carcass is retained for stephanuriasis on regular inspection, the PHV may find it necessary and helpful to perform the following examination:

(1) Re-examine the carcass and organs by incision into the liver, lungs, spleen, pancreas, kidney, and perirenal region.

(2) Upon finding numerous lesions during (1), make a lengthwise incision into each ham and loin. If no lesions are found, no further incisions are necessary. In particular, check the femoral and pelvic canal.

(3) If abscesses are found in the loin, make additional incisions into the loin and ham. Check all body cavities.

Condemn: When the disease is associated with generalized disease, such as uremia or septicemia

Pass: After removal and condemnation of all affected tissues

Special Note: The parasites themselves are usually of little significance unless secondary pathology has developed.

Anaplasmosis

Anaplasmosis is an infectious disease of cattle caused by the rickettsia, *Anaplasma marginale*. It is not commonly diagnosed on ante-mortem, although an anemia, debilitation, jaundice, or fever, plus the knowledge that an animal originated in an enzootic area, or the presence of ticks are signs associated with this condition.

If anaplasmosis is suspected, Veterinary Services shall be contacted as bovine anaplasmosis is a reportable disease, per FSIS Directive 6000.1. District Office personnel will contact the APHIS Area Veterinarian-in-Charge of the State Animal Health Official and provide the appropriate information.

Ante-mortem findings may include the following:

Anemia, pale mucous membranes

Icterus

Variable temperature

Debilitation

Listlessness

Polypnea

Ante-mortem disposition:

Condemn: All animals showing signs of this disease on ante-mortem.

Suspect: All animals that have reacted to a test for the disease, but which show no signs

Post-mortem findings may include the following:

Pale musculature

Marked splenomegaly, blackberry-jam consistency

Distended gall bladder with dark, thick, tarry bile

Thin, watery blood that clots very poorly

Lemon-yellow color exhibited by the connective tissue—check connective tissue sites such as aponeurosis of diaphragm, tendons, pleura, peritoneum, and sclera of the eye

Special Note: The spleen in malignant lymphoma, malignant myeloma, anthrax, and anemia may be similar in appearance to that in anaplasmosis. Detailed examination of the spleen and relation of these findings to other lesions in the carcass is required to arrive at a diagnosis.

Post-mortem disposition: (9 CFR 311.10(b))

Condemn: Carcasses showing lesions of anaplasmosis

Pass: Where recovery from anaplasmosis has occurred to the extent that the yellow carcass color disappears after chilling and other carcass lesions are not present

Melanosis

Melanin is a normal black pigment of the body. Melanosis is excessive melanin deposits or deposits in abnormal locations. Such deposits must be removed from product for human food purposes.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Melanin pigment in lungs, liver or other organs

Melanin in skin

Melanin in eye

Melanin associated with inflammation

Post-mortem disposition: (9 CFR 311.13)

Condemn:

(1) Carcasses with generalized pigmentary deposits shall be condemned

(2) When melanin cannot be removed or its removal is impractical, or when it renders a carcass, organ, or part unfit for human food, the affected carcass, organ, or part shall be condemned

Pass:

(1) When localized, pigmentary deposits can be effectively removed and condemned.

(2) Uniform melanin deposits over or in circumscribed skin areas of swine are not required to be removed unless they are tumorous or smeary.

(3) Slight melanin deposits in spinal meninges are insignificant. However, when extending into spinal nerves and into meat, they must be removed.

Icterus

If for any reason the amount of bilirubin increases in the blood and therefore in the tissues, a yellowish pigmentation of the tissues arises that is called icterus or jaundice. There are three basic types of icterus: obstructive, hemolytic, and toxic. Obstructive icterus is caused by obstruction of the bile duct by parasites, calculi, abscesses, tumors, etc. Hemolytic icterus is caused by increased destruction of erythrocytes such as may occur in anaplasmosis or eperythrozoonosis. Toxic icterus can be caused by a degeneration of liver cells that occurs during intoxication, such as copper toxicity.

Ante-mortem findings may include the following:

Yellowish discoloration of sclera

Extensive greenish-yellow discoloration of skin (white hogs only)

Ante-mortem disposition:

Special Note: Findings of icterus are inconclusive, making condemnation for icterus on ante-mortem difficult to justify; however, if it is possible to identify a disease or condition causing the icterus, disposition should be made for that cause.

Condemn: When it can be definitively established that the animal is icteric

Suspect: All animals with inconclusive evidence of icterus should be handled as suspects.

Post-mortem findings may include the following:

Yellow discoloration of connective tissues, sclera, visceral organs

Degenerative changes in liver

Ascarids, neoplasia, or calculi obstructing bile outflow

Special Notes:

(1) Look for icterus where the tissues are normally very white or pale, such as the sclera of the eye, tendons, pleura, peritoneum, omentum, joint surfaces, and mesentery.

(2) Fat may be yellow due to diet, breed, and age changes that are essentially normal. Yellow fat is normal in some animals.

Post-mortem disposition: (9 CFR 311.19)

Condemn: Carcasses showing any degree of icterus shall be condemned.

Special Note: Carcasses showing any degree of icterus associated with a degeneration of organs, the result of infection or intoxication, and those showing pronounced yellow or greenish-yellow discoloration without evidence of infection or intoxication shall be condemned.

Final disposition of carcasses showing slight yellow discoloration with no visible pathological changes in organs shall be deferred until they have been chilled out and reexamined, preferably under natural light or a good quality light of at least 50 footcandles. If discoloration disappears, such carcasses shall be passed for food, provided there are no other conditions warranting a different disposition.

Carotenosis

Carotenoid pigments enter the body with food. Therefore, they are classified as exogenous pigments. When carotenoid pigments are deposited in the fat tissues and liver to the extent that they become grossly visible, the resulting discoloration of tissues is carotenosis.

Ante-mortem findings—not applicable

Ante-mortem disposition—not applicable

Post-mortem findings may include the following:

Yellow fat

Yellow to yellow-orange liver

Special Notes: Certain conditions such as the following are not to be confused with carotenosis:

(1) Yellow fat common to certain breeds

(2) Pale yellow liver tissue common in pregnant cows (fatty infiltration)

(3) Steatitis-yellow fat disease (swine)

Post-mortem disposition: (9 CFR 311.31(a))

Condemn: Livers with carotenosis are to be condemned

Special Notes:

(1) Deposition of carotenoid pigments in the fatty tissue does not affect carcass disposition.

(2) Place a white paper towel or napkin on the cut surface of the liver. A bronze-orange stain indicates carotenoid pigment.

Xanthosis

Xanthosis is the deposition of excessive quantities of cellular waste pigments. The condition is usually seen in older cattle and those suffering from chronic wasting disease. It is recognized only on post-mortem. More commonly affects heart and head musculature.

Ante-mortem findings—not relevant

Ante-mortem disposition—not relevant

Post-mortem findings may include the following:

Cardiac muscle

Head muscle

Carcass muscle less frequently

Special Note: Affected muscle has dark brown or coffee-colored discoloration of otherwise normal tissue.

Post-mortem disposition: (9 CFR 311.13)

Condemn: Carcasses with generalized pigmentary deposits shall be condemned.

Pass: Carcasses with less than generalized distribution of pigmentary deposits, after condemnation and removal of the affected areas.

Special Note: By far, most cases of xanthosis are deemed to be localized and affected tissues are trimmed and condemned, and the remainder is passed for human food.

NEOPLASMS

Papilloma

Papillomas are benign tumors often occurring at multiple sites on the skin of the animal or the mucosa of the mouth, esophagus, and rumen.

Ante-mortem findings may include the following:

Cutaneous growths (warts)

Ante-mortem disposition:

These affect the skin and should not impact post-mortem decisions.

Condemn: When livestock plainly show any disease or condition that would cause condemnation of their carcasses on post-mortem

Suspect: When livestock, do not clearly show, but are suspected of being affected with a disease or condition that may cause condemnation of their carcasses on post-mortem

Post-mortem findings may include the following:

Esophageal lesions

Rumen lesions

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected with a neoplasm

(2) The entire carcass, if there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm

Embryonal Nephroma

Embryonal nephroma is a neoplasm most often seen in swine. It is generally benign; however, metastasis to the renal lymph nodes, lungs, or liver is possible. The general condition of the carcass is usually not affected by the tumor but a large nephroma may cause stenosis of the digestive tract, partial occlusion of the aorta, or renal dysfunction resulting in uremia.

Ante-mortem findings— not a consideration

Ante-mortem disposition—not relevant on ante-mortem

Post-mortem findings may include the following:

Found in or near kidney

Single or multiple tumors

Unilateral or bilateral

Firm, but may contain areas of necrosis

Size varies from small nodules buried in the renal cortex to a large mass completely replacing the kidney.

Grayish white on cross-section, but may contain multiple yellow foci

Separated into lobules by numerous connective tissue septa

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected by a neoplasm.

(2) The entire carcass, if there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm.

Pass: When criteria for condemnation are not met – affected tissues must be removed and condemned

Neurofibroma (Nerve Sheath Tumor)

This is a neoplasia of nerve sheath cells most often seen in cattle. It may be found along any nerve trunk of the carcass but are most often found in the intercostal and paravertebral spaces, heart, brachial plexus, and coeliac plexus. It may be seen as multiple nodular enlargements along any nerve. It is generally regarded as benign but may metastasize to regional lymph nodes. Neurofibromas are often seen in multiple sites because of their multicentric origin. The tumors may be firm or soft and often have gelatinous centers and appear as a shiny, glistening, white-to-gray, lobulated, firm nodular growth on or within the nerve. When identified on post-mortem inspection, be sure to examine brachial and coeliac plexus for lesions.

Ante-mortem findings—not normally recognized on ante-mortem

Ante-mortem disposition—not relevant

Post-mortem findings:

Along spine

Along ribs

Brachial plexus

Celiac plexus

Heart

Tongue

Special Note: Examine the brachial and celiac plexus for lesions when IPP find neurofibromas when performing post-mortem inspection.

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected with a neoplasm shall be condemned.

(2) The entire carcass, if there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm.

Mesothelioma

Mesothelioma is a neoplasia of the mesothelial cells lining the peritoneal and pleural cavities. Primarily found in cattle, it may be found on both the parietal and visceral serosal membranes, particularly the peritoneum. You will typically see multiple, grayish, firm, papillary growths which have homogenous consistency on cross section of the lesion.

Ante-mortem findings—not recognized on ante-mortem

Ante-mortem disposition—not relevant

Post-mortem findings may include the following:

Peritoneum, parietal serosa—nodular lesions

Peritoneum, visceral serosa—nodular lesions

Pleura, parietal serosa—nodular lesions

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected with a neoplasm

(2) The entire carcass if there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm

Adrenal Gland Tumors

Adrenal gland neoplasia may arise in both the cortex and medulla (pheochromocytoma). It may occur in many species but are usually seen in older animals, particularly cattle.
Tumors often have yellowish to orange to grayish consistency. Incision into the neoplasm may reveal mineralization. This neoplasia may be benign or malignant. Metastasis may occur in organs such as the lung, but frequently these tumors may grow or spread along blood vessels such as the vena cava.

Ante-mortem findings—not recognized on ante-mortem

Ante-mortem disposition—not a consideration

Post-mortem findings may include the following:

Neoplastic adrenal gland

Cortical tumor

Tumor of adrenal medulla

Metastasis to lung

Growth into and along vena cava

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected with a neoplasm shall be condemned.

(2) The entire carcass if there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm.

Ocular Squamous Cell Carcinoma (Epithelioma of the Eye)

This is a neoplasm of the epithelial cells surrounding the eye. These tumors should be regarded as malignant. They can metastasize and be extremely destructive locally or they can metastasize via the lymphatics to lymph nodes and or organs. It is found in all breeds of cattle, but Herefords are most commonly affected. It may be found in mature sheep at a frequency similar to cattle and has also been recognized in swine and equine, although rare.

Ante-mortem findings may include the following:

Ocular neoplastic lesion

Ocular neoplasia and infection

Ocular neoplasia and suppuration

Ocular neoplasia and necrosis

Ocular neoplasia and cachexia

Absence of an eye

Ante-mortem disposition:

Condemn: When the eye has been destroyed or obscured by neoplastic tissue and there is extensive infection, suppuration, and necrosis, or the epithelioma is accompanied by cachexia (9 CFR 309.6).

Suspect: (9 CFR 309.2(e))

(1) When epithelioma case does not require condemnation

(2) When the eye is missing from any bovine presented for ante-mortem inspection

Post-mortem findings may include the following:

Neoplastic lesion involving eye and/or orbital region

Metastasis to lymph node

Infection, suppuration, or necrosis of bony orbit

Metastasis to lungs

Emaciation

Post-mortem disposition: (9 CFR 311.12)

Condemn: the carcass of animals affected with epithelioma of the eye or the orbital region if one of the following three exists:

(1) The affection has involved the osseous structures of the head with extensive infection, suppuration, and necrosis; or

(2) There is metastasis from the eye, or the orbital region, to any lymph node, including the parotid lymph node, internal organs, muscles, skeleton, or other structures, regardless of the extent of the primary tumor; or

(3) The affection, regardless of extent, is associated with cachexia or primary evidence of adsorption or secondary changes.

Pass: When the carcass does not require condemnation, it may be passed for human food, after removal and condemnation of the head, including the tongue. Also condemn the head of mature cattle (e.g., cow) carcasses when there is an absence of the eye (or associated structure) that may indicate prior surgical removal of epithelioma.

Special Note: A carcass condemned for epithelioma is eligible for animal food (pet food) provided:

(1) The Frontline Supervisor has granted permission. (9 CFR 314.11)

(2) The neoplastic tissue has been removed and condemned to tankage.

(3) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (9 CFR 314.11)

Malignant Lymphoma

Lymphoma is a neoplastic condition of the lymphocytes and is by its very nature considered to be malignant. There are many manifestations of the disease, which allows it to be confused with other disease processes such as granulomas, abscesses, or other types of neoplasia.

Its occurrence in the carcass and or viscera, regardless of the extent and distribution of the disease process, requires that the carcass and viscera be condemned in its entirety (9 CFR 311.11(b)).

Ante-mortem findings may include the following:

Enlargement of superficial lymph nodes

Bloat due to abomasal neoplasms

Debilitated cachectic condition

Ocular protrusion due to retrobulbar neoplastic tissue

Ante-mortem disposition:

Condemn: Cannot be adequately diagnosed on ante-mortem; however, can be suspected.

Suspect: Ante-mortem signs may very well suggest malignant lymphoma and so animal would be suspected.

Post-mortem findings may include the following:

Gross enlargement of one or more lymph nodes

Focal or diffuse neoplastic growth in the heart

Focal or diffuse neoplastic growth in the cattle abomasum

Focal or diffuse neoplastic retrobulbar growth in the cattle

Focal or diffuse neoplastic growth in the uterus of cows

Post-mortem disposition: (9 CFR 311.11(b))

Condemn: The carcass of any species with malignant lymphoma regardless of the degree of involvement

Melanoma

Melanoma is a neoplasia of the naturally occurring melanocytes in the skin. They are usually found in swine and grey horses. Benign lesions (melanocytomas) and malignant lesions (malignant melanoma) occur, and these must be differentiated from melanosis.

Ante-mortem findings:

> Black tumors may be seen in the skin of any species. In swine these most often might be seen at the base of the ears, midback, tailhead and flanks, while in equines these are most often seen in the perineal region.

Ante-mortem disposition:

Condemn: Condemnation is not recommended on ante-mortem examination since it cannot be determined to have metastasized or not.

Suspect: Those animals that have melanoma that are likely to be condemned on post-mortem.

Post-mortem findings may include the following:

> Deep black, gray, or brown nodular protruding masses of variable size
>
> Metastasis to regional lymph nodes
>
> Metastasis to the lungs
>
> Metastasis to the liver, spleen, and other internal organs

Post-mortem disposition: (9 CFR 311.11(a))

Condemn:

(1) An individual organ or part of a carcass affected with a neoplasm shall be condemned.

(2) If there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm, the entire carcass shall be condemned.

Special Note: Carcasses condemned for malignant melanoma should be recorded on PHIS under “Carcinoma” in Animal Disposition.

POULTRY DISEASES AND CONDITIONS NOT OF PUBLIC HEALTH SIGNIFICANCE

Tuberculosis

Avian tuberculosis (TB) is caused by the bacterium Mycobacterium avium and usually is a chronic, slowly developing disease. For this reason, it is not identified in young healthy uniform flocks of poultry, as are typically presented for slaughter in large establishments. In addition, this disease has largely been eradicated in domestic poultry in the U.S. but is still found occasionally in mature birds.

Birds with TB develop a wasting condition characterized by loss of weight and diarrhea. At post-mortem examination their carcasses are typically emaciated. Gray to yellow, firm nodules (tubercles) are often scattered along the intestines and may be found in various organs, especially the liver and spleen. Lungs generally have no gross lesions although, in advanced cases, any organ or tissue can be involved.

Avian tuberculosis can infect humans but is not considered to be a serious threat to people with healthy immune systems.

One definitive lesion is all that is required to condemn a poultry carcass for tuberculosis (9 CFR 381.81).

Synovitis

Synovitis is caused by several organisms, most often members of the genus *Mycoplasma*. Injury and nutritional deficiencies also lead to synovitis. The result is acute or chronic inflammation of the membranes lining one or more joints and tendon sheaths.

Joints are often noticeably swollen and might contain varying amounts of exudate. The liver, kidneys, and spleen may be swollen, and the liver is sometimes stained green from bile stasis. Lesions vary depending upon whether or not the condition is confined to the joints or has overwhelmed the bird's defense mechanisms and caused systemic changes.

A carcass with synovitis is not condemned unless it also shows systemic or Sep/Tox changes (9 CFR 381.86).

Neoplasms

This category refers to neoplasia, including tumors caused by the leukosis complex. Some of the more common tumors include keratoacanthomas, adenocarcinomas, leiomyomas, and fibromas.

- Leukosis complex tumors are caused by various viruses, all appear similar grossly, and commonly occur in the liver, spleen, and cloacal bursa.

- Keratoacanthomas are skin tumors found in young chickens (previously known as dermal squamous cell carcinomas). These tumors arise from the feather follicle epithelium. At slaughter, the lesions may present as craterlike ulcers up to ~2cm in width.

- Adenocarcinomas are generally located in abdominal organs and are common in older birds.
- Leiomyomas are most often identified in the oviduct of fowl.
- Fibromas may develop in any connective tissue and are more common in older birds.

Numerous other types of tumors occur in domestic poultry but at a low frequency.

There is no evidence that any of these types of tumors are a health threat to humans.

Tumors, including those possibly caused by avian leukosis complex, may be trimmed from any affected organ or other part of a carcass where there is no evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor. Trimmed carcasses otherwise found to be not adulterated shall be passed as human food (9 CFR 381.87(a)).

Any organ or other part of a carcass which is affected by a tumor where there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, must be condemned (9 CFR 381.87(b)).

Instructions specific to keratoacanthomas are to condemn carcasses with large coalescing (joining together) lesions (9 CFR 381.87). Carcasses with a few small lesions can be trimmed.

Bruises

If bruises cause systemic change in a carcass, the carcass is condemned and recorded under this category. If there is *no* part of the carcass that can be salvaged, the carcass is condemned and recorded under this category. Otherwise, if *any* part *can* be salvaged from the carcass, the bruises are trimmed, and the remainder of the carcass is passed (9 CFR 381.89).

Cadavers

Cadavers are poultry that die from causes other than slaughter or are not physiologically dead because of ineffective slaughter before they enter the scald vat and drown. Carcasses of poultry that die from drowning may exhibit signs of incomplete exsanguination (bleed-out), resulting in an unwholesome carcass. The skin of the carcass or neck is cherry red to purple.

Birds that die from slaughter, however, are dead when they enter the scald vat, and their bodies are not able to react physiologically to the heat of the scald water. Therefore, their skin does not become red.

Carcasses of poultry showing evidence of having died from causes other than slaughter shall be condemned (9 CFR 381.90).

Overscald

Carcasses that are cooked in the poultry scalder are condemned. The muscle must be cooked through the level of the deep pectoral muscle to be classified as an overscald. Simply having a superficial cooked appearance does not make a carcass overscalded.

Many times, overscalded carcasses will also be mutilated by picking machines. However, the picking machines may also mutilate carcasses that are not cooked to the level of the deep pectoral muscle. These carcasses should not be condemned for overscald, but should either be salvaged or condemned for contamination, depending upon the extent of the damage. If a carcass is to be condemned for overscald, the deep pectoral muscle must have a cooked appearance (9 CFR 381.92)

Airsacculitis

Numerous microorganisms cause airsacculitis (inflammation of air sacs). Often more than one infectious agent is identified in an outbreak. Members of the genus *Mycoplasma* are frequently involved. Birds are more susceptible to infections of the air sacs when they are under stress. Vaccination, other disease, poor nutrition, insanitary conditions, and poor ventilation are contributing factors.

The lesions of airsacculitis can be acute or chronic. Their appearance ranges from slight clouding of air sac membranes and small amounts of watery exudate (which is generally an acute lesion) to thickened, opaque membranes and large amounts of thick, white-to- cream or yellow colored and/or cheesy exudates (which is generally a chronic lesion). Exudates can be confined to the air sacs and their diverticuli, or they may be found in other areas if the air sac membranes are ruptured.

Pneumonia, pericarditis, and perihepatitis might be present. In some cases, all portions of the respiratory tract (nasal passages, sinuses, trachea, bronchi, lungs, air sacs and their diverticuli) are affected. In other cases, little involvement beyond the air sacs is evident. Systemic change can occur.

Carcasses are condemned if airsacculitis is extensive or prevents evaluation of the wholesomeness of the carcass. If the exudate cannot be effectively removed, the carcass is condemned. Carcasses are also condemned if airsacculitis occurs in conjunction with systemic change (9 CFR 381.84).

Microorganisms which may be involved in causing airsacculitis include the following:

Aspergillus fumigatus - This is a mycotic disease of chickens and turkeys which cause respiratory disease, including airsacculitis. Synonyms for this disease include Brooder Pneumonia, Mycotic Pneumonia, and Pneumomycosis. Ante-mortem clinical signs are similar to other respiratory conditions in poultry and include anorexia, weakness, depression, nasal discharge, coughing, and sneezing. Post-mortem lesions include fuzzy gray/black material (sporulating fungi) present on air sacs, yellow/gray nodules or plaques in the lungs, air sacs, or trachea of affected birds. Secondary airsacculitis is common and the disposition is made using the same criteria as for airsacculitis (9 CFR 381.84).

Pasteurella multocida - This organism causes an acute to chronic infectious disease in chickens and, more commonly, turkeys. Synonyms for this disease include Fowl Cholera, Cholera, and Pasteurellosis. The disease is usually seen in mature or semi- mature birds. Ante-mortem clinical signs are similar to

other respiratory conditions in poultry and include anorexia, weakness, depression, nasal discharge, coughing, and sneezing. Post-mortem lesions include petechial hemorrhages when the disease is acute, a few to many small necrotic foci in the liver (known as cornmeal liver), localized inflammatory lesions of the joints, tendon sheaths, and wattles often with caseous exudate in the chronic form, and lung consolidation as the disease becomes more chronic. Fowl Cholera often develops in turkeys as a complication of primary airsacculitis caused by *Mycoplasma gallisepticum* and is demonstrated as marked airsacculitis, pericarditis, and a well-developed fibrinous pneumonia.

Chlamydia psittaci – This organism can also cause disease in humans through aerosol transmission. Synonyms for this disease include Ornithosis, Psittacosis, and Parrot Fever. This organism causes acute to chronic infectious disease in psittacine birds and turkeys. Ante-mortem clinical signs are similar to other respiratory conditions in poultry and include anorexia, weakness, depression, nasal discharge, coughing, and sneezing. Additionally affected birds may have sulphur colored diarrhea and may sit leaning forward on their keel bone due to pain and dyspnea. Post-mortem lesions include vascular congestion, fibrinous pericarditis, perihepatitis, and airsacculitis. Splenitis is also observed and may be the only lesion on occasion. *C. psittaci* forms intracytoplasmic inclusion bodies in various cells, including macrophages, which can be demonstrated in stained smears. Outbreaks of this disease are sporadic and generally occur in turkeys rather than chickens. The turkey industry watches closely for any evidence of chlamydiosis, so infected flocks are usually identified and treated before slaughter. However, PHV's must stay alert for any poultry showing signs suspicious for this disease.

Two important viral poultry diseases that may involve the air sac system are Virulent Newcastle Disease (vND) and Avian Influenza (AI).

Inflammatory Process (IP)

An inflammatory process is usually manifested in poultry as bright yellow caseous material underneath the skin. When the condition is generalized or cannot be practically removed the carcass would be condemned (9 CFR 381.86). Otherwise, it may be trimmed and passed.

Turkey Osteomyelitis Complex (TOC)

The classic lesions of TOC are osteomyelitis, swelling of the joints and adjacent soft tissue, and green discoloration of the liver. Two external signs are frequently seen in TOC-affected carcasses—joint swelling and green discoloration of the liver. The latter sign is the most consistent indicator that TOC may be present. However, it is not pathognomonic. Although, most carcasses affected by TOC exhibit a green liver, most carcasses exhibiting a green liver do not have TOC.

FSIS usually performs TOC checks in turkey establishments that slaughter flocks under one year of age and are not NPIS establishments. Although FSIS does not have specific regulations or a directive that addresses TOC checks, Inspection program personnel (IPP) are to ensure that only wholesome, unadulterated poultry products receive the mark of inspection.

Establishments are required to remove localized pathologic or inflammatory lesions, such as TOC lesions. 9 CFR 381.86 requires that any part of a carcass, which is affected by an inflammatory process shall be condemned and, if there is evidence of general systemic disturbance, the whole carcass shall be condemned.

What makes osteomyelitis different is that, unlike an inflammatory process in an air sac, you cannot see an inflammatory process inside a bone during routine post-mortem inspection. Therefore, the establishment should have a written program to identify and remove TOC lesions.

In NPIS establishments, FSIS does not conduct routine TOC checks. Establishments' written sorting procedures should include supportable methods to identify TOC lesions, and discard affected condemnable carcasses and parts. PHVs would verify compliance when they assess establishments' sorting procedures, depending on how establishments incorporate the sorting procedures in the food safety system. Establishments must incorporate written sorting procedures into the HACCP plan, Sanitation SOP plan, or other prerequisite program (9 CFR 381.76(b)(6)(ii)(C)).

FSIS does not perform TOC checks on flocks of mature turkeys/flocks that are no longer growing (one year or older). TOC is primarily a disease of adolescent male turkeys, although it is seen in both sexes. It is considered a flock problem and may be influenced more by deficiencies in the bird's immune response rather than the virulence of the different opportunistic organisms associated with the disease.

Ascites

Broiler ascites is an abnormal condition occurring in young, rapidly growing chickens. Rapid growth (resulting from nutritional and genetic improvements by the industry) may cause an increase in oxygen demands on the chicken. The higher oxygen demand placed on the cardiopulmonary system of the chicken under stress leads to right heart failure and the subsequent accumulation of clear to amber fluid around the heart. The right heart failure may force the ascitic fluid into the abdominal cavity. Fluid is present in the body cavity at post-mortem in varying amounts. Ascitic fluid in the thoracic cavity may prevent inspection of the interclavicular air sac space. The liver may also present with a ground-glass appearance because of the deposition of fibrin on the surface.

Condemn carcasses with any amount of ascitic fluid present in the body cavity that also has signs of Sep/Tox (9 CFR 381.83) or other disease conditions, including inflammatory lesions, tumors, or other degenerative conditions. Condemn carcasses with any amount of ascitic fluid present in the body cavity that prevents visualization of the interclavicular space.

Mutilation (including compound bone fractures)

Any organ or other part of a carcass which has been accidentally mutilated in the course of processing shall be condemned, and if the whole carcass is affected, the whole carcass shall be condemned (9 CFR 381.91(a)).

Establishment Rejects

When the establishment rejects a carcass before inspection, record on the lot tally sheet as a "Plant Reject". Carcasses rejected by the establishment at salvage should also be recorded under this category.

For establishments that do not operate under the NPIS, there are instructions in FSIS Directive 6100.3, "Ante-Mortem and Post-Mortem Poultry Inspection," regarding suspension of airsacculitis salvage operations and lot documentation by IPP.

Missing or No Viscera Carcasses

If a carcass has at least one major visceral part (heart, liver, or spleen) present, IPP can make a disposition based on inspection of that part and the carcass.

If the establishment presents a carcass with no viscera (some visceral parts present, but all three major organs are missing, or no viscera entirely), and IPP determine that they are unable to make a disposition, IPP are to retain the carcass for the IIC.

If IPP begin to observe no viscera carcasses presented with a disease condition or abnormality in the specific production that requires the presence of the viscera for IPP to make a disposition, then IPP are to retain the carcasses and notify the IIC.

IICs are to assess the specific production, if necessary. If no disease condition is present that would prevent IPP from making a disposition on the "no viscera" carcasses, then the IIC is to direct IPP to continue with post-mortem inspection on that specific production. If a condition is present that influences the disposition determination of the "no viscera" carcass, the IIC is to direct IPP to hang back the "no viscera" carcasses for final disposition by the IIC. IICs may also conduct a presentation check.

Liver and Kidney Dispositions

Only condemnation of carcass parts is required for some localized conditions. If there is an unwholesome portion or part that can be effectively removed, the remainder of the carcass is considered wholesome. Some organs or parts that may be condemned because of localized conditions without condemning the whole carcass are:

Condemn livers with:

- Fatty degeneration
- Hemorrhages or extensive petechiation
- Inflammation and necrosis
- Cirrhosis, tumor, or cyst
- Discoloration from gall bladder or bile duct or post-mortem changes
- A specific disease (i.e., chronic viral hepatitis)

Condemn kidneys when:

- Renal pathology, including tumors, is present
- Airsacculitis is present specifically in the abdominal air sac membranes making the kidneys an affected tissue, and the posterior (back) part of the carcass is salvaged for airsacculitis per 9 CFR 381.84 (establishment removes the kidneys from the carcass or salvaged portion).

Special Note: Hepatic (liver) or splenic (spleen) pathology which is determined by IPP to be localized and visibly limited to the affected organ require only the affected visceral organ to be condemned. Localized pathology of the liver or spleen does not require simultaneous condemnation of the kidneys unless the kidneys are also affected by visible pathological changes.

Residue Detection

OBJECTIVES

Scientific (Delivery/Holding context):

1. Explain the key aspects of directed and inspector-generated sampling techniques.
2. Given a scenario in the Delivery/Holding context, perform residue detection sampling, both directed and inspector-generated.

Scientific (Slaughter context):

1. Given a scenario, describe how to perform directed and inspector-generated sampling for detecting residue.
2. Given a scenario, interpret the results of KIS™ tests.
3. Demonstrate the appropriate action for a PHV when a KIS™ test is positive.
4. Given four different outcomes of a residue test – i.e., not detected, detected-not violative, detected-not quantified-violative, and detected-violative – identify the PHV's correct response to each.

Regulatory/Administrative (Delivery/Holding context):

1. Given an in-plant scenario, identify the conditions and animal classes that call for a PHV to perform inspector-generated, in-plant residue testing using FSIS Directives 10,800.1, 10,800.2, and 10,800.3.

Regulatory/Administrative (Slaughter context):

1. Identify the conditions and animal classes that call for a PHV to perform an in-plant residue test, based on FSIS Directive 10,800.3.
2. Describe how to use LIMS-Direct to access residue laboratory test results.

RESOURCES

FSIS Directive 10,800.1 – Residue Sampling, Testing, and Other Verification Procedures Under the National Residue Program (NRP) for Meat and Poultry Products
FSIS Directive 10,800.2 – Residue Sampling and Testing Under the NRP
FSIS Directive 10,800.3 – Prioritizing Inspector-Generated Sampling Under the NRP
FSIS Directive 10,800.4 – The NRP Roles, Functions and Responsibilities
FSIS Directive 10,210.5 – FSIS Sampling Data Reporting Through Laboratory Information Management System-Direct (LIMS-Direct)
KIS™ Test Instructions
Residue Repeat Violator List
FSIS Compliance Guide for Residue Prevention
FSIS Webpage – Chemical Residues and Contaminants
askFSIS Public Q&A: Animal Identification and Residue Sampling

INTRODUCTION

FSIS-regulated products may be adulterated because they bear or contain residues of drugs, pesticides, and other chemicals used in animal production or present in the animals' environment. The U.S. has a robust residue control system with rigorous processes for approval, sampling and testing,

and enforcement activities. FSIS works with the EPA and the FDA to accomplish these responsibilities under the National Residue Program (NRP). The NRP is designed to prevent the occurrence of violative levels of chemical residues in meat and poultry products. The NRP also provides for the collection of national data on the occurrence of residues to support risk assessment, enforcement, and educational activities.

FSIS's primary responsibility within the NRP is to collect samples to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat and poultry products through their HACCP systems. FDA establishes tolerances (maximum permissible levels) for veterinary drugs and food additives. EPA establishes tolerances for registered pesticides. FSIS enforces these tolerances through its various residue control programs. More information on each agency's roles and responsibilities is found in FSIS Directive 10,800.4 "The National Residue Program Roles, Functions, and Responsibilities" and MOU 225-85-8400.

In addition to sampling activities, IPP perform Slaughter HACCP Verification tasks and Hazard Analysis Verification (HAV) tasks to verify establishments address the hazard of chemical residues in their food safety systems, including verifying the establishment implements controls cited as support for decisions in the hazard analysis regarding chemical residues. In slaughter establishments, chemical contamination, veterinary drug residues, and pesticides are possible sources from which chemical food safety hazards may arise. Establishments must conduct a hazard analysis and consider these hazards in their production process. Prudent establishments consider if they are purchasing livestock from repeat violator producers, have adequate identification to trace cattle back to the producer, and consider the class of livestock they slaughter. A USDA OIG review (2010) reported that two slaughter classes, cull dairy cows and bob veal calves, account for a higher percent of residues found in animals presented for slaughter.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer, establishment, and IPP. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. FSIS posts a weekly Residue Repeat Violator List on its website that identifies producers with more than one violation in a rolling 12-month period. FSIS also shares the violation data with the EPA and FDA. FDA and cooperating State agencies investigate producers linked to residue violations and, if conditions leading to residue violations are not corrected, can enforce legal action. IPP actions in response to violative results are described in further detail below.

Within FSIS there is extensive teamwork among offices and personnel, including OPHS, OPPD, OPARM, OIEA, OFO District Offices, laboratories, and OFO IPP. More information on each program area's roles and responsibilities is found in FSIS Directive 10,800.4 "The National Residue Program Roles, Functions, and Responsibilities."

PHV RESPONSIBILITIES

As a PHV, you have many responsibilities concerning residues. First, you should be familiar with the policies surrounding residues. There are multiple regulations (e.g., 9 CFR 309.16, 309.17, 310.2, 310.21, 318.20, 320.1(b)(1)(ix), 381.74, 381.78, 381.80, and 417) and Agency issuances that relate to residues. Information related to residue policy and verification tasks performed as part of the NRP (including HAV and HACCP Verification tasks) to verify an establishment's residue control program is included in FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products." Information regarding sample collection methodologies

is included in FSIS Directive 10,800.2 “Residue Sampling and Testing under the NRP.” Information regarding pathologies and conditions warranting carcass retention and sampling under the NRP is included in FSIS Directive 10,800.3 “Prioritizing Inspector-Generated Sampling under the NRP.” Information regarding collection of National Antimicrobial Resistance Monitoring System (NARMS) cecal samples is included in FSIS Directive 10,100.1 “FSIS Cecal Sampling Under the NARMS Surveillance Program.”

Note: The information in this section focuses on domestic meat and poultry products, however information on egg product residue sampling is found in FSIS Directive 10,230.3 “FSIS Verification Testing of Domestic Egg Products”; information on Siluriformes fish residue sampling is found in FSIS Directive 14,010.1 “Siluriformes Sampling in Domestic Establishments”; and information on imported products is found in FSIS Directive 9900.6 “Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.”

In addition to understanding Agency policies surrounding residues, you are responsible for:

- Understanding how the establishment addresses residue control in its HACCP system.
- Identifying animals suspected of having violative residues at ante-mortem for residue testing and handling animals with known violative residue levels per 9 CFR 309.16 (see 9 CFR 381.74 for poultry).
- Selecting carcasses or products for testing and ensuring proper handling, labeling, processing, sealing and shipping of the samples to avoid discard of samples.
- Participating in training and verifying IPP are trained in residue testing sample submission procedures and in the appropriate identification of carcasses or products suspected of having violative residues on post-mortem inspection.
- Accurately completing FSIS Residue Sample Forms in PHIS and recording the carcass owner’s name, address, and other identifying information on the forms and in PHIS.
- Tracking the status of samples and determining carcass/part disposition by reviewing LIMS-Direct.
- Managing equipment and supplies at the duty station to ensure proper equipment for the effective collection of samples and performance of in-plant tests is available, and that control of supplies, incubators, and other equipment is maintained.
- Identifying and documenting noncompliance.

SAMPLING AND TESTING - OVERVIEW

The NRP domestic sampling plan includes surveillance sampling, inspector-generated sampling, and special project sampling in federal and state-inspected slaughter facilities.

Surveillance sampling (also known as directed sampling) is the sampling of specified slaughter subclasses at the time of slaughter, after passing ante-mortem inspection. IPP randomly select carcasses within a given production class for sampling as part of a nationally representative sample. These sampling requests appear as directed tasks on the establishment’s task list in PHIS. Instructions for accepting, scheduling, and completing these tasks in PHIS are found in FSIS Directive 13,000.2 “Performing Sampling Tasks in Official Establishments Using PHIS.” Instructions for collecting the samples are found in FSIS Directive 10,800.2 “Residue Sampling and Testing under the NRP.”

Special project sampling projects are periodically conducted by FSIS. IPP receive notification of special project residue sampling through FSIS notices.

Inspector-generated sampling is conducted by IPP when IPP suspect that an animal presented for slaughter may contain a violative level of one or more chemical residues. Inspector-generated sampling includes Kidney Inhibition Swab (KIS™) testing and Confirmatory Tissue Testing.

- The KIS™ test is an in-plant screening test used to screen for antibiotic drug residues. The test provides a way to screen animals that are seen as suspicious based on their herd history, ante-mortem or post-mortem findings, and in slaughter classes with a higher incidence of violative chemical residues. The tests are used as a follow up on producers who have been known in the past to have residue violation issues, and to verify the establishments HACCP system. When a KIS™ test result is positive, IPP submit tissue samples to the FSIS Laboratory for analysis.
  Note: KIS™ tests do not detect non-antimicrobial drugs (e.g., beta-agonist drugs or NSAIDs).
  Note: In-plant screening tests are not performed in poultry, exotic animals, or Siluriformes fish.

- IPP submit confirmatory tissue testing when a KIS™ test result is positive; when an animal is suspected of having violative levels of a chemical residue, other than antibiotic (e.g., NSAIDs, beta-agonists); when a producer is listed on the Residue Repeat Violator List for a chemical residue other than an antibiotic; or when ante-mortem or post-mortem examination findings indicate a condition where violative residues may be present, regardless of KIS™ test results.

Prioritizing Inspector-Generated Sampling

At slaughter, PHVs look for indications of violative chemical use or exposure and collect tissue samples for residue analysis. Certain pathological conditions are more likely to show a laboratory-confirmed positive residue test result compared to other pathologic conditions. PHVs use professional judgement when selecting carcasses for chemical or drug residue testing based on the prioritized conditions (see FSIS Directive 10,800.3 “Prioritizing Inspector-Generated Sampling under the NRP”), evidence of acute or subacute disease conditions, ante-mortem inspection findings, pathological lesions, production practices, herd history, and environmental security.

Examples of the pathologies and conditions listed in the directive include nephritis/cystitis, injection site lesions, recent surgery, pneumonia, emaciation, pyemia/septicemia, repeat violators, and metritis. Consult FSIS Directive 10,800.3 “Prioritizing Inspector-Generated Sampling under the NRP” for a list of prioritized pathologies and conditions. Again, PHVs are to use professional discretion when deciding to conduct a KIS™ test, regardless of the conditions listed on the prioritized condition list. PHVs should not “automatically” KIS™ test livestock with disease conditions listed above unless they can support why the animal is suspected of having a violative residue.

Increased KIS™ Testing

Several circumstances warrant increased KIS™ testing. The PHV is to increase the frequency of KIS™ testing when they determine that an establishment:

- Purchases or receives animals from a supplier on the Residue Repeat Violator List.
- Does not have a residue control program designed to control residue violations or the program has been determined to be ineffective in design or implementation.
- Fails to collect the name and address or other type of credible certification of the source of animals it slaughters that demonstrates the supplier is not on the Reside Repeat Violator List.
- Receives dairy cows or bob veal from any unknown source, even if the animals appear normal.
- Receives animals with pathologies listed in FSIS Directive 10,800.3 “Prioritizing Inspector-Generated Sampling under the NRP.”

The list above is not all-inclusive. You are to use sound professional judgment to determine when increased inspector-generated sampling is warranted. Consult your supervisory channels when necessary.

If you determine that an increased rate of testing is warranted, discuss the circumstances that warranted the increased sampling with the establishment at the weekly meeting. Refer to FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products" for more information on increased KIS™ testing and to FSIS Directive 5010.1 "Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management."

Testing for NSAIDs and Beta-Agonists

As mentioned previously, the KIS™ test does not detect non-antimicrobial drugs, such as beta-agonists or NSAIDs. When the PHV suspects beta-agonist or NSAID use in livestock, the PHV collects tissue samples and submits these to the FSIS Laboratory for sampling. The PHV notes their request for testing in the Remarks box provided in the Sample Collection Data tab in the Sample Management – Sample Collection field in PHIS.

Ante-mortem and post-mortem findings that may indicate possible NSAID use include: any inflammatory conditions, including arthritis, mastitis, metritis, pneumonia and peritonitis; injection sites showing marked local inflammation or necrosis; and chronic traumatic injuries or lameness.

Findings that may indicate possible beta-agonist use or abuse include excessive or unusually heavy muscle development and hyperexcitability.

Testing of Show Animals and Bob Veal Calves

FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products" provides specific instructions for KIS™ testing of show animals and bob veal calves.

When show animals appear unhealthy or are suspected of having antibiotic residues, they are handled as U.S. Suspects and KIS™ tested.

For bob veal calves, PHVs follow the level of testing described in 9 CFR 310.21(c)(4) to determine how many healthy animals to test. The number of healthy-appearing calves to sample is based on the percent of the day's estimated slaughter and will increase or decrease based on the number of violative sample results. PHVs will also perform KIS™ tests on bob veal calves that exhibit disease lesions or signs of treatment; however, these results are not used in calculating the healthy bob veal calf residue testing rate.

Consult FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products" for more specific instructions for KIS™ testing of show animals and bob veal calves.

ANIMAL IDENTIFICATION AND SUPPLIER INFORMATION

Establishments are required to collect all manufactured animal identification (ID) devices and maintain the ID identifiable with the carcass and parts until the completion of post-mortem inspection, including the reporting of FSIS residue test results (9 CFR 310.2(a), 310.2(b)). Types of animal IDs include, but are not limited to, livestock market or sale barn backtags; producer ear tags; feedlot ID tags; Canadian

tags; vaccination tags; tattoos and brands; and any special ID used on cattle imported from Mexico. IPP record animal ID information in the appropriate data fields in PHIS and hold all collected ID tags until KIS™ test results are reported negative or until FSIS laboratory test results report as negative or as positive-non violative. IPP document noncompliance under "Other Inspection Requirements" when the establishment fails to collect and maintain all animal ID until the completion of post-mortem inspection.

Establishments are required to maintain records of each transaction involving its purchase of livestock and poultry, including, but not limited to, the name and address of the supplier (9 CFR 320.1 and 381.175). IPP request from the establishment the animal producer information for all surveillance and inspector-generated samples submitted to FSIS laboratories for residue testing. If the establishment fails to provide information about the violator upon reporting of a violative residue on FSIS testing, IPP document an NR.

FSIS VERIFICATION AND ACTIONS IN RESPONSE TO TEST RESULTS

Inspection Tasks

IPP perform Slaughter HACCP Verification and HAV tasks as part of verifying an establishment's residue controls. In addition to the information in FSIS Directives 5000.1 "Verifying an Establishment's Food Safety System" and 5000.6 "Performance of the HAV Task," IPP should reference FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products" when completing these inspection tasks.

When performing the Slaughter HACCP Verification task, IPP verify implementation of the establishment's controls that are cited as support for decisions in the hazard analysis regarding chemical residues at receiving and collection of supplier information. Many establishments use PRPs to support decisions regarding chemical residues in the hazard analysis. For example, an establishment may use purchase specifications, an industry quality assurance certification program, or certification from the seller that animals purchased are not from a producer on the Residue Repeat Violator list. IPP are to verify whether these PRPs continue to support the decisions in the hazard analysis.

When performing the HAV task, IPP evaluate the design of the establishment's hazard analysis and HACCP plan. IPP verify the establishment has included animal receiving as a step in its flow chart and that the establishment has considered chemical residues (e.g., drugs, pesticides, chemical contaminants) at this step in the hazard analysis. If the establishment determines chemical residues are NRLTO, IPP verify that the establishment has a written prerequisite program with procedures designed to prevent the chemical hazard from occurring. IPP verify the establishment maintains supporting documentation that the program has been validated, that records are sufficient to demonstrate the program is implemented as written on an ongoing basis, and that the program effectively prevents the hazard. IPP should also verify that unforeseen food safety hazard corrective actions are taken when the hazard occurs (9 CFR 417.3(b)).

If the establishment determines that the chemical hazard is RLTO and develops a CCP to control the hazard, the respective 9 CFR part 417 HACCP regulations will apply. In addition to verifying the establishment's supporting documentation and validation, IPP will also verify the establishment reassesses its HACCP plan annually and in response to each violative test result through FSIS or other testing, and that the establishment takes appropriate corrective actions in response to violative residue test results.

If you or IPP on your team identify trends of noncompliance concerning residue controls, raise those concerns, through supervisory channels, to the DO for potential enforcement action.

Sample Collection

As described above, IPP collect surveillance sampling of specified slaughter subclasses when scheduled in PHIS, as well as inspector-generated sampling when they suspect livestock presented for slaughter may have violative levels of chemical residues. IPP are to ensure sample integrity when collecting, preparing, and packaging samples. IPP are to ship residue samples to the FSIS laboratory as soon as possible after collection, because residues in tissues can degrade over time, resulting in false negative results. As a supervisor, you are to ensure IPP are properly trained to conduct KIS™ testing.

Detailed instructions for sample collection, including how to order supplies, how to conduct KIS™ testing, which tissues (and how much) to collect and submit, and how to package and submit samples are found in FSIS Directive 10,800.2 "Residue Sampling and Testing under the NRP." Information on how to access, schedule, and complete residue sampling (surveillance) tasks in PHIS is found in FSIS Directive 13,000.2 "Performing Sampling Tasks in Official Establishments Using PHIS." Instructions on how to create inspector-generated (KIS™) residue sampling tasks are found in PHIS Help (VPN required).

Verifying Test and Hold (or Control)

IPP have verification responsibilities for the holding or control of livestock carcasses tested for residues.

For surveillance residue testing of livestock, IPP verify the establishment holds or controls carcasses selected for testing pending the test results. If the establishment does not hold or maintain control of product, IPP follow the instructions in FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products" for documenting noncompliance and notifying their supervisor. For surveillance testing of poultry, IPP recommend the establishment hold the specific poultry carcasses selected for testing pending the test results. Poultry establishments are not required to hold the sampled poultry carcasses.

For inspector-generated (KIS™) testing, IPP retain the carcass and its parts (if not already condemned), pending test results. If the KIS™ test is positive, IPP continue to retain the carcass and parts and submit kidney, liver, and muscle tissues for further analysis to the FSIS Laboratory.

Note: Establishments are not required to hold products pending NARMS cecal sampling results.

FSIS Actions in Response to Results

IPP monitor PHIS and LIMS-Direct for the test results of any residue samples submitted (surveillance and inspector-generated). **Note:** PHVs should monitor for FSIS Laboratory discards and take appropriate action in the event of a residue sample discard, following instructions in FSIS Directive 10,800.2 "Residue Sampling and Testing under the NRP." These actions will include ensuring future samples are not discarded, as well as determining what actions to take for the specific sample that was discarded.

The PHV makes a final disposition on the carcasses and parts and takes any necessary regulatory enforcement actions based on the results. The PHV (or IPP) notifies the establishment of residue test results as soon as they are reported and of the final disposition of any carcass and its parts.

Note: NARMS cecal sampling results are shared with the establishment upon request via askFSIS or for information sharing purposes. IPP do not take action on product based on NARMS sample results.

Disposition

PHVs are to **condemn** the **tissues** identified as violative in the test results for:

- Violations in muscle or in parts and muscle – condemn parts **and** carcass.
- Violations in parts but no violation in muscle – condemn parts, pass carcass.

PHVs are to **condemn** the **carcass and all parts** for:

- Results reported as "Detected but not Quantified, Violation"
- Results that have a quantified violation for some part (such as organ tissue) without a quantified muscle result

PHVs are to **release the carcass and its parts** for results reported as:

- "Not Detected"
- "Detected – non-violative"

Noncompliance and Discussion

When an establishment receives a violative residue result, both the establishment and IPP have responsibilities. In addition to notifying the establishment of the residue test results, IPP are to discuss any developing trends in violative residue results at the weekly meeting. IPP inform the establishment that its failure to prevent this hazard from recurring raises questions about the adequacy of the establishment's HACCP system. PHVs are to raise concerns through supervisory channels when an establishment demonstrates a trend of noncompliance.

IPP will verify the establishment meets the regulatory requirements in response to the violative residue result. IPP do not automatically document noncompliance in the event of a violative residue result. An establishment that determines in its hazard analysis that chemical residues are NRLTO is required to reassess its HACCP plan each time a violative drug residue is found (9 CFR 417.3(b)(4)). IPP are to verify that the establishment takes corrective actions that meet all appliable requirements of 9 CFR 417.3(b) including performing and documenting a reassessment of the hazard analysis. If IPP verify that appropriate corrective actions were followed, including adequate measures to prevent recurrence, and the establishment has a history of having an adequate residue control program, IPP are **not** to issue an NR.

If IPP determine that the establishment has not maintained adequate support for decisions in their hazard analysis or if IPP determine that the establishment failed to take corrective actions, IPP document an NR following the instructions in FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products." IPP issue an NR for each occurrence of additional residue violations between an establishment and a source listed on the Residue Repeat Violator List. IPP associate these NRs in accordance with FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System." As a supervisor, you are to ensure that IPP are properly documenting findings.

ANIMALS USED FOR RESEARCH

Livestock Used for Research

Section 9 CFR 309.17 prohibits the slaughter of any livestock that have been used in experiments involving biological products, drugs, or chemicals unless the establishment has written documentation of the safety of these animals from an appropriate authority, such as APHIS, EPA, or FDA. Per FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection," the IIC is to contact the Policy Development Staff through supervisory channels if they have not received a slaughter permit when an establishment presents for ante-mortem inspection animals used in a research investigation involving an experimental biological product, drug, or chemical. Any animals that have been subjected to food additives or pesticide chemicals must demonstrate compliance with the FDA tolerance levels for these substances. The PHV may deny or withdraw slaughter for any suspect animals to ensure that all products that are prepared at the establishment are free from adulteration. More information on PHV responsibilities regarding livestock used for research is found in FSIS Directive 10,800.1 "Residue Sampling, Testing, and Other Verification Procedures under the NRP for Meat and Poultry Products."

Poultry Used for Research

Regulation 9 CFR 381.75 covers poultry that have been used for research. The establishment must have appropriate documentation that the biological product, drug, or chemical used in the research will not result in poultry products being adulterated – or the products are condemned.

VERIFYING ELIGIBILITY OF VEAL CALVES WITH SUSPECTED IMPLANTS

Pre-ruminant calves raised for veal are considered adulterated if they are found to have hormonal/beta-agonist implants. IPP verify during ante-mortem inspection whether pre-ruminant calves whose meat will be labeled as "veal" have implants. If an implant is present, IPP will feel a linear, firm swelling under the skin when palpating the ear, brisket, or tail head. The implant may feel like "beads on a string". Signs that an implant may have been used include a palpable implant, missing ears, ears with incisions, mutilated ears, atrophied testicles, or unusually heavy muscle development.

When IPP observe signs of an implanted pre-ruminant calf on ante-mortem, they are to retain the animal and the PHV is to tag it as U.S. Suspect. The PHV will use professional judgement to determine when the entire lot from the same producer should be held for PHV disposition.

On post-mortem, IPP are to palpate the ears, brisket, and tail head of the U.S. Suspect carcasses for implants. The PHV may adjust the line speed if necessary to complete the inspection procedure. IPP are to retain the carcasses of pre-ruminant calves exhibiting signs of an implant for post-mortem inspection by the PHV. The PHV examines the rumen of retained carcasses to determine its functionality. After post-mortem exam, the PHV is to condemn the carcass if the rumen was not functioning and the animal had an implant, missing ears, ears with incisions that indicate recent surgery, or ears mutilated to the extent that the PHV is unable to determine whether an implant was present; or, pass the carcass for human food if the animal has a functioning rumen and does not meet any of the criteria for condemnation.

If the PHV determines that the calf had an implant and a non-functioning rumen, IPP are to document an NR and verify the establishment takes appropriate corrective actions.

Foreign and Reportable Animal Diseases

OBJECTIVES

Scientific (Delivery/Holding context):

1. Given a scenario, identify specific ante-mortem signs in livestock or poultry that suggest a foreign or other reportable animal disease (FAD or RAD).
2. Demonstrate how to convey to IPP a professional commitment to FAD/RAD in this work context.
3. Demonstrate how to train IPP to recognize specific ante-mortem signs of FAD/RAD and report them to a PHV.

Scientific (Slaughter context):

1. Given a scenario in the Slaughter/Kill Floor context, identify specific post-mortem signs in livestock and poultry that suggest a FAD or RAD.
2. Given a post-mortem inspection scenario, demonstrate how to respond to a suspected FAD or RAD.
3. Demonstrate how to train IPP to recognize post-mortem signs of FAD/RADs and report them to a PHV.

Regulatory/Administrative (Delivery/Holding context):

1. Given a scenario in the delivery/holding context, follow FSIS Directive 6000.1 to respond to ante-mortem signs of FAD/RAD.
2. Locate and explain the instructions in FSIS Directive 10,400.1 regarding BSE surveillance.
3. Given a scenario, identify the process described in FSIS Directive 10,400.1 regarding an animal condemned for suspected rabies.
4. Given a scenario involving notification of a highly pathogenic avian influenza (HPAI) outbreak, respond according to the instructions in FSIS Directive 6020.1.
5. Given a scenario in the Delivery/Holding context involving cattle suspected of tuberculosis, demonstrate ante-mortem inspection, correct disposition, and sampling, and verify segregation and documentation involved.
6. Identify internationally notifiable animal diseases recognized by the World Organisation for Animal Health.
7. Identify animal diseases that PHVs must report to the District Office (DO).
8. Explain how to teach IPP, establishment management, and the general public ways in which FAD and RAD could be introduced into U.S. livestock and poultry and the economic and health consequences.

Regulatory/Administrative (Slaughter context):

1. Given a scenario in the Slaughter/Kill Floor context, follow instructions in FSIS Directive 6100.4 to verify that a beef establishment's controls for specified risk materials (SRM) during processing comply with regulatory requirements.
2. Given a scenario, conduct inspection, sampling, and disposition of animals suspected of FAD/RADs according to FSIS Directive 6240.1, Guideline No. 4, and APHIS-VS TB Sample Submission Manual for Meat Inspection Personnel.

RESOURCES

FSIS Directive 6000.1 – Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions

FSIS Directive 6020.1 – Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak
FSIS Directive 6240.1 – Inspection, Sampling, and Disposition of Animals for Tuberculosis (TB)
FSIS Directive 6100.4 – Verification Instructions Related to Specified Risk Materials in Cattle of all Ages
FSIS Directive 10,400.1 – Sample Collection from Cattle Under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program
Guideline No. 4 "Inspection of Tuberculin Reactors"
TB Sample Submission Manual for Meat Inspection Personnel
Questions & Answers - FSIS Directive 6100.4
APHIS AVIC Contacts
State Animal Health Officials Contacts

INTRODUCTION

As a PHV in a slaughter facility, you have the responsibility of conducting ante-mortem and post-mortem inspection on up to thousands of animals each day. You play a valuable role in detecting and assisting in the control and eradication of reportable and foreign animal diseases. This module will focus on the significance of reportable and foreign animal diseases, clinical and pathological diagnosis of significant disease conditions, and procedures to report suspected reportable and foreign animal diseases.

FSIS OFO cooperates with APHIS Veterinary Services (VS) in their various activities and plays an important role in the disease eradication program that APHIS VS administers. APHIS has the primary responsibility to investigate suspect conditions and to respond appropriately. The intent of this module is not to make you an expert at recognizing by name the various reportable diseases when seen, but rather to make you aware of your responsibility to report abnormal symptoms and lesions to APHIS VS.

Your work in the establishment is very important to the animal disease eradication effort because you work at a place in the food animal chain where often you are the first to encounter a disease process in an animal. Remember that you are the first line of defense in bringing to the attention of your chain of command and APHIS VS any symptoms seen on ante-mortem or lesions seen on post-mortem that could be part of a disease entity that should be reported.

Notifiable diseases are those that are designated by the World Organisation for Animal Health (Office International des Epizooties or OIE). The U.S. is a member country of the OIE and is required to report the animal diseases it detects in its territory to the OIE, who then disseminates information from the reports to other countries so those countries can take necessary preventative action. When suspected, either on ante-mortem or post-mortem, these diseases must be reported to your APHIS Area Veterinarian in Charge (AVIC). The list of notifiable diseases is located online as well as in FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions." Some of these diseases are considered by APHIS to be foreign to the U.S. Some of these diseases are transmissible to humans. Some of the diseases are not foreign but are reportable. Most states also provide a list of reportable diseases specific to that state.

FADs may enter the U.S. accidentally through the importation of infected animals or animal products. They may be carried inadvertently into the U.S. via contaminated clothing, shoes, or other objects. Diseases also may be introduced as an act of terrorism. The control of FADs is important because the unchecked spread of FADs into agricultural environments will have a ripple effect on many segments of

the U.S. economy, including disruption of livestock marketing and trade. Outbreaks of certain animal diseases, especially zoonotic diseases, can cause considerable economic and social disruption.

As a PHV, you should be familiar with ante-mortem and post-mortem findings that could indicate a foreign or reportable animal disease, as well as the procedures on how to report your findings. You should also understand how to train IPP and verify that IPP performing ante-mortem and post-mortem inspection know what to look for and how to report their findings.

See FSIS Science and Technology Seminar Series FAD/RAD Part 1 and Part 2 for additional training.

Note: Much of the information below describing specific diseases, clinical signs and gross findings is sourced from the CFSPH, Merck Veterinary Manual and the APHIS Website.

SIGNS OF FADS OR REPORTABLE CONDITIONS

PHVs should be familiar with the signs of FADs and reportable conditions described in FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions." PHVs must also ensure that IPP under their supervision recognize these signs and report them to their supervisor.

If IPP observe the following signs or symptoms, or come across the following information related to animals presented for slaughter, an FAD or reportable disease should be considered:

Animal History

If animal history is available (animal records, verbal information from drivers, or other sources of information) it needs to be accurately passed on to the DO. The following signs observed in animals transported to slaughter or other information provided that may point toward an FAD or reportable disease include:

- High morbidity
- High mortality
- Severe abortion storms of unknown etiology
- Avian disease with acute deaths or CNS signs
- History of foreign travel; foreign visitors; foreign mail or gifts; or importation of animals, embryos, or semen

Ante-mortem Conditions

- Vesicular lesions
- Excessive salivation or drooling
- Sudden lameness
- Severe respiratory conditions
- Pox or lumpy skin conditions
- CNS conditions or signs of encephalitic conditions (e.g., head pressing, head tilt, circling)
- Mucosal disease
- Larvae in wounds, unusual myiasis or acariasis
- Unusual or unexplained illness or symptoms

Post-mortem Conditions

- Hemorrhagic septicemia

- Suspicious or unusual post-mortem findings that do not fit typical conditions, such as necrotic foci on tonsils, enlarged spleen, or hydropericardium. These may be seen with some domestic diseases but if coupled with suspicious information (e.g., ante-mortem findings, records) should warrant further investigation.

PHV REPORTING RESPONSIBILITIES

PHVs are to consider animals exhibiting the signs or symptoms described in the above section as U.S. Suspects or U.S. Condemned as appropriate under the regulations. They are to notify the DO as soon as possible when they suspect disease conditions that are reportable, foreign, or both.

PHVs must provide the following information, if available, to the DO:

- Producer's name, address, county, and phone number.
- Any clinical history, including any treatments given and responses noted from the certification accompanying the animal.
- Number and species of animals affected that were presented for slaughter.
- What conditions or signs are present.
- Any gross lesions seen.
- The PHVs contact information, including name, address, and relevant phone numbers.

The DO will notify the AVIC of APHIS or the State Animal Health Official (SAHO) and provide them with the information above. The SAHO or AVIC will determine how to handle the case and provide the DO with specific instructions.

Note: The APHIS or SAHO may want the animal(s) held so they can examine it. The PHV should have the animal(s) placed in a separate pen identified with a pen card, apply a U.S. Retained tag, and notify the establishment not to move the animal(s) without the permission of the PHV or other animal health official.

SPECIFIC FAD/RADS

Avian Influenza

Avian influenza (AI) is caused by an influenza type A virus which can infect poultry and wild birds. Highly pathogenic avian influenza (HPAI) virus strains are extremely infectious, often fatal to chickens, and can spread rapidly from flock-to-flock. Low pathogenicity avian influenza (LPAI) virus strains occur naturally in wild birds (waterfowl and shorebirds) without causing illness and can infect domestic poultry. APHIS works closely with states and the poultry industry to prevent AI from becoming established in the U.S. poultry population.

Birds infected with HPAI virus may show one or more of the following signs: sudden death without clinical signs; lack of energy and appetite; swelling of head, comb, eyelid, wattles, and hocks; purple discoloration of wattles, comb, and legs; nasal discharge, coughing, and sneezing; incoordination; or diarrhea.

On post-mortem, HPAI lesions are variable and include edema and cyanosis of the head, wattle, and comb; excess fluid (may be blood-stained) in the nares and oral cavity; edema and diffuse subcutaneous hemorrhages on the feet and shanks; and petechia on the viscera and sometimes in the muscles. There may also be hemorrhages, edema and/or congestion in various internal organs including the lungs, as well as severe airsacculitis and peritonitis.

See CFSPH AI Disease Information, APHIS NVAP Exotic Avian Diseases, APHIS NVAP AI and Newcastle Disease, and the APHIS Website for Avian Influenza for additional training. See FSIS Science and Technology Seminar Series on U.S. HPAI Outbreak and Response.

FSIS IPP Responsibilities in HPAI Outbreak

PHVs and other IPP have specific responsibilities during HPAI outbreaks. FSIS Directive 6020.1 "Enhanced Inspection of Poultry in Response to a Notification of a HPAI Outbreak" instructs IPP at poultry slaughter establishments on conducting enhanced inspection for domestic poultry in the event of a HPAI outbreak. **Note:** The instructions in this directive are followed when FSIS issues specific instructions via an FSIS user notice. Do **not** implement this directive (instructions described in this section) unless FSIS issues specific instruction via an FSIS user notice.

When IPP receive notification that APHIS has designated a control area for HPAI to restrict poultry movement, IPP are to review FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions," Avian Influenza Training materials, and the establishment's sanitary and hygiene procedures and biosecurity measures.

If flocks originate from within an APHIS control area or if the establishment is located in an APHIS control area, IPP are to perform enhanced ante-mortem and post-mortem inspection. On ante-mortem, IPP verify that APHIS issued or signed a permit for movement of restricted animals. APHIS must give permission prior to moving the flock from a control zone.

On ante-mortem, PHVs are to examine live, moribund, and dead birds on each truckload of poultry represented by the permit for movement. PHVs should examine the poultry with special attention to clinical signs of HPAI, including lethargy, depression, ruffled feathers; watery white to green diarrhea; ataxia or torticollis; combs and wattles that exhibit a cyanotic (bluish) color, edematous appearance, and petechial hemorrhages at the tips; or hocks that exhibit subcutaneous hemorrhages and edema. If PHVs identify birds that exhibit clinical signs for HPAI, they are to quarantine the flock and contact the DO. APHIS will decide the appropriate disposition of the quarantined birds.

On post-mortem, PHVs are to notify on-line IPP to hang back all carcasses with viscera that exhibit signs of hemorrhage, congestion, necrosis, or edema for veterinary disposition and notify the PHV if the lot has a high incidence of airsacculitis. PHVs are to perform specific procedures on the carcasses that on-line IPP hang back, which are described in detail in FSIS Directive 6020.1 "Enhanced Inspection of Poultry in Response to a Notification of a HPAI Outbreak." The directive also provides specific post-mortem instructions to PHVs at NPIS establishments.

When PHVs determine any bird or carcass exhibits lesions consistent with HPAI, they are to stop the establishment from further slaughtering the flock, retain all carcasses and parts that have already been slaughtered, contact the DO, and provide the:

- Producers name, address, county, and phone number.
- Number and species of birds for slaughter.
- Conditions, signs, or lesions observed.
- PHVs contact information, including name, establishment number, and telephone numbers.

The DO will notify APHIS or the SAHO, who will provide specific instructions on how to handle the case.

Tuberculosis (TB)

TB is a contagious disease of both animals and humans. It is caused by three specific types of bacteria that are part of the Mycobacterium group: *M. bovis*, *M. avium*, and *M. tuberculosis*. Bovine TB, caused by *M. bovis*, can be transmitted from livestock to humans and other animals. Once the most prevalent infectious disease of cattle and swine in the U.S., bovine TB caused more losses among U.S. farm animals in the early part of the 20th century than all other infectious diseases combined.

The National Tuberculosis Eradication Program has nearly eradicated bovine TB from the Nation's livestock population. However, animal health officials continue to detect TB sporadically in livestock herds. APHIS bovine TB surveillance efforts focus primarily on identifying new sources of TB from *M. bovis* in bovines. APHIS relies greatly on the inspection efforts of FSIS IPP at federally inspected establishments to detect, retain, and submit granulomatous lesions suggestive of TB from cattle carcasses. To ensure a minimum level of sampling for national surveillance, APHIS has set a goal for IPP to collect a minimum of one granulomatous or other atypical lesion suggestive of TB per 2,000 normal unrestricted adult cattle. IPP are also to submit any granulomatous lesions from any cattle to the National Veterinary Services Laboratories (NVSL) in Ames, IA.

In addition to the ante-mortem and post-mortem regulations discussed in Multi-species Disposition Basics section, regulations relevant to TB include 9 CFR 77.17 (outlines requirements applicable to the interstate movement of TB reactor, suspect, or exposed cattle and the official means of identifying them) and 9 CFR 310.2 (requires an establishment collect all man-made ID devices from livestock, which IPP verify for purposes of reportable disease traceback).

As a PHV, you should be familiar with the TB policies and resources available to you. Much of your responsibilities as a PHV regarding TB are discussed in the Multi-species Disposition Basics section. FSIS Directive 6240.1 "Inspection, Sampling, and Disposition of Cattle for TB" provides instructions to IPP and PHVs regarding the inspection, sampling, and disposition of cattle identified by APHIS because of TB, or regular cattle found to have TB lesions on post-mortem. The directive also includes information on how to verify the establishment collects and maintains identification of livestock during slaughter and how to document slaughter of bovine with TB in PHIS. PHIS Help provides information on how IPP enter data for TB surveillance samples in PHIS.

APHIS Classifications of Cattle whose Movement is Restricted for TB

While you are not responsible for classifying TB restricted cattle, you should understand both IPP and the establishment's responsibilities when these cattle are presented for slaughter. APHIS defines TB reactors, suspects, and exposed cattle in APHIS's Cattle TB Eradication Uniform Methods and Rules (UMR).

- TB Reactor: shows a response to an official TB test and is classified as a reactor by the testing veterinarian or Designated Tuberculosis Epidemiologist.
- TB Suspect: shows a response to the Caudal Fold Tuberculin (CFT) test and is not classified as reactor; or has been classified as suspect by CCT tests; the bovine interferon gamma assay; or any other official test for TB.
- TB Exposed Category 1: cattle that have been moved from an infected herd before the time the infection was disclosed, but after the herd apparently became infected.
- TB Exposed Category 2: cattle that are part of a known affected herd that test negative or are untested.

- TB Exposed Unclassified: cattle classified as “exposed”; however exposed category is not specified and are therefore handled as under Category 2.

Considerations Relative to Collection of Man-Made ID Devices and Inspection

You should ensure IPP verify that the establishment is collecting and handling all man-made ID and maintaining such ID until post-mortem inspection is completed (9 CFR 310.2). These ID devices must be included with the TB sample submission.

To pinpoint the origin of new cases, NVSL may conduct DNA testing on tissue samples submitted for TB testing. Animal ID must be collected in a manner that preserves the integrity of the DNA identifying the affected cattle (removed from the carcass with a dime sized piece of hide attached to the tag; removed with hair/hair roots attached to the back tag; collected in a manner to minimize contamination with blood from more than one animal; and not cleaned).

Ante-mortem and Post-mortem Procedures of Restricted Cattle

Live cattle whose movement is restricted by APHIS for TB are accompanied by APHIS VS Form 1-27. When cattle with official TB ID (e.g., tuberculin brand or ear tag) without the proper accompanying paperwork identifying the animal (i.e. VS 1-27) or restricted cattle identified on the VS 1-27 without official TB ID are presented for ante-mortem, the PHV is to verify that the establishment has segregated the cattle from other livestock, maintains regulatory control of such cattle, and withholds such animals from slaughter until the PHV receives further instructions from APHIS.

As previously discussed in Multi-species Disposition Basics, there are specific ante- and post-mortem procedures the PHV and IPP must follow when TB restricted cattle arrive at the establishment for slaughter. You should refer to the instructions in FSIS Directive 6240.1 “Inspection, Sampling, and Disposition of Cattle for TB” to understand PHV and IPP responsibilities. As a supervisor, you ensure IPP are performing their duties in accordance with prescribed procedures.

On ante-mortem, these procedures will include the PHV completing a physical examination of the cattle, including taking temperatures of TB reactors; identifying the cattle as U.S. Suspects; and recording the reactor tag number on FSIS Form 6150-1. For restricted cattle that are dead-on-arrival, died in pens, or that are condemned on ante-mortem, the PHV will perform a necropsy and submit tissues per the directive.

For post-mortem, the PHV will coordinate with the establishment the orderly slaughter and thorough inspection of all restricted cattle passed for slaughter. The PHV will make all dispositions of cattle with TB based on requirements in 9 CFR 311.2. Whether the cattle receive Routine, Expanded, and/or Modified Expanded PM inspection procedures will vary depending on their TB status and the post-mortem findings. Refer to Table 1 in FSIS Directive 6240.1 “Inspection, Sampling, and Disposition of Cattle for TB” for more information.

TB Sampling

Slaughter surveillance is the primary means of detecting bovine TB and the success of the TB eradication program depends to a large degree on IPP efforts to identify and submit lesions resembling TB to the NVSL in Ames, IA.

You should ensure IPP are following standard sanitary procedures and good hygienic practices for maintaining personal equipment and hygiene after detecting or handling issues with granulomatous lesions.

Mycobacterium species cause granulomas. Most *M. bovis* granulomas are found in the thorax and in lymph nodes, but can also be found in the liver, spleen, and mesentery. TB granulomas can be granular to pyogenous in nature. Not all pyogenous granulomas are "acti". Complete incision of all lymph nodes is essential for identification because some granulomas can be very small.

Regardless of a cattle's age or TB status classification, IPP are to submit:

- All head and thoracic granulomas where TB lesions are most common and
- Any other granulomatous lesions suggestive of TB regardless of the anatomical location. Examples of these types of lesions can be found in FSIS Guideline No. 4 and APHIS's Tuberculosis Sample Submission Manual for Meat Inspection Personnel.

Note: All lesions resembling TB should be submitted from all regular kill cattle. This includes adults, feeder cattle, and calves. Other thoracic granulomas should also be submitted from all classes of cattle except those considered to be caused by coccidiomycosis found in feedlot steers and heifers. For TB reactors, the PHV will submit representative samples of lymph nodes of the head and thorax from TB Reactors when no lesions are observed.

For all **cattle** found with granulomatous lesions on PM, the PHV is to:

- Perform the Expanded Post-mortem inspection procedures described in Guideline No. 4, in addition to regular post-mortem inspection procedures.
- Record observations of all granulomatous lesions into Animal Disposition Reporting in PHIS.
- Submit all granulomatous lesions to NVSL.
- Retain the carcass whose disposition is pending laboratory results.
- Use professional judgment and laboratory results in making the appropriate final presumptive diagnosis based on gross pathology, stage of the disease, and overall condition of the carcass.
- Consider a histopathology result from NVSL, "Compatible with mycobacteriosis" as positive for *M. bovis*.
- Verify proper disposal of carcass and parts identified as positive for *M. bovis* in accordance with 9 CFR 311.2.

For **swine**, submit specimens to NVSL only from animals having generalized thoracic granulomas. For samples collected from swine suspected of having TB lesions that do not exhibit generalized thoracic granulomas, PHVs are to send samples to the Eastern Laboratory using the FSIS supplied yellow pathology boxes.

Step-by-step instructions for submitting the tissues for sampling and completing applicable paperwork are in FSIS Directive 6240.1 "Inspection, Sampling, and Disposition of Cattle for TB." PHIS Help provides information on how IPP enter data for TB surveillance samples in PHIS.

See FSIS Science and Technology Seminar Series on Bovine TB and TB Look-alikes and TB Sampling and Updates; and APHIS NVAP Bovine TB in Cattle for additional training.

Bovine Spongiform Encephalopathy (BSE)

BSE, also referred to as “mad cow disease,” is a progressive and fatal neurologic disease of cattle. It is caused by a “prion”, an abnormal cellular protein. BSE presents a public health concern because occurrences of variant Creutzfeldt-Jakob disease (CJD) in humans have been linked to the consumption of food containing ingredients derived from BSE-infected cattle. Cattle affected by BSE develop a progressive degeneration of the nervous system. Clinical signs may include gait abnormalities (particularly hindlimb ataxia) and difficulty negotiating obstacles, low carriage of the head, hyperresponsiveness to stimuli, tremors and behavioral changes such as aggression, nervousness or apprehension, and changes in temperament. Nonspecific signs include loss of condition, weight loss, and teeth grinding. A combination of behavioral changes, hyperactivity to stimuli, and gait abnormalities is highly suggestive of BSE, but some animals exhibit only one category of neurologic signs. There are no gross post-mortem lesions found in BSE, with the exception of nonspecific signs, such as emaciation or wasting.

See CFSPH BSE Disease Information and APHIS webpage on Bovine Spongiform Encephalopathy for more information.

FSIS designates certain materials from cattle as Specified Risk Materials (SRMs), declares these materials inedible, and prohibits the use of these materials for human food (9 CFR 310.22(a) and (b)). The materials identified as SRMs are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebra of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the distal ileum of the small intestine and tonsils from all cattle. FSIS designates these materials as SRMs because they have been found to contain BSE infectivity at some point during the disease incubation period.

Establishments that slaughter and/or process cattle are required to incorporate procedures for removal, segregation, and disposition of SRMs into their HACCP plans, Sanitation SOPs, or other prerequisite program (9 CFR 310.22(e)(1)). They must also routinely evaluate the effectiveness of their procedures and revise the procedures as necessary (9 CFR 310.22(e)(3)). They must maintain daily records sufficient to document the implementation and monitoring of all SRM procedures (9 CFR 310.22(e)(4)(i)). Establishments must also take corrective actions when either the establishment or FSIS determines that the establishment’s SRM removal procedures have failed (9 CFR 310.22(e)(2)). FSIS IPP verify the establishment meets the regulatory requirements by following instructions in FSIS Directive 6100.4 “Verification Instructions Related to SRM in Cattle of All Ages.” FSIS Website SRM Resources also has additional resources regarding SRM.

IPP SRM Verification Activities in Cattle of All Ages

IPP verification includes verifying establishments have performed a hazard analysis and assessed whether SRMs represent a food safety hazard; directly observing establishment employees performing segregation, removal, and disposal of SRMs; reinspecting cattle carcasses and parts after removal of SRMs to verify the products are free of SRMs; and reviewing of records. IPP document this verification using the SRM Control Verification Task in PHIS. As a supervisor, you will ensure IPP are performing these duties in accordance with prescribed inspection methods and procedures.

Note: IPP are to verify the spinal cords from carcasses of cattle 30 months and older are removed at the establishment where the cattle are slaughtered (9 CFR 310.22(c)). The only beef products containing SRMs that may be transported from one federally-inspected facility to another for further processing and removal are carcasses (from cattle 30 months of age and older) with the vertebral column still intact (9 CFR 310.22(g)). In such cases, IPP at the shipping and receiving establishments have specific verification activities they must complete, as detailed in FSIS Directive 6100.4 "Verification Instructions Related to SRM in Cattle of All Ages."

Reviewing Records

IPP are to verify establishments have written SRM procedures and maintain daily records demonstrating that those establishments effectively segregate, remove, and dispose of SRMs. The written procedures must be incorporated into the establishment's HACCP, Sanitation SOPs, or PRPs. The establishment should sufficiently document daily the procedures performed, the establishment monitoring, and the results of establishment monitoring. IPP verify that records demonstrate carcasses containing SRMs are correctly identified and handled throughout slaughter and fabrication until the SRMs are removed and disposed of. IPP also verify that any corrective actions performed meet the regulatory requirements and determine if any changes to the food safety system made after noncompliant product with SRMs is found are adequate and effective. As a supervisor, you assist IPP in making supportable decisions about the adequacy of the establishment's food safety systems.

Verifying Sanitation – Slaughter and Processing

Both on-line and off-line IPP have sanitation verification responsibilities. When inspecting heads, viscera, and carcasses, on-line IPP ensure that carcasses/parts are not contaminated visibly with SRM tissue displaced from its normal anatomical location at the time of inspection and that visible SRM contamination of the head, viscera, or carcass is removed in a satisfactory and sanitary manner before completing inspection and passing the carcass/part. On-line IPP notify off-line IPP whenever the establishment fails to consistently present carcasses and parts for inspection that are free of visibly intact and identifiable SRM contamination.

The SRM regulations require establishments to clean and sanitize food contact surfaces used to cut through SRMs from cattle 30 months of age and older before using on cattle less than 30 months of age with 180°F water or chemical equivalent (9 CFR 310.22(f)(1)(ii)). Routine sanitary procedures are required and performed on equipment or food contact surfaces with visibly intact and identifiable SRM tissue (9 CFR 310.22(f)(2)). During slaughter, IPP verify that the establishment uses routine sanitary procedures whenever equipment is contaminated with visibly intact or identifiable SRM material to prevent adulteration of edible product. IPP also verify that the establishment cleans and sanitizes all equipment used to cut through SRMs from cattle 30 months and older before using on cattle less than 30 months of age or that the establishment handles all cattle as 30 months and older.

Note: Also during slaughter, IPP verify the establishment is not using any captive bolt stunning devices that inject air into the cranium of cattle per 9 CFR 313.15(b)(2)(ii).

Verifying Age Using Dentition or Livestock Producer Records

Identification of SRMs is dependent on accurate determination of cattle age. Establishments may determine age of cattle using dentition or accurate livestock producer records.

When establishments make age determinations by examining cattle dentition, IPP are to ensure those age determinations are consistent with FSIS guidelines. FSIS considers cattle that exhibit eruption of

one or both of the second set of permanent incisors (i.e., third or fourth permanent incisor) above the gum line to be 30 months or older in age. Off-line IPP verify establishments are using this standard by observing employees performing dentition examinations; verifying that the employee correctly determines and records the age per their written procedures and identifies the carcass according to establishment procedures; performing dentition checks and comparing inspection results with establishment results; and reviewing establishment records documenting procedures performed as above.

When establishments determine cattle age using livestock producer records, IPP verify that producer records are sufficient to accurately identify the particular cattle and indicate the age of cattle. More specific instruction on what IPP should verify concerning producer records is provided in FSIS Directive 6100.4 "Verification Instructions Related to SRM in Cattle of All Ages." If IPP determine that records are not sufficient or show a significant discrepancy between records and dentition, you as the PHV have the authority to reject the establishment's determination, use dentition to age the cattle, and take regulatory control action when necessary.

Removal of Tonsils and Distal Ileum

Tonsils (existing in the head and tongue) and the distal ileum are SRMs in all ages of cattle and IPP verify the establishment effectively identifies, removes, and disposes of these SRMs. Detailed instructions on IPP verification are located in FSIS Directive 6100.4 "Verification Instructions Related to SRM in Cattle of All Ages." When shipping beef market heads, the establishment must remove the lingual and palatine tonsils before the market heads or tongues enter commerce. (**Note:** The remaining tonsils in beef market heads are typically discarded with the gullet-larynx and the skull not used for human food.) The establishment must identify, remove, and dispose of no less than 80 inches of uncoiled, unstretched, and trimmed distal end of small intestine as measured from the ceco-colic junction (9 CFR 310.22(d)).

Segregation and Disposal of SRMs

Off-line IPP verify the establishment segregates cattle 30 months of age and older from cattle less than 30 months of age during slaughter and processing, or that the establishment handles all cattle as 30 months of age and older. Off-line IPP also verify the establishment maintains the identity of carcasses 30 months of age and older or parts with SRMs throughout slaughter and final processing.

IPP also verify that SRMs removed from the carcasses and parts of cattle are segregated from edible materials and disposed of in accordance with 9 CFR 314.1 or 314.3. IPP verify that SRMs are handled as condemned product and denatured prior to transport or rendered on site.

SRM Noncompliance and Enforcement

IPP document noncompliance when they determine the establishment does not meet the regulatory requirements while performing SRM related tasks. Examples of noncompliance include a failure of the establishment to implement written SRM control procedures or the production or packaging of processed product with visibly identifiable SRM. When IPP determine there is noncompliance, they are to take appropriate RCA and retain adulterated product; notify the establishment; verify the establishment takes corrective actions regarding any edible product adulterated with SRMs, restores sanitary conditions, and properly disposes of SRMs; and document noncompliance. If adulterated product has shipped into commerce, IPP are to immediately notify their chain-of-command.

Mechanically Separated (MS) and Advanced Meat Recovery (AMR)

MS beef is prohibited from use for human food. MS product has a paste-like consistency as a result of forcing bones, with attached edible meat, under high pressure through a sieve or similar device to separate the bone from the edible meat tissue. The MS process usually crushes bones, resulting in a product that contains high levels of calcium, iron and any nervous tissue that may be associated with the bones used.

AMR also removes muscle tissue from the bone of beef carcasses under high pressure. However, in contrast to MS product, this is achieved without incorporating bone material into the product. The AMR process is sometimes referred to as a "soft" extrusion method. An AMR product can be labeled as "meat." Regulations define the materials that may go into the process and what may be contained in the recovered product. "Meat" may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or DRG (9 CFR 318.24). SRMs are never permitted as raw materials for AMR product. Recycled, crushed, or spent beef skulls and vertebral bones of any cattle are prohibited as an ingredient in any meat food product.

Establishments must develop, implement, and maintain procedures to ensure product derived from livestock AMR systems meets the requirements of 9 CFR 318.24. IPP have specific verification activities in livestock establishments that produce AMR, including additional verification in beef AMR producing establishments, which are described in FSIS Directive 7160.3 "Verification Activities for AMR Systems." These activities include verifying the establishment's procedures and conducting FSIS sampling of beef AMR products.

BSE Surveillance

APHIS conducts a BSE surveillance program which includes the collection of brain samples from cattle that display signs of a CNS disorder. IPP responsibilities regarding this program are described in FSIS Directive 10400.1 "Sample Collection from Cattle Under the BSE Ongoing Surveillance Program." As described in FSIS Directive 6000.1 "Responsibilities Related to FADs and Reportable Conditions," PHVs report animals exhibiting CNS signs (e.g., head pressing, head tilt, circling) to APHIS through their chain of command. For cattle surveillance sample collection, local procedures will vary. Consult with your FLS for further information on these procedures.

Canadian Cattle, Sheep, and Goat Imports

Instructions to IPP on APHIS requirements regarding the receipt, slaughter, and inspection of live cattle, sheep, and goats imported or originating from Canada are found in FSIS Directive 9530.1 "Importation of Live Canadian Cattle, Sheep, and Goats into the U.S."

OTHER FAD/RADS

Below is a list of additional FAD/RADs with links to additional factsheets and trainings. Remember, while you are not responsible for diagnosing specific FAD/RADs, it is your responsibility to ensure you and your team observe for signs, symptoms, and history that may be evidence of FAD/RADs and report these through your chain of command.

Also see CFSPH Disease Information, APHIS FAD PReP Ready Reference Guides and APHIS NVAP Training Modules for additional information and training.

Virulent Newcastle Disease

Virulent Newcastle disease is a contagious and fatal viral disease affecting the respiratory, nervous, and digestive systems of birds and poultry. The disease is so virulent that many poultry die without showing any clinical signs. Clinical signs vary depending on the pathogenicity of the isolate and the species of bird. They may include respiratory disease with coughing, gasping, sneezing, and rales. Lethargy, inappetence, ruffled feathers, and conjunctival reddening and edema may be seen. Some birds develop watery, greenish, or white diarrhea, cyanosis, and swelling of the tissues of the head and neck. Neurological signs may occur, including tremors, clonic spasms, paresis, or paralysis of the wings and/or legs, torticollis, and circling.

On post-mortem, the head or periorbital region may be swollen, and the interstitial tissue of the neck can be edematous, especially near the thoracic inlet. Congestion or hemorrhages are sometimes found in the caudal pharynx and tracheal mucosa, and diphtheritic membranes may occur in the oropharynx, trachea, and esophagus. Petechia and small ecchymoses may be seen in the mucosa of the proventriculus. Hemorrhages, ulcers, edema and/or necrosis often occur in the cecal tonsils and lymphoid tissues of the intestinal wall. Thymic and bursal hemorrhages may also be present. The spleen may be enlarged, friable, and dark red or mottled. Some birds also have pancreatic necrosis and pulmonary edema. The ovaries are often edematous or degenerated and may contain hemorrhages.

See CFSPH Newcastle Disease Information, APHIS NVAP Exotic Avian Diseases, APHIS NVAP AI and Newcastle Disease, and the APHIS Website for Virulent Newcastle Disease for additional training.

Brucellosis

Brucellosis is a contagious, infectious, and communicable disease primarily affecting cattle, bison, and swine. The most obvious signs in pregnant animals are abortion or birth of weak calves. Other signs of brucellosis include retained afterbirths with resulting uterine infection and occasionally enlarged, arthritic joints.

On post-mortem, the placenta is usually edematous and hyperemic after a reproductive loss. Aborted fetuses may appear normal, be autolyzed, or have evidence of a generalized bacterial infection. Some females may have metritis. Epididymitis, orchitis and seminal vesiculitis, with inflammatory lesions, abscesses or calcified foci may be observed in males. Abscesses and granulomatous inflammation may also be found in many other organs and tissues.

The regulations of the APHIS Brucellosis Eradication Program vary based on the brucellosis status of each state. Check with your supervisor for local testing requirements at your duty station. See the CFSPH Brucellosis Disease Information and APHIS National Brucellosis Eradication Program for more information.

See MOU between FSIS and APHIS regarding surveillance for brucellosis. See also FSIS Directive 6600.2 “Inspection Procedures Related to Feral Swine and Reactor Pigs” for additional supervisory responsibilities at establishments where IPP inspect feral swine and reactor pigs suspected of having brucellosis.

Vesicular Diseases

Vesicular Stomatitis (VS) is a viral disease which causes blister-like lesions to form in the mouth and on the dental pad, tongue, lips, nostrils, hooves, and teats. These blisters swell and break, leaving raw

tissue that is so painful that infected animals generally refuse to eat and drink and show signs of lameness. Severe weight loss usually follows. Post-mortem lesions resemble the lesions in live animals. The disease primarily affects horses, cattle, and swine, though it can occasionally infect sheep and goats. While VS can cause economic losses to livestock producers, it is a particularly significant disease because its outward signs are similar to those of Foot and Mouth Disease and Swine Vesicular Disease, both of which are foreign animal diseases. See the AHPIS Website on Vesicular Stomatitis and CFSPH VS Disease Information for additional information.

Foot and Mouth Disease (FMD) is a highly contagious viral disease affecting cows, pigs, sheep, goats, and other animals with divided hooves. FMD has been eradicated from the U.S. FMD can spread quickly and cause significant economic losses. A single detection of FMD will likely stop international trade completely for a period of time. Clinical signs of the disease include vesicles that quickly pop and cause erosions in the mouth or on the feet. Vesicles may also occur on the mammary gland. Other signs include fever, anorexia, depression, excessive salivation, lameness, and abortions. On post-mortem, earliest lesions can appear as small pale areas or vesicles, while ruptured vesicles become red, eroded areas or ulcers. Erosions may be covered with a gray fibrinous coating. Loss of vesicular fluid through the epidermis can lead to the development of "dry" lesions, which appear necrotic rather than vesicular (particularly common in the oral cavity of pigs). Location and prominence of lesions can differ with species; however common sites for lesions include the oral cavity and snout/muzzle; the heel, coronary band, and feet; the teats or udder; pressure points of the legs; the ruminal pillars; and the prepuce or vulva. In young animals, cardiac degeneration and necrosis can result in irregular gray or yellow lesions, including streaking in the myocardium. See "Foot and Mouth Disease" in the IPP Help Media Library, CFSPH FMD Disease Information, and the APHIS Website on Foot and Mouth Disease for additional training.

Swine Vesicular Disease is a viral disease of pigs that is characterized by the formation of vesicles and erosions on the hooves and around the mouth. Post-mortem lesions are the same vesicles seen in live pigs. Clinical signs vary in severity but are typically short and not life-threatening. However, the disease strongly resembles other vesicular diseases, including FMD, and thus must be rapidly differentiated. Swine vesicular disease can cause economic losses from export restrictions. See CFSPH SVD Disease Information for additional information.

See "Vesicular Diseases" in the IPP Help Media Library and APHIS NVAP Vesicular Diseases for additional training.

Classical Swine Fever

Classical Swine Fever (CSF) is a highly contagious and economically significant viral disease of pigs. CSF has been eradicated from the U.S. Signs of CSF vary with the strain of virus and the age and susceptibility of the pigs. High fever, huddling, constipation followed by diarrhea, and reddened eyes are often seen. The skin may show hemorrhages with discoloration of the ears, abdomen, or inner thighs. Young pigs may have incoordination or weakness. The disease can adversely affect reproduction with sows aborting or delivering stillborn or malformed piglets. In acute CSF, morbidity and mortality are high.

On post-mortem, lesions are highly variable. In acute disease, the most common lesion is hemorrhage. The skin may be discolored purple, and the lymph nodes may be swollen and hemorrhagic. Petechial or ecchymotic hemorrhages can often be seen on serosal and mucosal surfaces. Hemorrhagic lesions may be seen in the GI tract. Straw-colored fluid may be found in the peritoneal and thoracic cavities

and the pericardial sac. Severe tonsillitis, sometimes with necrotic foci, is common. Splenic infarcts are seen occasionally. Lungs may be congested and hemorrhagic.

See the APHIS Website on Classical Swine Fever and CFSPH CSF Disease Information for additional information.

African Swine Fever

African Swine Fever (ASF) is a highly contagious and deadly viral disease affecting both domestic and feral swine of all ages. ASF has never been found in the U.S. ASF would have significant impact on U.S. livestock producers, their communities, and the economy.

ASF can present as peracute, acute, subacute, or chronic disease. Sudden deaths with few lesions may occur in peracute cases. Acute cases are characterized by a high fever, anorexia, lethargy, weakness, and recumbency. Erythema can be seen. Some pigs develop cyanotic skin blotching especially on the ears, tail, lower legs, or hams. Diarrhea, constipation, vomiting and abdominal pain may be seen. Other hemorrhagic signs, including epistaxis and hemorrhages in the skin may occur. Respiratory signs, including dyspnea, nasal and conjunctival discharges, and neurological signs have been reported. Pregnant animals may abort. Subacute ASF is similar, but with less severe signs. Pigs with the chronic form have nonspecific signs such as intermittent low fever, appetite loss and depression. Coughing, diarrhea, and vomiting may occur. Ulcers and reddened or raised necrotic skin foci may appear.

On post-mortem, gross lesions are highly variable and influenced by the virulence of the isolate and the course of the disease. Numerous organs may be affected. The major internal lesions are hemorrhagic and occur most consistently in the spleen, lymph nodes, kidneys, and heart. The spleen can be very large, friable, and dark red to black. The lymph nodes are often swollen and hemorrhagic and may look like blood clots. Petechia are common on the cortical and cut surfaces of the kidneys and sometimes in the renal pelvis. Perirenal edema may be present. Hemorrhages, petechia, and/or ecchymosis sometimes occur in other organs and pulmonary edema and congestion can occur. There may also be congestion of the liver and edema in the wall of the gallbladder and bile duct. The pleural, pericardial and/or peritoneal cavities may contain straw colored or blood-stained fluid.

See FSIS Science and Technology Seminar Series on African Swine Fever, CFSPH ASF Disease Information, and the APHIS Website for African Swine Fever for more information.

Contagious Bovine Pleuropneumonia

Contagious bovine pleuropneumonia (CBPP) is caused by *Mycoplasma mycoides*. The disease has been eradicated from the U.S. Some cattle die peracutely with no clinical signs. Acute cases are characterized by signs of fever, loss of appetite, and depression followed by respiratory signs which may include coughing, purulent or mucoid nasal discharge and rapid respiration. Some cases progress to dyspnea, and respiration can be painful. Severely affected cattle may stand with their head and neck extended, forelegs apart, breathing through their mouth. Epistaxis, diarrhea, and abortions or stillbirths may occur. In calves up to six months of age, the primary sign may be polyarthritis.

On post-mortem, the lesions are often unilateral. In acute disease, large amounts of straw-colored fluid may be present in the thoracic cavity and pericardial sac. The lymph nodes of the chest are enlarged, edematous, and may contain petechia and small necrotic foci. The lungs are consolidated and typically marbled; areas of different color (pale pink, red, and dark red) may be separated by a network of pale bands. Extensive fibrin accumulation can be found on the pleural surfaces and within the interlobular

septa, causing enlargement of the septa. Necrotic lung tissue becomes encapsulated, forming pulmonary sequestra.

See the APHIS CBPP FAD PReP and CFSPH CBPP Disease Information for additional information.

Rinderpest

Rinderpest is an acute, highly contagious, viral disease of cattle and domesticated buffalo. Rinderpest was the first animal disease to be globally eradicated. Clinical signs vary in severity depending on the virulence of the strain and resistance of the infected animal. In the peracute form, high fever and sudden death are seen. In the acute form, a period of fever, depression, decreased appetite, congestion of mucous membranes, and serous ocular and nasal discharge occurs, followed by development of necrotic oral lesions. Necrotic epithelium can be found on the lips, tongue, gums, buccal mucosa, soft and hard palates. These lesions begin as pinpoints but enlarge rapidly to form gray plaques or a thick, yellow pseudomembrane. They slough to form shallow, nonhemorrhagic erosions. The muzzle eventually dries and develops cracks, and the animal becomes anorexic and develops mucopurulent ocular and nasal discharge. Profuse watery diarrhea starts after the onset of oral necrosis. Severe abdominal pain, thirst, and tenesmus often accompany the diarrhea. Dyspnea and a maculopapular rash may be seen in sparsely haired areas.

On post-mortem, dehydration, emaciation, and sunken eyes may be seen. Congestion, pinhead or larger gray necrotic foci, or extensive necrosis and erosions may be seen in the oral cavity. Necrotic areas are sharply demarcated from healthy mucosa and often extend to the soft palate, pharynx, and upper esophagus. Necrotic plaques are occasionally found on the pillars of the rumen and erosions and hemorrhage may be seen in the omasum. Severe congestion, petechiation and edema may be found in the abomasum. White necrotic foci may be seen in Peyer's patches. In the large intestine, blood and blood clots may be found in the lumen and edema, erosions, and congestion may be seen in the walls. The ileocecal valve, cecal tonsil, and crests of the longitudinal folds of the cecal, colonic, and rectal mucosa may be greatly congested in animals that die acutely or may be darkened in more chronic cases. Lymph nodes are usually enlarged and edematous, and the spleen may be slightly larger than normal. Congestion and secondary bronchopneumonia may be present in the lungs.

See CFSPH Rinderpest Disease Information for additional information.

Heartwater

Heartwater is a rickettsial disease of ruminants. Peracute disease is rare and can cause sudden death and terminal convulsions, preceded by fever, severe respiratory distress, hyperesthesia, and lacrimation. Acute disease is more common, and initially presents with sudden fever, anorexia, listlessness, congested mucous membranes and respiratory signs (moist cough, bronchial rales, rapid breathing) which can progress to dyspnea. Some animals have diarrhea. Neurological signs often develop, including chewing movements, protrusion of the tongue, twitching of the eyelids and circling, and a high-stepping gait. Some animals stand rigidly with muscle tremors or become aggressive or anxious. As the disease progresses, the neurological signs become more severe, and the animal goes into convulsions. In terminal stages, lateral recumbency with paddling or galloping movements, opisthotonos, hyperesthesia, nystagmus and frothing at the mouth are common.

Post-mortem lesions include hydropericardium with straw-colored to reddish pericardial fluid (more consistently found in sheep and goats than in cattle), pulmonary and mediastinal edema, froth in the trachea, hydrothorax, ascites, perirenal edema, and edema of the mediastinal and bronchial lymph

nodes. There may also be congestion and/or edema in the GI tract. Subendocardial petechial hemorrhages are common and submucosal and subserosal hemorrhages may also be seen in other organs. Splenomegaly may occur.

See the APHIS FAD Heartwater PReP and CFSPH Heartwater Disease Information for more information.

Sheep and Goat Pox

Sheep pox and goat pox are contagious viral diseases of small ruminants. Sheep and goat pox have the potential to cause significant economic consequences and can limit trade. Clinical signs in sheep and goats appear similar and include fever, enlarged superficial lymph nodes, oculonasal discharge, and poxvirus lesions that may affect the skin, mucous membranes, and internal organs. Skin lesions tend to be more frequent and visible on sparsely wooled/haired skin such as the axillae, muzzle, eyelids, ears, mammary gland, and inguinal area. Skin lesions begin as erythematous macules and develop into hard papules. The center of the papules become depressed, whitish gray and necrotic, and are surrounded by an area of hyperemia. They eventually develop dark, hard, sharply demarcated scabs. Mucosal lesions can develop at various sites including the mouth, nares, eyes, anus, vagina, and prepuce. These tend to ulcerate or become necrotic. Oral and nasal lesions can cause inappetence, rhinitis, and excessive salivation. Papules on the eyelids and ocular lesions can result in blepharitis and conjunctivitis. Other signs vary but can include depression, coughing and dyspnea, diarrhea, and emaciation. Some animals may abort.

On post-mortem, the skin usually contains macules, papules, and/or necrotic lesions and scabs surrounded by areas of edema, hemorrhage, and congestion. The papules penetrate through both the dermis and epidermis and in severe cases may extend into the musculature. Mucous membranes of the eyes, nose, mouth, vulva, and prepuce may be necrotic or ulcerated. Lungs often contain congested, edematous, or consolidated areas and firm gray or white nodules. Papules or ulcerated papules are common on the abomasal mucosa. Nodules, papules, and other lesions may also be found in other parts of the digestive tract, including the rumen, large intestine, pharynx, trachea, and esophagus. Pale, discrete subcapsular foci are sometimes present on the surface of the kidney, liver, and testes. Lymph nodes throughout the body are usually enlarged and edematous, and they may be congested and hemorrhagic.

See the APHIS FAD Sheep Pox/Goat Pox PReP and CFSPH Sheep Pox/Goat Pox Disease Information for more information.

Scrapie

Scrapie is a progressive disease affecting the CNS of sheep and goats and belongs to a group of diseases called transmissible spongiform encephalopathies. APHIS manages a National Scrapie Eradication Program. As described in FSIS Directive 6000.1 “Responsibilities Related to FADs and Reportable Conditions,” PHVs report animals exhibiting CNS signs (e.g., head pressing, head tilt, circling) to APHIS through their chain of command. APHIS will determine if samples need to be collected.

Clinical signs of classical scrapie can be variable in sheep. The first signs are usually behavioral. Sheep tend to stand apart from the flock and may either trail or lead when the flock is driven. Other common signs include hypersensitivity to stimuli, a fixed stare, ataxia and/or a high-stepping or unusual hopping gait. Animals may develop tremors, grind their teeth, and have an impaired menace response

or carry their heads low. Many sheep become intensely pruritic and may rub, scrape, or chew at these areas. Loss of condition is common in the early stages and significant weight loss or emaciation may be seen later in the disease. Some goats have neurologic and behavioral signs similar to those in sheep, though pruritis seems to be less common. Clinical signs of atypical scrapie include incoordination and ataxia in sheep.

There are no characteristic gross lesions in classical or atypical scrapie on post-mortem, although there may be nonspecific changes such as wasting or emaciation, and skin or wool lesions resulting from pruritis.

See CFSPH Scrapie Disease Information and APHIS NVAP Sheep and Goats: Disease Awareness for additional training.

Screwworm Myiasis

Screwworms are fly larvae that feed on living flesh that infest all mammals and rarely, birds. Screwworms can infest a wide variety of wounds and are very common in the navels of newborns and the vulval and perineal regions of their dams. If a screwworm deposits its eggs on a mucous membrane, the larva may enter any orifice including the nostrils, sinuses, mouth, orbits of the eye, ears, or genitalia. Clinical signs initially appear as slight motion inside the wound. The wound gradually enlarges and deepens and often has a serosanguinous discharge and distinctive odor. By the third day of infestation the larvae are easily found inside the wound. They generally do not crawl on the surface and tend to burrow deeper when disturbed. Sometimes there may be large pockets of larvae with only small openings in the skin. Screwworms may be found post-mortem in any wound.

See CFSPH Screwworm Myiasis Disease Information for more information.

Preparation for Mentoring

OBJECTIVES

1. Become familiar with the concept of being a mentor.
2. Become familiar with the requirements of mentees.
3. Become familiar with the interpersonal and professional relationship aspects of a mentorship situation.

RESOURCES

PHV Intern/Trainee Guide for Veterinary Mentors of Procedures to Demonstrate and Evaluate
Employee Help: FSIS Mentoring Resources (VPN required)
OPM Mentorship Resources

INTRODUCTION

Mentoring is a process that focuses specifically on providing guidance, direction, and career advice. It is instrumental to maximize learning and development. The success of mentoring is greatly dependent upon clearly defined roles and expectations, in addition to participants' awareness of the benefits of participating in the mentoring program. Your commitment to mentorship is essential to the experience. This module will explore the roles of the mentor and mentee, how to prepare for mentorship, and the benefits you'll gain when participating in this program.

There are many types of mentoring. This section focuses on the formal mentoring program you will complete as part of your training. As a new PHV, part of your initial training is a three-week mentoring program in which you work with a PHV mentor (or mentors) in one or more establishments. During this time, you gain hands-on experience to achieve basic awareness/proficiency in the procedures required by your position, as well as a better understanding of and application of related policies you learned in class.

BENEFITS OF MENTORING

Benefits of mentoring are shared by both mentors and mentees. Mentors can experience renewed enthusiasm for the role of expert; enhance their skills in coaching, counseling, listening, and modeling; develop a more personal style of leadership; demonstrate expertise and share knowledge; and increase generational awareness. They can gain friendship and exposure to new ideas.

Mentees benefit from mentoring by receiving a smoother transition into the workforce; furthering their professional development; applying formal study/training to the workplace; developing new or different perspectives; getting assistance with ideas; demonstrating and exploring their strengths and potential; and increasing career networks.

RESPONSIBILITIES OF MENTORS AND MENTEES

Both mentors and mentees have responsibilities during mentoring.

Mentor Responsibilities

PHV mentors complete a training course that prepares them to be successful mentors. The course covers PHV Training Course logistics, mentor responsibilities and benefits, soft skills such as emotional intelligence, the PHV Mentoring checklist, and challenges of the PHV position. PHV mentors provide advice, guidance, and subject-matter expertise. In this program, the PHV mentors will complete and submit a PHV Mentoring checklist that verifies you have demonstrated basic awareness and proficiency in PHV procedures and concepts necessary to your position.

Some PHVs volunteer to be mentors, while others are assigned the responsibility. All mentors have their own unique experiences and backgrounds. Forming a network of mentors you can consult with will be most beneficial to your career.

PHV Mentee Responsibilities

As a mentee, you too have responsibilities in the mentoring program. Your attention to and preparation for this program will greatly improve the value of your experience. You should be familiar with and regularly consult your PHV Mentoring checklist to determine your progress and speak up if you notice areas you still need to cover.

Be actively engaged in the mentoring process. Consider your own learning style and your mentor's teaching style and find a balance that works for both of you. For example, if you prefer to absorb facts before proceeding with a task, but your mentor is action-oriented and prefers to take up a task without reading the directions first, consider how you could approach this during your mentoring. Perhaps you could ask your mentor what they plan to work with you on tomorrow, so you can spend some time reading in advance. Or perhaps you dive into the task with your mentor and jot down your notes and questions along the way, so you can read up on those later. Ask questions and speak up if there are procedures or concepts with which you need additional information or experience.

Engage in effective listening. Focus first on what your mentor says, instead of what you plan to say next. After you hear what your mentor says, paraphrase the information/question back to them, to verify you understood. For example, you could say "Let me make sure I'm with you so far…". Then, to elicit more information, you can use "door-openers" like "I'd like to hear more about….". This will result in a more engaging information exchange between you and your mentor.

If you are not clear on your upcoming schedule, proactively reach out to who is managing your schedule for clarification. If you have major concerns with how the experience is progressing, you should contact your supervisor as soon as possible.

MENTEE BEST PRACTICES

To get the most out of your mentoring experience, consider the following mentee best practices you can apply. These are suggested practices, and the mentorship program is an opportunity for that practice. Even if you don't emulate each practice to perfection, the experience of trying will likely enhance what you get out of the program.

- Be confident. Confidence is an important characteristic for a mentee. Remember that despite being new to this position, every PHV mentee has valuable experience to bring to the relationship. If you struggle with confidence, try completing exercises to boost your confidence prior to your mentoring – such as affirmations or courage rituals. Being confident will enhance your mentoring experience.

- Build rapport and connection with your mentor. Identifying similarities early on between you and your mentor can help establish connection. Consider sharing information about yourself with your mentor and asking them questions about themselves.
- Be trustworthy – for example, if your mentor shares experiences with you about times where they were wrong and learned from their mistakes, keep this information in confidence.
- Provide gratitude towards your mentor by expressing your appreciation for their role. A simple "thank you" or an e-mail to your mentor's supervisor expressing your gratitude is a great way to show you appreciate your mentor.
- Proactively seek out and understand your mentor's expectations. Ask questions of your mentor such as "What's your recommendation for next steps before we meet tomorrow?" Then, act on those expectations.
- Consider any SMART goals you want to achieve during your mentoring experience. At a minimum, you will complete the PHV Mentoring checklist. However, it's a good idea to take time in advance to consider any goals you personally want to accomplish. Discuss your goals with your mentor from the beginning.
- Ask for critical feedback. Some individuals may be reluctant to give critical feedback. Asking for feedback proactively can help you identify your strengths and weaknesses, and help you prioritize your learning.

CHALLENGES DURING MENTORSHIP

Challenges are a normal part of a mentoring relationship. Being aware of and prepared for these challenges will help you navigate through them successfully. Most importantly, if the experience is not accomplishing your goals, you need to communicate this with your supervisor.

- Short-staffing and limited time can be a challenge during mentoring. These are challenges you may face even after mentoring, so mentoring is a good opportunity to see how your PHV mentor tackles these challenges. It is important to be respectful of your mentor's time, but just as important that you are achieving your mentoring goals. Be prepared to be flexible and work with your mentor, but also be prepared to take the initiative where necessary to ensure you achieve your goals. Do not be hesitant to ask your mentor for help in specific areas, when needed.
- Job culture shock may be something you experience as you begin visiting inspected establishments and learning your role as a PHV. Expect that it may take some time to acclimate to your new role. You may feel overwhelmed with the amount of new information that is necessary to learn. Ask for support from your mentor, colleagues, or personal contacts. Remember to take time to focus on your personal health and wellbeing during this time of transition.
- Travel and separation from your home, family, and pets can be a challenge during your mentorship, especially if you have to travel far from home. If it hasn't already been provided to you, ask your mentors and supervisor for advice on travel – where to stay, where to eat, what to do. Planning in advance and expecting some travel will better prepare you for this time.
- Every individual is unique and has their own background and experiences. You may have much in common with your mentor, or you may work to find common ground. Be flexible and plan to proactively work towards effectively communicating with your mentor. Differences can lead to learning opportunities for both you and your mentor. If you are struggling significantly with compatibility between you and your mentor, reach out to your supervisor.

Expecting and preparing for the challenges that come with mentorship will ensure you have the most beneficial experience possible. In addition to asking for help from your supervisor, colleagues, and mentor, consider reaching out to the Employee Assistance Program and WorkLife4You Program if you need additional support.

MENTORSHIP BEYOND TRAINING

After your formal mentorship, you may seek out additional mentoring opportunities. You and your mentor may continue to have a mentoring relationship, if you both have agreed to do so. You may seek out other mentors, formally or informally. You may become a mentor yourself! The benefits of mentoring continue beyond this formal training program.

As with our formal mentorship program, preparation for future mentoring opportunities is important to your success. Check out the resources section to learn more about how to expand your network, seek out new mentoring opportunities, or learn to be a mentor yourself. Keep an eye out for Agency e-mails that provide mentoring resources and formal mentoring programs. Add mentoring to your Individual Development Plan and ask your supervisor if they have any suggestions.

FSIS Statutes and Your Role

OBJECTIVES

1. Understand the purpose of the Acts.
2. Identify key definitions from the Acts.
3. Understand the statutory authority for FSIS activities.
4. Understand how those activities plus authorities in the statutes support enforcement actions.

RESOURCES

FSIS Webpage: Food Safety Acts

INTRODUCTION

This module is a brief review of what you covered in the Inspection Methods course. As we go through this module, keep in mind the inspection and verification activities you performed or supervised while in the establishment working alongside your mentor. It's important for us to discuss some practical examples of how the statutory authorities apply to your work.

OVERVIEW OF THE STATUTES

The statutes related to FSIS activities include the:

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Products Inspection Act (EPIA)
- Humane Methods of Slaughter Act (HMSA)

These Acts provide for the basis for FSIS's ability to perform as a public health agency. Section 602 of the FMIA, Congressional statement of findings, states the following:

FMIA Sec. 602: "Meat and meat food products are an important source of the Nation's total supply of food… It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged… It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers."

These three things - verifying that meat or poultry products are wholesome, not adulterated, and properly marked/labeled, and packaged, are the essentials of the job you have in protecting public health. All of your inspection and verification activities focus around one or more of the things covered in the Acts.

The Congressional statement of findings in the PPIA (Section 451) is almost identical to that of the FMIA. Again, it emphasizes public health, and it emphasizes the same essentials – wholesome, not adulterated, properly marked/labeled, and packaged. All the things you do or you supervise as part of your job can be traced back to the statutes to protect public health by making sure meat, poultry, or egg product that is adulterated or misbranded does not enter commerce. You will do that through the enforcement authorities discussed later in the module.

DEFINITION OF "ADULTERATED"

One of the key provisions in the statutes is the provision related to the term "adulterated" product. What does the term "adulterated" mean, and how does it apply to the work that you do? The term "adulterated" is defined in the FMIA under Section 601, which contains all the definitions for the statute. The term "adulteration" applies to any of the following: carcass, part thereof, meat or meat food product under one or more of the circumstances described in Section 601(m) of the FMIA.

The definition found in Section 601(m) has 9 parts. Listed below are the first few parts which are most applicable to your daily work:

- **FMIA Sec. 601(m)(1)**: "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health;"

  The definition of adulterated product in Section 601m(1) focuses on added substances. Two examples of added substances that have been declared to be adulterants in certain meat products include *Listeria monocytogenes (Lm*) and *E. coli* O157:H7.

- **FMIA Sec. 601(m)(2)(A)**: "If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) color additive) which may, in the judgment of the Secretary, make such article unfit for human food;"

  The second definition of the term "adulterated" in Section 601(m)(2)(A) of the FMIA relates to the residues of drugs in live animals that have been declared to be harmful to human health. The FDA considers what, if any, residues of animal drugs should be viewed as safe. FSIS is responsible for enforcing the levels that are established by FDA. In your duties, you will conduct tests for animal drug residues, such as antibiotics, hormones, or NSAIDs.

- **FMIA Sec. 601(m)(2)(B)**: "If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;"

  The definition of the term "adulteration" found in Section 601(m)(2)(B) of the FMIA covers pesticide chemicals. The EPA consider what, if any, levels of pesticide residues, if found on food, can be viewed as safe. FSIS is responsible for enforcing the tolerances that are established by EPA. In your duties, you will sample products for pesticide residues and send the samples to the appropriate laboratory. In this case, if the residue level for the pesticide chemical

is found to have exceeded the tolerance level set by EPA, the product (which may be a carcass or part) is considered to be adulterated based on this statutory definition.

- **FMIA Sec. 601(m)(2)(C)**: "If it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;"

  Section 601(m)(2)(C) defines meat or meat products bearing any unsafe food additives to be adulterated. The FDA defines food additives as "any substance the intended use of which results or may reasonably be expected to result – directly or indirectly – in it becoming a component or otherwise affecting the characteristics of any food." The FDA reviews all food additives for safety before use in food production. FDA establishes the conditions for use.

  There are two types of food additives: direct and indirect. Direct food additives are those that are added to a food for a specific purpose in that food (e.g., using phosphates in meat and poultry products to retain moisture and protect flavor). Indirect food additives are those that become part of the food in trace amounts due to its packaging, storage, or other handling (e.g., sanitizers used on food contact surfaces). All food additives used in federal establishments must be approved by FDA. FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" lists food additives that have been approved for use. So, again, FSIS enforces the policy that is set by FDA.

- **FMIA Sec. 601(m)(3):** "If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;"

  Section 601(m)(3) emphasizes health. Legally, the burden is on FSIS to prove that these conditions – filthy, putrid, and decomposed – exist. This is why being graphic and accurate in descriptions of conditions is very important when documenting noncompliance in NRs. Some examples of filthy conditions include rail dust, rust, or rodent droppings on product.

  Be aware that the adulteration provisions of the statutes are not mutually exclusive. For example, a product may be adulterated under 601(m)(3) AND 601(m)(1) because it is positive for *E. coli* O157:H7.

- **FMIA Sec. 601(m)(4):** "If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

  Section 601(m)(4) covers the definition of "adulterated" related to insanitary conditions. The SPS and Sanitation SOP regulations (9 CFR 416) as well as the HACCP regulations (9 CFR 417) are about ensuring that products are not adulterated through insanitary conditions. It's about ensuring that sanitary conditions are maintained throughout the production process. If we apply this to the slaughter process, establishments must ensure that their processes (such as de-hiding and opening the digestive tract of livestock) do not create insanitary conditions that may contaminate the carcasses with filth. You will also be responsible for verifying that there are no insanitary conditions in the establishment.

  The inspection duties that you and other IPP perform that can be traced back to this part of the FMIA are those covered by HACCP, Sanitation SOPs and the Sanitation Performance

Standards. Your inspection duties, including your supervisory responsibilities, related to ensuring that the establishments maintain sanitary conditions are outlined thoroughly in FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System."

The remainder of Section 601 of the FMIA covers additional definitions of the term "adulterated." There are parallel definitions of the term "adulterated" in the PPIA. You can review these, as well as the definitions dealing with the term "misbranded," on the FSIS Webpage: Food Safety Acts.

STATUTORY PROVISIONS FOR INSPECTION ACTIVITIES

The following are examples of inspection activities and the corresponding statutes that provide authority for these activities:

Ante-mortem Inspection

Sections 603(a) of the FMIA and 455(a) of the PPIA are the statutory authorities for the inspection activities IPP conduct during ante-mortem inspection.

FMIA Sec. 603(a): "For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce;"

These are the provisions upon which the regulations for ante-mortem inspection were promulgated. For example, the regulation that corresponds with Section 603(a) regarding ante-mortem inspection in livestock is 9 CFR 309. This regulation contains more specific information that you should use in judging whether an official establishment that slaughters livestock is meeting the standard established by Section 603(a). For example, the inspection tasks include inspecting the livestock at rest and in motion to detect abnormal conditions or symptoms of diseases that are identified in the regulations. If any of these animals are suspected of having abnormal conditions or diseases, they must be identified for further examination, and if necessary, identified for final disposition in post-mortem inspection. Any animals found with symptoms of diseases must be disposed of properly. Remember, the authority for these actions as a result of ante-mortem inspection comes from the Section 603(a).

Post-mortem Inspection

The statutory authorities for post-mortem inspection are found in Section 604 of the FMIA, and in Section 455 (b) and (c) of the PPIA.

FMIA Sec. 604: "…the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering…or similar establishment…which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed;" and…label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts…found to be adulterated;"

These provisions cover two important concepts. One is the jurisdiction for inspection. The other is the requirement for inspection.

For jurisdiction, post-mortem inspection must be performed on all of the carcasses and parts prepared at an official establishment. The wording used in the poultry statutes is slightly different. Instead of

“prepared” it uses the word “processed.” The definition for the term “prepared” is found in Section 601(l) of the FMIA. It includes, “slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processes.” You should be aware that the only products FSIS inspects are those that are defined as “prepared” in the FMIA or “processed” in the PPIA. In other words, FSIS does not have jurisdiction to inspect warehouses or distribution centers, although FSIS has the authority to visit these facilities. The inspection of other types of products is covered by other federal agencies, such as FDA. You should also be aware that FSIS has statutory authorities to conduct activities other than inspection. For example, if we look at Section 624 of the FMIA, which is the same as Section 453 of the PPIA, you’ll see the authority to prescribe by regulations the conditions under which carcasses, parts, and meat products are stored or handled during buying, selling, freezing, storing, or transportation. While FSIS can conduct examinations outside of the establishment locations where these processes are performed, these examinations are not “inspection.”

Regarding the requirement for inspection, this provision establishes the basis for the inspection tasks performed. Post-mortem inspection involves performing specific tasks that include observation and palpation or incision of lymph nodes in the head and viscera, and observation of the carcass. The purpose of inspection is to detect any carcasses or parts that exhibit signs of disease or conditions that otherwise make the carcass or parts unwholesome or unfit for human food. These tasks must be performed using methods that are safe and sanitary. The legal authority for these tasks can be traced directly back to this statutory provision.

This statute has been held in the court system to require that FSIS make a determination about each carcass during inspection. You may hear this called a “carcass by carcass” inspection legal requirement.

The statutes continue by indicating that for those carcasses and parts that are found not to be adulterated, inspectors are to mark them as “inspected and passed.” Inspectors are to mark those carcasses and parts that are found to be adulterated as “inspected and condemned.” This is the statutory basis for your inspection duties. You apply the standards established by the definitions of adulteration in making this judgment.

Marks of Inspection

Sections 604 and 606 of the FMIA and Section 455 (b) and (c) of the PPIA cover the concept that carcasses and parts that are found NOT to be adulterated are to be marked as “inspected and passed.”

FMIA Sec. 606: “…said inspectors shall mark, stamp, tag, or label as “Inspected and passed” all such product found to be NOT adulterated; and said inspectors shall label, mark, stamp, or tag as “Inspected and condemned” all such products found adulterated….”

We call these labels, marks, stamps, and tags the marks of inspection. These marks of inspection, stating “Inspected and passed,” show that all meat products are cleared to enter commerce after they are found to be fit for human consumption. Product cannot move out of the establishment into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the establishment. If you have questions about whether or not to pass the product, don’t pass it and don’t stamp it as “Inspected and passed” unless, and until, you get satisfactory answers to your questions by the establishment. If you cannot find that the product is not adulterated, you must follow the Rules of Practice (9 CFR 500). So, Section 606 defines our product control authority.

Those carcasses and parts that are found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated are to be marked “inspected and condemned” or placed in receptacles which are marked “U.S. Condemned.” Refer to the section on Condemned and Inedible for more information. The statute also specifies that if the establishment fails to destroy a condemned carcass or part, the Secretary may remove the inspectors from the establishment. We call this removal of inspection “suspension” of inspection (see “Enforcement Authorities and Actions” below).

Reinspection

Reinspection is covered in Section 605 of the FMIA and 455(b) in the PPIA. IPP may reinspect products as often as they deem necessary in order to determine the products are not adulterated or misbranded (9 CFR 318.2, 381.145(b)). Reinspection also covers the situation when products are shipped from one establishment to another. For example, this could be carcasses coming from one establishment to be fabricated into special cuts at another establishment. It could be ground beef and trimmings coming from one establishment to another to be ground more finely, or to be used as a meat ingredient in a fully cooked product.

When you work in an establishment that receives meat or poultry products from another establishment, part of your responsibility will be to ensure that those products entering the establishment are reinspected using the same standards that you use in the initial inspection – that products are wholesome, not adulterated, and properly marked, labeled, and packaged. Another condition requiring reinspection is when products are returned to the establishment for any reason. Again, your role is to ensure that these products are reinspected using the standards in the statutes, regulations, and directives.

Under both of these conditions you should ask questions to verify that the product is wholesome, not adulterated, and properly marked, labeled, and packaged. For example, if the product has been transported to the establishment, was it held under conditions in a manner that would ensure that it did not become filthy, putrid, or decomposed, or for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food? Examples of questions you might ask to make this determination include “Was the temperature of the product controlled throughout transportation?” and “Are there measures to prevent cross contamination of the product with the environment”? These questions should be part of the decision-making process you use in determining if product is wholesome and not adulterated.

Sanitation

Section 608 of the FMIA and 456(a) of the PPIA focus on the requirement for the establishment to maintain sanitary conditions.

FMIA Sec. 608: “The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained;”

These statutes give FSIS the ability to ensure that product is handled and held in a sanitary manner. This is one of the provisions upon which the HACCP regulations (9 CFR 417), the Sanitation Performance Standard regulations and the Sanitation SOP regulations (both covered in 9 CFR 416) are

based. If the sanitary conditions are found by inspectors to be such that the meat or meat food products are rendered adulterated, inspectors shall refuse to allow the meat or meat food products to be labeled, marked, stamped, or tagged as “Inspected and passed.”

“Sanitation” and “HACCP” are not terms defined in the statutes. However, FSIS can legally demonstrate to a court that the HACCP and sanitation regulations are sanitary measures and that an establishment’s failure to follow the sanitary measures required by HACCP or sanitation rules creates insanitary conditions in its operation. Insanitary conditions during operations may result in the production of product that may be injurious to health.

To ensure that products are handled and held in a sanitary manner, establishments must follow the HACCP regulations. A failure by an establishment to perform an adequate hazard analysis, for example, would create insanitary conditions because, without such an analysis, the establishment cannot be sure that it has identified and addressed conditions that could cause the product to be injurious to health.

Having Sanitation SOPs that are effective in preventing direct contamination of product with environment contaminants is a necessary precaution against producing product that may be injurious to health. A failure to implement effective Sanitation SOPs or to ensure the ongoing effectiveness of the Sanitation SOPs, for example, would create conditions under which such contamination may occur; and thus, product is rendered injurious to health.

Recordkeeping

Section 642 of the FMIA and 460(b) of the PPIA outline recordkeeping requirements and classes of businesses that are required to keep records. These also give FSIS the right to be in the establishment and to have access to the establishment facilities and records.

The U.S. Constitution has a provision that protects citizens from unreasonable searches and seizure. The establishment has this same right, and just like other rights, it must be protected. However, it’s important for inspection personnel to have access to establishment records (production, shipment, and other business records), particularly records related to the implementation of HACCP and Sanitation SOP. A review of those records can tell us important information about how product was handled, prepared, shipped, received, and stored to help us in making the determination about whether product that is being produced is wholesome, not adulterated, and properly labeled.

Establishments must maintain production records and provide the records within a reasonable amount of time when given notice. FSIS has issued regulations (9 CFR 320, 381.175, and 381.178) which further address entry into places of business and examination of records, including record keeping requirements. Tracing these authorities from the Acts to the regulations, remember that the HACCP and sanitation regulations (9 CFR 417 and 416) both outline more specific recordkeeping requirements. For example, the right of FSIS to access establishment records is reflected in the HACCP regulations in 9 CFR 417.5, which outlines the recordkeeping requirements related to HACCP plans. FSIS Directive 5000.1 “Verifying an Establishment’s Food Safety System” outlines inspection methods covering these recordkeeping requirements. Another example of a directive dealing with establishment records is FSIS Directive 5000.2 “Review of Establishment Data by Inspection Personnel.” It reminds inspection personnel that they have access to any type of record that the establishment maintains that relates to maintaining its food safety system, whether the records are referenced in the HACCP plan or not (e.g., records of microbiological sampling).

Other Statutory Authorities

Additional statutory authorities that relate to your work include Section 603(b) of the FMIA (humane handling), Section 607 of the FMIA and Section 457 of the PPIA (labeling), and Section 615 of the FMIA (exports). The entire FMIA, PPIA, and EPIA can be accessed on the FSIS Webpage: Food Safety Acts.

ENFORCEMENT AUTHORITIES AND ACTIONS

There are three basic enforcement authorities covered in the Acts: administrative, civil, and criminal. Among these, enforcement actions that come from the administrative authority will be the most common in your work. For example, you or other inspection personnel may withhold the marks of inspection or retain product, actions which are covered under administrative authority.

Administrative Authorities

Section 671 of the FMIA provides the authority to refuse or withdraw grants of inspection from federally inspected meat slaughter and processing establishments. Section 467 of the PPIA provides similar authority for the refusal and withdrawal of inspection services. Actions to refuse or withdraw grants of inspection can be initiated for such things as:

- Violation of agency's sanitation, adulteration, and related requirements.
- Conviction of an establishment or of a responsibly connected individual for certain crimes.
- Inhumane slaughter.

In addition, under Section 607 of the FMIA and Section 457 of the PPIA, FSIS can rescind or refuse the approval of marks, labels, and containers.

The administrative enforcement authorities covered in the statutes include retaining product, withholding the marks of inspection, suspending inspection, and withdrawing inspection. Remember that the Rules of Practice (9 CFR 500) outline the due process that we must ensure takes place to protect the rights of establishments. As a supervisor, you ensure IPP are taking appropriate enforcement actions.

- **9 CFR 500.2** covers the regulatory control actions that take place in the establishment, such as tagging product, equipment, or facilities. These actions are taken to prevent product that has been determined through inspection, to be unwholesome or adulterated from leaving the establishment and entering commerce. We are authorized to take regulatory control actions when we find insanitary conditions or practices, product adulteration, conditions that prevent us from determining that product is not adulterated or misbranded, and when there is inhumane handling or slaughter of livestock. When a regulatory control action is taken, you must notify the establishment immediately orally or in writing of the action and the reason for the action. Remember that for any type of enforcement action, the establishment has the right to appeal that action.
- **9 CFR 500.3** covers situations that warrant a withholding action or suspension without prior notification to the establishment. These actions are authorized when: the establishment has produced and shipped adulterated or misbranded product and there is an imminent hazard to health, the establishment does not have a HACCP plan, the establishment does not have a Sanitation SOP, sanitary conditions are such that products in the establishment are or would be rendered adulterated, the establishment violated the terms of a regulatory control action, someone associated with the establishment assaults or threatens to assault or intimidate or

interfere with an FSIS employee or FSIS inspection, the establishment fails to destroy condemned product according to regulatory requirements, or the establishment handles or slaughters animals inhumanely. Section 500.5(a) covers the notification that must be provided to the establishment as promptly as circumstances permit.

- **9 CFR 500.4** covers the conditions under which withholding actions are taken or when suspensions occur with prior notification to the establishment. The prior notification is called a notice of intended enforcement action (NOIE). Specifics about what is contained in the NOIE are covered in 500.5(b). The conditions that require prior notification include: an inadequate HACCP plan, a Sanitation SOP that has not been properly implemented or maintained, failure to maintain sanitary conditions due to multiple or recurring noncompliance, failure to collect generic *E. coli* samples, and failure to meet the *Salmonella* performance standards.
- **9 CFR 500.6** covers withdrawal of inspection, an action which is initiated at the FSIS Administrator level. The documentation you provide in the NRs that you write are the evidentiary basis upon which this action is taken.

Civil Authorities

You will probably not have direct involvement with actions under civil authority. However, you might provide information about adulterated or misbranded product that has left the establishment, which could lead to an action under civil authority.

The civil authorities covered in the Acts are found in Section 674 of the FMIA and 467(c) of the PPIA. Under these authorities, FSIS can enforce, prevent, and restrain violations of the Acts. The actions involve U.S. District courts. The primary actions will be detention and seizure of product.

Detention authorities cover unwholesome, adulterated, or misbranded product that has left the establishment and has entered commerce. Detention actions are taken by OIEA or EIAOs (OFO). The detention action places the product on hold for 20 days. During this time, a decision is made on the ultimate disposition of the detained product.

Seizure is also an action that is taken against product that is no longer in an establishment and has entered commerce. Typically, the first step in a civil action is detention, which is then followed by seizure and condemnation. It involves a court judgment that affirms that the product is in violation of the Acts and must be condemned and destroyed. When the court determines that the product is to be condemned, it is released under bond to be destroyed. Court costs and fees, storage and other expenses are charged to the violator.

Although you will not be involved in taking any civil enforcement action, some of the documentation created in the establishment, such as NRs or memoranda, may be included in a case file that is submitted to the court. Therefore, it's very important that you, and the inspection personnel you supervise, follow the instructions in the directives on completing NRs accurately, completely, and in a timely manner. They are important pieces that may make a difference in court decisions.

Criminal Authorities

You will probably not have direct involvement with actions under criminal authority. However, the documentation that you and inspection personnel you supervise generate may be used in actions under this authority.

The Acts cover, among other things, intent to defraud the public by distributing adulterated articles, prohibited acts, criminal acts of assault and intimidation of a person engaged in official duties, and

bribing or offering a bribe to an inspection official. Prohibited acts apply to persons, firms, and corporations and include:

- Slaughter or preparation of product except in compliance with the Act.
- Inhumane slaughter or handling.
- Sale, transport, offering, or receipt, in commerce, of articles capable for use as human food that are either adulterated, misbranded, or not inspected.
- Causing products to become adulterated or misbranded.
- Misuse or unauthorized use of official marks, certificates, labels or devices of inspection.
- The knowing misrepresentation of any article as inspected and passed or exempt under the Act.

FMIA Section 675 and PPIA Section 461(c) cover criminal acts related to assault and intimidation of inspection personnel. Under these statutes, no person shall forcibly assault, resist, oppose, impede, intimidate, or interfere with any USDA employee engaged in or on account of official duties. Therefore, it is prohibited for establishment employees to impede you, or interfere in any way with your work. Assault and intimidation are conditions that result in immediate removal of inspection personnel with no requirement to notify the establishment (9 CFR 500). If you or any other inspection personnel in the establishment are threatened in any way by a person at the establishment, consider safety first. Report it immediately to your supervisor as you have been instructed. The Acts outline that these conditions can result in fines and prison time for violators.

Section 676(a) of the FMIA and Section 461(a) of the PPIA define that persons who intend to defraud or distribute, or attempt to distribute a meat or poultry article that is adulterated is subject to fines, imprisonment, or both.

Section 622 of the FMIA covers the criminal act of bribery. It prohibits any person, firm or corporation from paying or offering to pay any money or other thing of value to an agency employee with the intent to influence the agency employee's discharge of duties. Bribery is defined as a felony act, and violators are subject to a fine and imprisonment. In addition to these penalties, FSIS may withdraw inspection. This section also prohibits FSIS employees from accepting or receiving money or something of value from representatives of the establishment, or industry. You are not to accept any item of value from an establishment employee. Other felonies include failing to destroy condemned product or having an owner/operator who has been convicted on a felony, or two or more misdemeanors. Be aware that the USDA's Office of the Inspector General (OIG) conducts investigations into allegations of bribery. The investigations are usually initiated as a result of an anonymous call to the OIG's hotline. Per FSIS Directive 4735.3 "Employee Responsibilities and Conduct," **IPP are to report situations involving bribery directly to OIG**.

EXEMPTIONS FROM INSPECTION REQUIREMENTS

The statutes outline some exemptions to the inspection requirements. These are found in the FMIA in Section 623 and 624, and in Section 454 and 464 of the PPIA. For example, personal slaughtering and custom slaughter for personal, household, guest, or employee uses are exempt from inspection. The exempt products are still subject to the adulteration and misbranding provisions of the statutes (FMIA 623(d)).

In these exempt facilities, the establishment performs activities that constitute preparation of meat products, or processing of poultry products, but they have been exempted from inspection by Congress.

You may conduct periodic reviews of custom exempt facilities that operate at official establishments to determine if the operator complies with applicable statutory and regulatory requirements. See FSIS Directive 8160.1 “Custom Exempt Review Process” for more information.

SUMMARY

The Acts discussed above provide for the basis for FSIS’s ability to perform as a public health agency. Although you find direction for your day-to-day activities in the Code of Federal Regulations, FSIS directives, and notices, the statutes underlie all of these activities and provide the legal basis for them. As you perform your inspection and verification duties, you should always be conscious of the Acts, as they are the foundation for all that we do.

Meat, Poultry and Egg Products Recalls

OBJECTIVES

1. Explain the key steps in the product recall process, i.e., identification, outbreak notification, investigation, evidence collection, decision document, event assessment committee, recall, and follow-up.
2. Identify the points in the product recall process at which a PHV would become involved and the PHV's role at those points in the process.
3. Explain how the PHV interacts with other entities involved in a recall.
4. List allergens of concern in the Processing context.

RESOURCES

FSIS Directive 8080.1 – Managing Adulterated or Misbranded Meat, Poultry, and Egg Products
FSIS Directive 5000.8 – Verifying Compliance with Requirements for Written Recall Plan Procedures
FSIS Directive 8140.1 – Notice of Receipt of Adulterated or Misbranded Product
FSIS Directive 7230.1 – Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common ("Big 9") Food Allergens
PHIS Help: APM tutorials (Requires VPN)
FSIS Webpage: Recalls & Public Health Alerts
How to Develop a Meat and Poultry Product Recall Plan Booklet
FSIS Form 5020-3 "Preliminary Inquiry Worksheet"

INTRODUCTION

A recall is a firm's voluntary action to remove adulterated or misbranded products from commerce.

Although recalls are voluntary, FSIS will coordinate with the firm to ensure that the firm has properly identified and removed recalled product from commerce. If a company refuses to recall its product, then FSIS has the legal authority to detain and/or seize product(s) in commerce when there is a reason to believe they are hazardous to public health or if other consumer protection requirements are not met.

FSIS Directive 8080.1 "Recall of Meat and Poultry Products" provides FSIS program personnel with the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat, poultry, and egg products. This module will focus on official establishment recalls, however the directive also covers recalls conducted by State-inspected firms or retailers and importers.

Each official establishment is required to prepare and maintain written recall procedures. The written procedures must specify how the establishment will decide if they need to conduct a product recall and how they will implement a recall. The written procedures and all records associated with recalls must be available for FSIS review (9 CFR 418). FSIS Directive 5000.8 "Verifying Compliance with Requirements for Written Recall Plan Procedures" provides IPP instructions for verifying that official establishments establish and actively maintain the required written recall plan procedures.

TERMINOLOGY

Recall Hazard Classifications

FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the recall based on the relative health risk as follows:

- **Class I**: This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For example, the presence of pathogens in ready-to-eat product, the presence of *E. coli* O157:H7 in ground beef, or product that contains an allergen likely to elicit an adverse human health reaction (e.g. milk or soybeans) not declared on the product label.
- **Class II**: This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. For example, product that contains a highly refined/denatured allergen not likely to elicit an adverse human health reaction, (e.g. hydrolyzed soy protein) not declared on the product label.
- **Class III**: This is a health hazard situation where the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe non-allergenic substances, such as excess water.

Scope

The **scope** of a recall is defined by the amount and type of product in question. Multiple factors are used in determining the scope, such as establishment sanitation procedures and process flow. The Event Assessment Committee determines the scope of a recall.

Event Assessment Committee

A committee of representatives from various FSIS offices and staffs assembles to respond to potential or real health hazard incidents reported to the Recall Management and Technical Analysis Staff (RMTAS). The primary members of the committee are representatives of the following program areas: RMTAS, OPPD, OPHS, OPACE/CPAS (Congressional and Public Affairs Staff), and OIEA/CID (Compliance and Investigations Division). FSIS Directive 8080.1 “Recall of Meat and Poultry Products” provides further information on the specific roles of each committee member.

Recall Officer

Designated by the District Office (OFO) with jurisdiction in the district of the firm conducting the recall (e.g., a DDM, DCS, or EIAO in the district where the recalling firm is located). The Recall Officer’s (RO) responsibilities include:

- Coordinating field recall activities if a recall is recommended.
- Serving as a primary point of contact for the recalling firm, other districts, and RMTAS.
- Clarifying and explaining to the Event Assessment Committee the information collected during the preliminary inquiry.
- Coordinating effectiveness checks and directing the activities of FSIS personnel.
- Interpreting results of the effectiveness checks and disposition of affected product.
- Submitting a memo to RMTAS to close the recall.

Consumer Complaint Monitoring System

The Consumer Complaint Monitoring System (CCMS) is an electronic database used by FSIS to document, analyze, and coordinate responses to consumer complaints. It provides FSIS with a surveillance tool that facilitates identification of food safety risks to human health that require an Agency response. See FSIS Directive 5610.1 "Consumer Complaint Monitoring System" for more information.

RECALL PROCESS

Problem Identification

The process of recalling a product begins with problem identification. A problem with a product is identified through various sources such as the firm, the Agency, or sources outside of the Agency. FSIS may receive information from:

- The company that manufactures, distributes, or receives the product.
- Test results from FSIS sampling programs.
- Observations or information gathered by FSIS personnel in the course of their routine duties or investigations.
- Consumer complaints reported through the FSIS CCMS.
- Complaints reported to FSIS through sources other than CCMS.
- Epidemiological or laboratory data submitted by state or local public health departments or authorities, other USDA agencies, and other federal agencies such as the FDA, the CDC, or the Department of Defense.
- Information from other agencies, such as the Department of Homeland Security, Customs and Border Protection, APHIS, or foreign inspection officials.

Preliminary Inquiry

When FSIS learns there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry. When the problem is identified at a federally inspected establishment, the OFO DM assigns personnel to lead the preliminary inquiry effort. The DM designee will contact IPP and the establishment to gather product information, contact information, and any additional relevant information. The DM will determine if the event should be escalated for further RMTAS analysis.

If the DM determines the event should be escalated, the DM designee and involved IPP work with the firm to complete and forward a copy of FSIS Form 5020-3 "Preliminary Inquiry Worksheet" to RMTAS for an assessment. The establishment is responsible for providing this information, however as in-plant PHVs with working knowledge of establishment protocols and records, you may be asked to assist with information gathering and verifying the information on the form is accurate. It is important that this information is gathered accurately and in a timely manner. You may also assist in gathering product label information, including photographs or digital scans of labels.

RMTAS assesses all information gathered during the preliminary inquiry. RMTAS may determine that the Event Assessment Committee should be engaged. Or, RMTAS may determine that further recall consideration is unnecessary.

Event Assessment Committee Meeting

Event Assessment Committee members meet when an adulteration or misbranding event requires the committee's consideration. The Committee discusses the details of the event, including the applicable statutory requirements to determine the Agency's best approach for addressing the event. This may include reasons that a particular product may need to be removed from commerce and whether there is statutory basis to recommend a recall. If the Event Assessment Committee decides to recommend a recall, it will also determine the appropriate recall classification.

When determining whether to recommend a product recall, the Event Assessment Committee seeks the answers to questions such as:

- Does FSIS have evidence to demonstrate that the product in question is adulterated or misbranded under the FMIA, PPIA, or EPIA? For example, if the results of a laboratory analysis show that raw ground beef or beef manufacturing trimmings contains *E. coli* O157:H7, the product is adulterated because it is likely to be injurious to health.
- Does any of the product in question remain in commerce or remain available to consumers?

To determine if product remains available to consumers, the Committee seeks answers to questions such as:

- Is the product readily identifiable and able to be differentiated from similar unaffected product?
- When was the product produced?
- To whom has the product been distributed?
- What type of product is involved?
- What is the typical, useable shelf life of the product?
- What are the typical consumer practices concerning handling and storage of the product?
- Is the agency able to verify that the product previously distributed in commerce is no longer free to move to consignees or otherwise available to consumers?

Event Assessment Committee Decision and Notification of the Firm

If there is evidence that product is adulterated or misbranded and that product remains in commerce available for sale or use, the Committee recommends a recall. In such instances, the Committee then reaches a consensus on the classification (Class I, Class II, Class III). The Committee contacts the firm and allows the firm to join the Committee discussion. RMTAS submits a Recall Recommendation memo for approval by the OFO AA or designee. If approved, RMTAS follows-up in writing with an e-mail to the firm. If the firm decides not to accept the Agency's recommendation and chooses not to conduct a recall, FSIS personnel may detain and seize product found in commerce that would have been subject to the recall.

If the Committee finds that the establishment has recovered or controlled all products from commerce that would have been subject to a recall, the Committee does not recommend a recall, as no product should remain available for sale or use in commerce. Information on various circumstances when the Committee should not recommend a recall is found in FSIS Directive 8080.1 "Recall of Meat and Poultry Products."

Action of the Firm and Announcing the Recall

The establishment is responsible for notifying all consignees of the need to remove recalled product from commerce.

FSIS notifies the public through a press release entitled **Recall Release**. CPAS issues a Recall Release for Class I and Class II recalls to media wire services, media outlets in the areas that received recalled products, the FSIS e-mail subscription service for recalls, and FSIS-affiliated social media outlets. Class III Recall Releases are not distributed to the media. FSIS posts all Recall Releases on the FSIS website.

The Recall Release includes information such as the identity of the firm that produced the product, a description of the product involved, the reason for the recall, pictures of the product label (when possible), instructions on how the public should handle the product, the name and telephone number of a company contact to call with questions, and general information about the products known destination.

For Class I recalls, the RO or designee develops a **retail consignee list**. This list includes retail consignees that may have, or may have had, the recalled products in their possession. This list is posted on the FSIS website.

Note: In certain situations, instead of or in addition to recommending a recall, FSIS may issue a Public Health Alert (PHA). These inform the public of specific public health risks posed by products in commerce when there is no product recall or when available product has already been recovered from commerce but may still pose a risk to consumers at their homes. FSIS also issues PHAs when firms decline to initiate a recall upon FSIS recommendation. PHAs include information on the product involved, identify whether the product presents any health risk, and instructs consumers on how to properly handle the product if they have it in their possession. PHAs are issued through press releases and posted on the FSIS website.

Effectiveness Checks

The RO or designee will follow up on the recalling firm's actions by verifying the distribution information and coordinating effectiveness checks. The RO directs FSIS personnel in the DO where the recall originated to conduct recall effectiveness checks.

Effectiveness checks are a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly.

The RO or designee will perform effectiveness checks using the process outlined in FSIS Directive 8080.1 "Recall of Meat and Poultry Products." FSIS will conduct effectiveness checks throughout the distribution chain. Effectiveness checks are risk-based and dependent on the class of the recall (which is based on the hazard and any available epidemiological data), the number of consignees, and other relevant factors.

A sufficient number of effectiveness checks are made to verify that the recall is conducted in an effective manner, and that the firm locating, retrieving, controlling, and determining the disposition of the product is acting according to regulatory requirements. FSIS personnel conducting effectiveness checks are to notify the RO immediately when recalled product remains available to the consumer and when the recalling firm has not properly implemented its recall strategy.

The outcome of the recall is deemed effective or ineffective based on the information gathered during the effectiveness checks. If RMTAS determines the recall is ineffective, they will notify the recalling firm immediately. If the recalling firm is unwilling or unable to correct its recall strategy, the Agency may take further action to mitigate the risk to the public.

Recall Closure

When appropriate, the RO recommends closure of the recall to RMTAS and RMTAS recommends closure of the recall to the OFO AA. FSIS notifies the firm in writing through e-mail that the recall is closed.

ROLE OF THE PUBLIC HEALTH VETERINARIAN

As a PHV, you may play a role in multiple parts of the recall process described above. The PHV may play a role in identifying a problem that may lead to a recall. As you go about your daily in-plant activities, if you suspect that there is a problem with product such that it may need to be recalled, discuss your concerns with your supervisor first. You may then be asked to report your concerns to the DO.

The PHV may assist the DM designee in the timely and accurate gathering and verifying of information to complete the FSIS Form 5020-3 "Preliminary Inquiry Worksheet." For example, you may be asked to provide information about whether the product represented by an FSIS or establishment sample that tested positive for *E. coli* O157:H7 has been held under the establishment's control, or whether it has left the establishment's control and has entered commerce. You might also be asked to help the RO designee gather information about a consumer complaint concerning a product that was produced in an establishment within your assignment.

Establishment personnel may notify you that they learned or determined that they shipped adulterated or misbranded product into commerce. If this happens, you need to contact the DO, through supervisory channels, as soon as possible. You also need to notify establishment managers that they need to contact the DO directly within 24 hours (9 CFR 418.2). Also note that, per FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System," IPP are to initiate a directed HACCP verification task and verify that establishments implement corrective actions when an unforeseen hazard has occurred.

Note: FSIS utilizes the PHIS Adulterated Product Monitoring (APM) module to document industry reports required by 9 CFR 418.2, as described in FSIS Directive 8140.1 "Notice of Receipt or Distribution of Adulterated or Misbranded Product." PHVs should be familiar with the regulatory requirements and IPP responsibilities within this directive and utilize the APM tutorials in PHIS Help for information on how to enter information into APM as necessary.

If you are an EIAO-trained PHV, you may be asked to investigate a consumer complaint at your duty station or other nearby establishments. You may be asked to complete recall effectiveness checks if product subject to recall was produced or distributed in your local area.

If you are the PHV assigned to an establishment that has shipped adulterated or misbranded product into commerce, you and your team will document noncompliance, as necessary. You will verify what actions the establishment takes in response to the food safety system failure. For example, if an establishment shipped product into commerce with an undeclared allergen, its food safety system failed to control the chemical hazards associated with allergens. You would follow the information in FSIS Directive 7230.1 "Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common ("Big 9") Food Allergens" to document any noncompliance and would verify that the establishment has implemented appropriate corrective actions in response to the noncompliance.

Verifying Written Recall Plans

Part of your routine responsibilities is to verify that establishments have written recall procedures as required by 9 CFR 418.3. To do this, at least once a year, you or your designee will perform a directed Other Inspection Requirements task. Document your findings in PHIS as described in FSIS Directive 5000.8 "Verifying Compliance with Requirements for Written Recall Plan Procedures."

THE "BIG 9" VERIFICATION

In 2023, there were 15 recalls of FSIS-regulated products due to undeclared allergens, totaling 232,277 pounds of recalled product. You learned about how IPP verify that establishments are accurately controlling and labeling the nine most common food allergens during Inspection Methods. To review, FSIS Directive 7230.1 "Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common ("Big 9") Food Allergens" provides IPP instructions for performing the "Big 9" Formulation Verification task in PHIS. IPP verify that establishments are accurately controlling and labeling the nine most common food allergens in meat, poultry, and egg products establishments (wheat, crustacean shellfish, eggs, fish, peanuts, milk, tree nuts, soybeans, sesame).

As a supervisor, you must ensure that IPP have been trained and understand how to review labels and product formulations. IPP must be familiar with the verification activities associated with food allergens. If IPP find evidence the establishment has not effectively ensured that allergens are properly used and declared, or if there are questions about the adequacy of the establishment's food safety system, IPP must notify their chain of command. If IPP determine that a product with undeclared allergens may have entered commerce, they must contact their chain of command so that, if needed, a preliminary inquiry for a recall can be initiated.

Administrative Enforcement Action Decision-Making/Methodology & Critical Thinking

OBJECTIVES

1. Explain and/or list the following concepts: What is critical thinking? What is the importance of critical thinking to the administrative enforcement process?
2. Explain the role of the PHV in the administrative enforcement process.
3. Explain the role of administrative enforcement within the FSIS regulatory framework.
4. List and describe the main supporting components of the AER case file.
5. Accurately document a Memorandum of Interview.
6. List two “other” sources of information pertinent to the administrative enforcement process.

RESOURCES

FSIS Directive 5100.3 – Administrative Enforcement Action Decision-Making and Methodology

INTRODUCTION

Federally inspected meat, poultry, and egg products establishments are required by the FMIA, PPIA, and EPIA to be maintained and operated in a sanitary manner to prevent adulterated products from entering commerce. Establishments that handle and slaughter livestock are required by the HMSA to use humane methods. When establishments do not meet the provisions of the Acts or regulations, OFO will investigate and may determine there is support for an administrative enforcement action under the Rules of Practice (ROP) (9 CFR 500). Under the ROP, when FSIS determines that enforcement action is warranted, FSIS is required to notify the establishment promptly both orally and in writing (e.g., NOS, NOIE) prior to or upon taking such action.

When the DO decides to pursue an enforcement action, the DO prepares an Administrative Enforcement Report (AER) case file. The AER case file includes establishment documentation, FSIS and establishment communications, supporting documents, evidence collected, and verification plans. The DO explains the rationale and factual basis for the enforcement action and describes supporting documents for inclusion in the AER. The DO links establishment violations to FSIS statutory and regulatory requirements. The DO assembles the AER in a manner that would enable a person unfamiliar with the facts of the establishment’s processes to understand the sequence of events that led to the noncompliance findings and the enforcement action. The AER, including FSIS Form 5400-9 “Administrative Enforcement Report,” is maintained electronically by the DO. FSIS Form 5400-9 may also be completed for other activities (e.g., custom exempt reviews, investigations of prohibited activities).

Administrative enforcement actions (e.g., suspension of inspection) can immediately affect the establishment’s right to conduct business. The establishment may appeal the DO’s decision to take an enforcement action, or it can request an expedited hearing before an Administrative Law Judge to contest the Agency’s decision. It is essential that the AER and accompanying exhibits support that FSIS has a basis for the enforcement action taken. FSIS needs this documentation immediately available if

an appeal by the establishment is received, if the establishment requests an expedited hearing, if FSIS requests a complaint to withdraw the grant of inspection, or if legal actions are taken such as hearings, injunctions, requests for seizure, etc.

The administrative enforcement action decision-making and documentation process is used to ensure that FSIS personnel have analyzed all available information, applied critical thinking in their decision-making, and have documented those decisions in a manner that will support the actions taken by FSIS. The AER method of documentation demonstrates that FSIS has an effective and efficient means to document and maintain administrative actions taken under the Rules of Practice. The methodology helps to ensure uniformity and consistency.

Understanding and participating in the administrative enforcement action decision-making process is an important part of your job as a PHV. The process entails using your critical thinking skills to assess information and take or recommend actions based on those assessments. The assessment will only be as good as the quality and completeness of the information that is analyzed. Likewise, the accuracy of the conclusion will be heavily dependent on the objectivity of your assessment.

One of your main functions in the process will be to ensure accurate, relevant, and complete documentation of all information related to a problem or concern. FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" describes supervisory responsibilities, which include ensuring that IPP are correctly applying inspection methodology, making informed decisions, properly documenting findings, and taking appropriate enforcement actions. For example, as a supervisor, you will make onsite observations of how well IPP conduct FSIS inspection and verification procedures. You will compare your observations of plant conditions to inspection results and NRs on file. You will engage in discussion with IPP about their findings and assess their knowledge. You will review documentation written by IPP (e.g., NRs, MOIs) and verify the documentation is written in accordance with agency policy.

Your in-plant inspection team plays a vital role in identifying problems and collecting information. If this is not properly documented, then the information will not be available as support for a potential future case. Proper documentation also means that the appropriate regulation is cited.

Remember, your team's documentation and assessments are the **foundations** of the AER case files. It is your responsibility as the in-plant team leader to ensure that the foundation is rock solid.

Note: As a leader, it is important to ensure both you and your team maintain professionalism throughout the enforcement process, which includes being issue-oriented (do not personalize) and maintaining open, honest, straightforward communication with the establishment. It is also important to maintain a safe workplace and ensure any incidences of workplace violence (e.g., assault, harassment, interference, intimidation or threat against employees while performing or as a result of performing their duties) are reported. See FSIS Directive 4735.7 "Industry Complaints Against FSIS Program Employees" Attachment 2-1 (Relationship Principles) and FSIS Directive 4735.4 "Reporting Assault, Harassment, Interference, Intimidation or Threat" for more information.

CRITICAL THINKING AND ADMINISTRATIVE ENFORCEMENT

Administrative enforcement decision-making requires use of critical thinking. It may take several rounds of information gathering/documenting and analyses before a recommendation for an enforcement action can or should be made. Under many circumstances, the issue may be resolved by the establishment without the need for such a recommendation.

Merriam-Webster Dictionary defines “critical thinking” as “the act or practice of thinking critically (as by applying reason and questioning assumptions) in order to solve problems, evaluate information, discern biases, etc.” Your education in veterinary medicine has set you up for a career in “critical thinking.”

Applying critical thinking and analysis will help ensure that any recommendation made by you as the PHV, whether it be to recommend or not to recommend enforcement, is well thought out and based on a thorough review of all pertinent information.

You are probably familiar with several types of critical thinking frameworks, such as the scientific method, a medical diagnosis, or a systems analysis. You have used the “scientific method” in veterinary school and in practice. A medical diagnosis is basically a mixture of the scientific method and a systems analysis. When you make a veterinary diagnosis, you use the basic framework of the scientific method, but also include a “systems analysis” approach when you assess the symptoms by organ system(s). You must have an understanding of the organ systems to rule out certain differential diagnoses. When performing an analysis of the effectiveness of an establishment’s food safety system, you will use these same basic principles.

You may not be as familiar with the regulatory analysis method as with the other methods mentioned. This method is used when assessing an establishment’s compliance with regulatory requirements, as they relate to their food safety system and public health.

You will be using a mixture of the above methods to achieve your goal. You will be analyzing a variety of both scientific and regulatory information that is intertwined in an establishment’s food safety system. It will be your job to determine whether the mixture that the establishment has put together is effective and meets the regulatory requirements. FSIS Directive 5000.1 “Verifying an Establishment’s Food Safety System” provides information on the general verification thought process that IPP are to follow when conducting verification activities.

Critical Thinking, Regulatory Analysis, and Public Health

It is part of a regulatory public health agency’s mission to seamlessly integrate scientific principles with a legal (statutory and regulatory) framework and public health values (Steven D. Schafersman, 1997, Miami University). Critical thinking is important in achieving this seamless integration. It is used by leadership, while making significant organizational and necessary changes at the agency level, and it will be as important when you are making public health and related enforcement decisions at the local level.

You will be performing a regulatory analysis in your role. When performing a regulatory analysis, you will follow a framework that is very similar to the scientific methodology with which you are acquainted.

When conducting verification activities, you follow this thought process:

1. Gather all available information.
2. Assess the significance and meaning of the information gathered.
3. Determine whether the information supports a finding of regulatory compliance.
4. Put it all together and document your findings.

The first step is basically the same as in the scientific methods—gather the facts or information needed to determine what the problem is. When gathering information, you will review establishment programs and supporting documentation, review establishment records documenting implementation of its programs, observe establishment employees implementing the establishment’s programs and

procedures, observe the conditions in the establishment, and observe product and occasionally take measurements as specified in the establishment programs. You will ask questions such as:

- Who are the persons involved?
- What event has happened?
- Where is the location that is involved?
- Why did the event happen?

It is important that the information gathered is pertinent and based on *objective facts*—not subjective opinions or assumptions. All of the gathered evidence is to be properly documented.

After the facts have been gathered, then the evidence must be assessed. If you determine that there is evidence of a potential noncompliance, then the next step is to identify the regulatory elements involved. This, of course, *requires a basic understanding and good working knowledge* of the regulations and current policies (i.e., directives, notices).

To determine whether the information gathered supports a finding of regulatory compliance, you are to decide, based on all the available information, whether one of the following findings emerges from the evidence:

1. That the establishment is not maintaining sanitary conditions.
2. That the establishment has produced or shipped adulterated products.
3. The establishment's food safety system is not effectively controlling the relevant food safety hazard.
4. That the establishment is not meeting the requirements in one or more regulations.

It is not expected that you will be an expert in *all* the regulatory language. You may also need an interpretation of the most current policies, since these are frequently updated to meet changing conditions. If you need technical assistance with regulations or policies, then you can contact your supervisor, mentor, or askFSIS.

You will also assess the significance and meaning of the information gathered, consider what each piece of information, either taken separately or with other findings, says about how the food safety system is functioning to ensure that products are safe and wholesome. Consider information you have gathered in the context of past findings and look for any patterns or trends in the findings. Consider:

1. Are conditions in the establishment getting worse over time?
2. Are the same or similar problems occurring repeatedly or consistently occurring on a seasonal basis?
3. Is the establishment responding effectively and in a timely manner to problems that do arise?

To put it all together, it is important to consider each piece of information in the context of the food safety system. Consider:

1. Is this piece of information part of a pattern?
2. Is there other information to indicate that the system is working or is not working?
3. Does the information seem to agree with the other available information about the food safety system?
4. Do these results support each other or is there an apparent contradiction?

In your role, you will ensure you and your team document your thought processes and findings on NRs and in memoranda. You will discuss any concerns about systemic problems with the establishment's food safety system with your supervisor.

INFORMATION SOURCES AND DOCUMENTATION

There are many sources of information to consider in the administrative enforcement action decision-making process. These include sources of documentation from "within" the establishment (e.g., NRs, MOIs, FSIS and/or in-plant sampling/testing results, prior AER enforcements) and sources of information "outside" the establishment (e.g., CCMS, recalls). See FSIS Directive 5610.1 "Consumer Complaint Monitoring System" for more information on how CCMS tracks consumer complaints reported to the Agency. See FSIS Directive 8080.1 "Recall of Meat and Poultry Products" or the previous section on Meat, Poultry and Egg Products Recalls for more information on recalls. With both CCMS complaints and potential recall situations, you may be working with your supervisor and/or an EIAO to investigate and, if necessary, provide support to build a case for the AER.

Proper and well thought out documentation is the key to supporting any conclusions or decisions made. You must ensure that all documentation generated by you and your inspection team is complete, accurate, well thought out, and well supported. This documentation may be uploaded by the DO team to the AER case file as evidence.

The most common types of documentation encountered in the AER process include:

- **Noncompliance Records (NRs):** NRs are the format that you will use most frequently in the establishment environment. You will use NRs to document regulatory noncompliance and build a history through **associating** noncompliance when there is an ongoing trend of related noncompliance or systemic problems with the establishment's food safety system. It is important to ensure that the proper regulatory citation is included on the NR so that the NR will stand up to the appeals process or in a court of law. The documentation on an NR is to be complete and accurately depict the circumstances and relevant facts. **NRs are the foundation for enforcement action** and the legal support for further enforcement will hinge upon the quality of the NRs and the factual evidence presented therein.

- **Memoranda of Interview (MOIs):** MOIs document an interview with Agency personnel (e.g., a weekly meeting between FSIS and establishment management). An interview is conducted if the pertinent facts are unclear, if there is additional relevant information that is otherwise not documented, and as instructed in policy issuances and by the OFO supervisory chain. These are important pieces of documentation in establishing a history. Such memoranda are to: 1) include the date of the meeting and all participants (including their official position) present at the meeting; 2) explain all facts that provide the basis for the meeting; 3) fully describe the meeting (including any topics discussed and answers to any questions asked during the meeting) and 4) be written in a concise and clear manner. IPP are to use the instructions in FSIS Directive 5010.1 "Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management."

  When documenting the information, it is important to accurately depict the relevant ***facts*** as they have been revealed in the interview. Do not document opinions or speculation. Like any other memorandum, the interviewer documents the information and is the one who signs and dates the document.

- **Decision Memos:** A decision memo explains the reasoning behind a decision or recommendation for an enforcement action based on credible evidence. Decision memos *synthesize* the available information and supporting documents into a single document. They relay to the reader the *critical thought process* used in analyzing the information and how a conclusion was reached. The decision memo relates the information not only back to regulatory requirements, but also back to the statutory authority of the Agency. This is an important aspect of the AER documentation process, since the AER case file is a legal document. As a PHV, you may be documenting decision memos pertaining to the recommendation of enforcement action related to repeated noncompliances or inhumane handling.

- **Other Agency Letters:** There are many types of official Agency letters that are issued to establishments by the District Office. These letters officially inform an establishment, in writing, of an intended enforcement action or one in effect. These are *enforcement letters* and are not issued by PHV. These include the Notice of Intended Enforcement (NOIE), Letter of Deferral (LOD), Notice of Suspension (NOS), Notice of Suspension Held in Abeyance (NOSA), Notice of Reinstatement of Suspension (NROS), Notice of Reinstatement of Suspension Held in Abeyance (NROSA), Letter of Information (LOI), and Letter of Warning (LOW). More information on this type of documentation is found in FSIS Directive 5100.3 "Administrative Enforcement Action Decision-making and Methodology."

At the point that a recommendation is made to take an enforcement action against an establishment, an AER case file is initiated. The AER case file is assembled with the relevant supporting documentation and managed at the District level, typically by a District Case Specialist.

BUILDING A CASE

The first step in building a case for enforcement is determining the "enforcement stage" that the establishment is currently in. Each stage requires different actions in your role. Refer to FSIS Directive 5100.3 "Administrative Enforcement Action Decision-making and Methodology" for flow charts depicting the responsibilities of IPP and other FSIS personnel in enforcement and verification plan development and workflow.

The enforcement stages include:

- **Pre-enforcement stage:** In this stage, the establishment is not currently under any type of active enforcement action. This is the stage that most establishments operate under. In this stage, you will ensure proper documentation of regulatory noncompliance on NRs and appropriate association of recurring noncompliance. (**Note**: This also includes IPP discussing associations with the establishment at weekly meetings and documenting those discussions in MOIs.) This is important for two reasons. First, you are building a history of any recurring problems while taking the establishment's entire food safety system into account. Second, you are ensuring that the establishment's due process rights are not violated by providing them with the feedback they need to comply with the regulatory and statutory requirements of the Agency.

  If you determine through your critical thinking process that the establishment's food safety system is not effective and that there is a food safety concern, you are required to act. In doing so, you will follow the ROP. If there is an *immediate* concern, you will take immediate action and ensure that there is no imminent threat to the public's health. You will then contact your

supervisor for further guidance. If there is *no immediate* concern, you will recommend an enforcement action to your supervisor. Depending on the situation, an EIAO may be assigned to assist you. In both instances, your documentation of the information and the justification you provide regarding your conclusion is an integral part of the process.

- **Enforcement stage:** In this stage, the establishment has been issued an NOIE or been placed immediately (without prior notification) under a suspension (**Note:** These decisions are determined by the DO). Under an NOIE, the establishment is provided three days to demonstrate or achieve compliance prior to FSIS taking a further enforcement action. Under a NOS, the establishment must provide the DO with acceptable corrective actions and preventative measures for the enforcement action to be placed in abeyance (also a decision determined by the DO).

  Your role is to ensure you and your in-plant team actively engage in the evaluation process of the establishment's response to the enforcement or intended enforcement while the establishment is in this stage. The District Manager ultimately determines if the corrective actions and preventative measures proffered by the establishment are acceptable.

- **Deferral or Abeyance stage:** An establishment is in deferral when the DM determines the establishment has adequately responded to the NOIE issued by FSIS. In other words, FSIS has deferred the decision to take further enforcement based on the establishment's corrective actions and preventative measures. An establishment is in abeyance when the DM determines the establishment has adequately responded to the NOS issued by FSIS. In these instances, the DO will develop a verification plan for your team to utilize when verifying the effectiveness of the establishment's proposed measures.

  Your role is to ensure you and your in-plant team schedule, perform, and document verification activities in PHIS, and to provide any follow-up information to the DO as needed.

- **Referral to OIEA Enforcement Operations Staff (EOS) stage:** In this stage, the Agency has filed a legal complaint for withdrawal of inspection. This means that the establishment's Grant of Inspection, which allows them to operate under federal inspection, may be permanently revoked. The Agency may file a complaint for withdrawing inspection from an establishment (see 9 CFR 500.6 and 500.7 and FSIS Directive 8010.5 "Case Referral and Disposition").

  It is the DM's responsibility to determine when to refer the AER. As a PHV, it is unlikely that you will play a direct role in this stage of the process.

The decision to place an establishment under an enforcement action is a multi-layered process and should not be taken lightly. It must be well thought out and supported. Recommending or taking enforcement actions is based on a conclusion reached through a critical analysis of the pertinent and credible information. Ultimately, portions of the analysis will be performed by various members of the District, such as EIAOs, FLSs, and DMs. But, under normal circumstances, the in-plant inspection team will be the driving force that initiates the process. This recommendation will or will not be supportable based on the strength of the documented case history and the objectivity and logic of the justification. It is your responsibility as a PHV to ensure that all in-plant pieces of the process are well thought out, properly documented, and supportable.

The action that you recommend will depend on several factors that you must consider during your critical thinking process:

- The enforcement stage the establishment is in.
- The egregiousness of the issue(s)—depending on the severity of the issue you will recommend a further enforcement action either with or without prior notification, or under extreme situations, a complaint for withdrawal of inspection. The ROP (9 CFR 500) are the regulations used for making these decisions.
- Prior actions taken—the regulatory and enforcement history of the establishment will play an important role in your recommendation. As such, an establishment that repeatedly cannot, or will not, comply with the regulatory and statutory requirements will be considered for regulatory enforcement based on the repetitive noncompliance. FSIS documentation of the establishment's failures is critical in this case.

It cannot be stressed enough that the recommended or implemented action must be adequately *supported and justified*. The documented history found in the relevant NRs, memoranda, and other Agency letters, builds the foundation for the critical thought process leading to the recommendation. The synopsis of the entire thought process and the justification for the recommendation is then documented in the decision memo and attached to the AER file. Once again, it is your responsibility as a PHV to ensure that all in-plant pieces of the AER process are well thought out, properly documented, and supportable.

VERIFYING ESTABLISHMENT RESPONSE TO ENFORCEMENT ACTION

A verification plan (VP) is a tool designed to verify the effectiveness of the establishment's proposed corrective actions and preventative measures that were proffered and led to the DM decision to defer a decision of enforcement or hold a suspension in abeyance. When you complete the activities in the VP, you are verifying the establishment has fully and effectively implemented its corrective actions and preventative measures (e.g., revisions to Sanitation SOP and HACCP system). The VP also assists the establishment in understanding the nature and importance of FSIS's verification activities. This is an important factor in the establishment's due process rights.

The DO (often an EIAO or DCS) develops the VP and shares it with you and your team. The VP provides instructions for verifying the establishment's corrective actions and preventative measures. You and your team will be responsible for completing the VP and documenting your findings, including any noncompliance, in PHIS. VPs are also included in the AER case file.

The VP includes information such as the background of the enforcement, a list of the establishment's proposed measures, your verification requirements for documents/programs/processes/products, frequency of verification, the PHIS task associated with each verification and free space to add additional information. **Note:** The DO must be informed if the establishment makes any changes to the corrective actions and preventative measures during the verification period and will revise the VP prior to the establishment implementing the change.

The VP will cover a minimum of 90 calendar days, throughout which your FLS and DO (usually an EIAO) will periodically review and assess your findings. An EIAO (or other DO personnel) will conduct 30-, 60-, and 90-day visits during this time to review and assess verification activity results. The EIAO will make a recommendation to the DO as to whether the VP should be continued, the enforcement action should be closed, or if the enforcement should be reinstated.

If your verification results lead to the conclusion that the establishment's measures are not implemented or are ineffective, FSIS has the authority to reinstate an enforcement action or take the intended enforcement action.

PHV ROLE: SUMMARY OVERVIEW

This section summarizes the role you as a PHV play in various parts of the administrative enforcement and decision-making process discussed above. Throughout the process, you serve as the in-plant team leader. You apply your knowledge of the regulations and directives to complete inspection per agency policy. You make inspection decisions using sound critical thinking. As a leader, you also ensure that your in-plant inspection team is properly identifying and documenting noncompliance. You will ensure your team is using critical thinking to identify and document trends of noncompliance. You will ensure that when your team identifies findings that may indicate systemic problems with the establishment's food safety system, or patterns of noncompliance, your team discusses these findings with their immediate supervisor. This is important because you and your team may be the first to identify findings at an establishment that may warrant further enforcement.

You will contact your supervisor when you identify or observe noncompliance findings that may warrant intended enforcement or enforcement (e.g., trend demonstrating the establishment has failed to maintain sanitary conditions) and provide timely information on the conditions at the establishment. You will ensure that your team's inspection findings are accurately documented (e.g., NRs) and that documentation is completed in a timely manner. This is important because this supporting documentation must be accurate and available when the agency proposes or imposes an enforcement action. You will also ensure constant communication with establishment management to provide and obtain relevant information and ensure these discussions are documented in MOIs.

You will review enforcement related documentation (e.g., NOS, NOIE, FSA findings) at establishments in your assignment and ensure important information regarding any action to be taken is communicated to establishment management. You will work with your FLS, any assigned EIAO, and your in-plant inspection team to provide accurate and pertinent information to the DO for inclusion in the NOIE or suspension letter. During enforcement, you will remain in communication with your FLS and provide them with timely information and updates on the current and continuing conditions in the establishment. You will ensure that your in-plant team remains objective and professional, as well as ensure that they are not subjected to intimidation or harassment from establishment personnel.

After an establishment has responded to an enforcement or intended enforcement, you may be involved in the review of the establishment's proposed corrective actions and preventative measures. You may facilitate additional communication between the establishment and the DO on clarifying information about the measures. You may also work with your FLS and the assigned EIAO to ensure that the VP is complete and comprehensive.

As the in-plant leader, you will discuss the VP with your in-plant team and provide them guidance on appropriate execution of the activities in the VP. You and your team will perform the activities as described in the VP to verify the adequacy of the establishment's corrective actions and preventative measures. You will collaborate with your FLS and the EIAO assigned to the case to summarize the verification activities, discuss significant findings or concerns, and provide any additional information needed to determine if a recommendation to close out, continue, or reinstate enforcement is appropriate.

You will continue to conduct weekly meetings with the establishment and discuss any issues that emerge during the deferral/abeyance period. This communication and documentation are important parts of the establishment's due process.

If you identify noncompliance when performing VP verification tasks, you will document your findings in a timely and accurate manner and communicate your findings to your supervisor. This is important because if an establishment fails to implement its proposed corrective actions and preventative measures, or if those measures are not effective, FSIS has the authority to reinstate an enforcement action or take the intended enforcement action. In very rare instances, you may be asked to provide information or testify in the event that the Agency files a complaint for withdrawal of inspection from an establishment.

Food Microbiology and Microbial Sampling

OBJECTIVES

Scientific:

1. List pathogens of concern in the Slaughter and Processing contexts.
2. Given a scenario, review an example of how an establishment may analyze and interpret microbiological data using process control charts.
3. Explain how establishment sampling may be used to validate and support the establishment's food safety system.
4. Given a scenario about an establishment's sampling practices, identify and explain observable pitfalls that could skew sampling results.
5. Identify and give an example of observable pitfalls that could skew FSIS sampling results.
6. Demonstrate correct techniques for collecting FSIS samples (raw beef cloth sampling, RTE sampling, and *Salmonella*/*Campylobacter* sampling of poultry).

Regulatory/Administrative:

1. Identify FSIS sampling programs related to Slaughter and Processing.
2. Identify the pathogens of focus for each of those FSIS programs and products eligible for sampling.
3. Identify and locate the directives and notices related to those FSIS sampling programs.

RESOURCES

FSIS Directive 5000.1 – Verifying an Establishment's Food Safety System
FSIS Directive 5000.2 – Review of Establishment Data by Inspection Personnel
FSIS Directive 6410.1 – Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age
FSIS Directive 6410.4 – Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens
FSIS Directive 6420.5 – Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens
FSIS Meat and Poultry Hazards and Controls Guide
FSIS Directives 10000 series – Laboratory Services
IPP Help – Sampling (VPN required)
FSIS EIAO Training Materials: Statistics and their role in evaluating an establishment's process control procedures

INTRODUCTION

This module covers a variety of topics that relate to food microbiology and sampling in both slaughter and processing, including a brief overview of pathogens of concern in the slaughter and processing contexts. It covers how establishments may use antimicrobial interventions in their process, sampling and testing procedures and pitfalls, and how IPP are to verify the establishment's microbial sampling and testing for process control. An overview of FSIS sampling projects is also covered. **Note:** This

module will cover establishment responsibilities first, and then discuss IPP verification and FSIS sampling.

PATHOGENS OF CONCERN IN SLAUGHTER AND PROCESSING

In slaughter and processing, foodborne pathogens can be introduced into the process from a variety of sources, including the live animals (feces, ingesta, hide, feathers), people in the slaughter and processing environment, equipment, ingredients, pests, etc. You should maintain a working knowledge of the potential sources of pathogens in the establishments within your assignment because part of your role will be to verify the establishment addresses potential sources of pathogens in their food safety systems. Similarly, you should understand the factors affecting microbial growth (e.g., FATTOM: Food composition, Acidity, Temperature, Time, Oxygen, and Moisture) in the food products produced by establishments within your assignment. Part of your role will be to verify how the establishment's food safety systems may control or alter those parameters to impact pathogen growth.

Bacteria account for a large portion of foodborne illness in the meat, poultry, and egg products we regulate. Which type of bacteria the establishment should consider in the hazard analysis depends on the species, product, and process. Good starting points in determining which bacteria are a hazard in which species and processes are the Meat and Poultry Hazards and Controls Guide and the FSIS HACCP Models. Below are additional resources to help you identify and understand more about common bacterial pathogens of concern in slaughter and processing, depending on the species, product, and process. Please use the information below as a guide, not an all-inclusive list.

- ***Salmonella*** hazards in:
  - Swine and poultry slaughter
    - FSIS Guideline to Control Salmonella in Swine Slaughter and Pork Processing Establishments
    - FSIS Guideline for Controlling Salmonella in Raw Poultry
  - Beef (including veal), chicken, turkey (and other poultry), pork, sheep and goat products
    - FSIS Cooking Guideline for Meat and Poultry Products
    - Minimizing the Risk of Campylobacter and Salmonella Illnesses Associated with Chicken Liver
  - Non-meat ingredients (spices, herbs)
    - FSIS Cooking Guideline for Meat and Poultry Products
  - Cross-contamination of cooked products with raw products
    - FSIS Cooking Guideline for Meat and Poultry Products

- ***Campylobacter*** hazards in:
  - Poultry slaughter
    - FSIS Guideline for Controlling Campylobacter in Raw Poultry
  - Chicken, turkey, and other poultry products
    - Minimizing the Risk of Campylobacter and Salmonella Illnesses Associated with Chicken Liver
    - FSIS Cooking Guideline for Meat and Poultry Products

- **Shiga Toxin-Producing *Escherichia coli* (STEC)** hazards in:
  - Beef (including veal) slaughter
    - FSIS Industry Guideline for Minimizing the Risk of STEC in Beef (including Veal) Slaughter Operations
    - Sanitary Dressing and Antimicrobial Intervention Implementation at Veal Slaughter Establishments
  - Raw beef and veal products
    - FSIS Industry Guideline for Minimizing the Risk of STEC in Beef (including Veal) Processing Operations
    - Compliance Guideline for Establishments Sampling Beef Trimmings for STEC Organisms or Virulence Markers
  - Non-meat ingredients (leafy greens)

- ***Clostridium*** spp. hazards in:
  - Cooling of product that receives heat treatment or are cooked
    - FSIS Stabilization Guideline for Meat and Poultry Products
  - Heating/smoking/charring/breaded and pre-browned processes (not fully cooked)
    - FSIS Stabilization Guideline for Meat and Poultry Products
  - Hot-holding of ready to eat products
    - FSIS Stabilization Guideline for Meat and Poultry Products
  - Curing/drying of meat and poultry products
    - FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline
  - Thermally processed products
    - HACCP Model for Thermally Processed, Commercially Sterile Product

- ***Listeria monocytogenes*** hazards in:
  - Non-meat ingredients (frozen fruit and vegetables)
    - FSIS Cooking Guideline for Meat and Poultry Products
  - Ready to eat products (environmental contamination)
    - Controlling Lm in Post-lethality Exposed RTE Products
  - Brine chilling of cooked products
    - Controlling Lm in Post-lethality Exposed RTE Products

- ***Staphylococcus aureus*** hazards in:
  - Fermentation/drying processes
    - FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline
  - Heating/smoking/charring/breaded and pre-browned processes (not fully cooked)
    - FSIS Cooking Guideline for Meat and Poultry Products
  - Hydrated batter mixes
    - FDA “Fish and Fishery Products Hazards and Controls Guidance” Chapter 15
  - Ready to eat products
    - FSIS Cooking Guideline for Meat and Poultry Products
    - FSIS Stabilization Guideline for Meat and Poultry Products
  - Jerky Products
    - FSIS Compliance Guideline for Meat and Poultry Jerky Products

Other biological hazards of concern include SRMs (see FSIS Directive 6100.4 "Verification Instructions Related to SRM in Cattle of all Ages" and FSIS Website: SRM Resources) and parasites such as *Trichinella* (see FSIS Directive 7320.1 "Prevention and Control of *Trichinella* in Domestic Pork Products and the FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork). You will assess the various food safety systems at the establishments in your assignment to verify the establishment has considered the biological hazards relevant to their products and processes.

ESTABLISHMENT RESPONSIBILITIES

Use of Antimicrobial Interventions

Establishments implement antimicrobial interventions as needed to reduce pathogens. Despite good slaughter and dressing practices, contamination of carcasses can occur. Thus, the use of effective antimicrobial intervention strategies is an important component of a food safety system.

The HACCP regulations require establishments to provide scientific support for their interventions and to implement their interventions according to that support. Antimicrobial interventions may be incorporated into an establishment's HACCP plan, Sanitation SOPs, or other prerequisite program.

The establishment should identify critical operating parameters for any antimicrobial interventions used in its supporting documentation. These parameters are the specific conditions (e.g., time, concentration, temperature, method of application, product coverage) that the intervention must operate under for it to be effective. These parameters may be incorporated into critical limits (CCPs) or other appropriate procedures (Sanitation SOPs, PRPs), depending on what the establishment has determined in its hazard analysis and how the establishment supports its decisions. To be effective, the process procedures should be consistent with the critical operational parameters in the scientific support.

Note: Establishments must ensure that antimicrobial interventions and the levels used are safe and suitable. FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" and 9 CFR 424.21 provide a list of substances that have been deemed safe and suitable. However, in addition to the safe and suitable information, the establishment must also have support that contains efficacy data and the critical operational parameters of use.

FSIS provides guidance to establishments for validating antimicrobial interventions (FSIS Compliance Guideline: HACCP Systems Validation) and for implementing antimicrobial interventions to reduce microbial contamination during slaughter and processing, including examples of ineffective implementation of antimicrobial interventions (FSIS Industry Guideline for Minimizing the Risk of STEC in Beef (including Veal) Slaughter Operations, Sanitary Dressing and Antimicrobial Intervention Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices, and FSIS Guideline for Controlling Salmonella in Raw Poultry).

Examples of ineffective implementation of antimicrobial interventions include (but are not limited to):

- Failing to apply antimicrobial interventions according to the supporting documentation.
- Failing to identify the critical operational parameters in supporting documentation.
- Failing to incorporate the critical operational parameters into the HACCP system.
- Failing to implement the antimicrobial treatments so that the critical operational parameters are met (e.g., failing to achieve full carcass or product coverage).

- Application of the antimicrobial intervention in a manner that spreads contamination to other areas of the carcass or other carcasses.

Establishment Sampling and Testing for Process Control

Note: This section addresses establishment sampling and testing for process control. Generally, establishments test for indicators (e.g., Aerobic Plate Count (APC)) rather than pathogens for process control testing. The establishment conducts this sampling and testing. IPP verify the establishment meets the regulatory requirements.

Requirements to Demonstrate Process Control discussed the importance of establishments maintaining process control during slaughter. Establishments must effectively prevent contamination throughout the slaughter and dressing operation as required in:

- Cattle: 9 CFR 310.18(a) and 310.25
- Swine: 9 CFR 310.18(a) and 310.18(c)
- Sheep/Goats: 9 CFR 310.25
- Poultry: 9 CFR 381.65(g) and 381.65(f)
- Ratites: 9 CFR 381.94

FSIS has numerous resources available online that you may use to become familiar with the various steps in the slaughter process, including where and how contamination may occur at each step:

- Meat and Poultry Hazards and Controls Guide
- Industry Guideline for Minimizing the Risk of STEC in Beef (including veal) Slaughter Operations
- Guideline to Control *Salmonella* in Swine Slaughter and Pork Processing Establishments
- Guideline for Controlling *Salmonella* in Raw Poultry
- HACCP Models

Slaughter establishments are required to conduct microbial testing to verify the effectiveness of their process control. For those that slaughter livestock (other than swine) and ratites, establishments are required to test for generic *E. coli* (9 CFR 310.25(a) and 381.94(a)). For those that slaughter swine and poultry (other than ratites), establishments are required to determine which microbial organisms will be effective in monitoring process control and implement their own sampling plans to monitor their ability to maintain process control (9 CFR 310.18(c)) and 381.65(g)).

Note: Typically, swine and poultry (other than ratite) establishments sample for indicator organisms (e.g., APC, *Enterobacteriaceae*, generic *E. coli*, and total coliforms), rather than pathogens, to assess process control. FSIS recommends an establishment use APC, however, it is up to the establishment to determine which microbial organisms will be effective. See FSIS Guideline: Modernization of Swine Slaughter Inspection – Developing Microbial Sampling Programs in Swine Slaughter Establishments for additional information on indicator organisms.

Statistical Process Control

Livestock (other than swine) and ratite slaughter establishments using the sponge method to collect generic *E. coli* must evaluate the test results using statistical process control (SPC). Swine and poultry slaughter establishments must record and analyze microbial test results to monitor process control. Swine and poultry establishments must sample at a frequency that is adequate to monitor their ability to

maintain process control for enteric pathogens and take corrective actions when results exceed selected parameters per their written program. Establishments must maintain accurate records of all test results and retain these records.

SPC uses statistics to analyze data collected by an establishment to monitor and improve processes by reducing variation from the process. SPC provides a powerful tool for establishments to monitor and interpret data collected for ongoing HACCP verification. SPC can provide establishments with an early warning that the process may not be functioning as designed. This warning can allow establishments to make modifications to bring the process back into control prior to failing a performance standard or individual establishment-identified, pre-determined performance criteria. SPC can provide establishments with reasonable assurance that the HACCP system is functioning as designed and that they are likely to meet applicable performance standards. Several methods and approaches for SPC are available for establishments to follow. Establishment methods for interpreting sample results should be statistically valid.

An establishment must apply SPC principles to analyze trends in its own sampling data over time to assess its process, with the intention of optimizing its process control. Part of this evaluation is to evaluate, at some frequency, whether the defined control limits used are still appropriate, based on the application of SPC principles to an analysis of the establishment's own sampling results. In other words, the establishment must use the data collected from its own sampling programs to conduct SPC analysis. The establishment is expected to use process control analysis to determine its upper control limit.

Generic E. coli Testing Requirements for Livestock (other than Swine) and Ratites

The purpose of the establishment's generic *E. coli* testing is to verify the effectiveness of sanitation and process control in these slaughter facilities. Prior to receiving a grant of inspection, the FLS verifies that the establishment's written *E. coli* testing procedures meet the basic regulatory requirements. A slaughter facility will not receive a grant of inspection until they have a written program that meets the applicable regulatory requirements. Once a slaughter establishment has been granted inspection, IPP verify that the implementation of the generic *E. coli* testing program meets the requirements.

Note: FSIS has available the Guidelines for *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments. Remember however that swine slaughter establishments may choose to test for an indicator organism other than generic *E. coli*.

Microbial Testing for Process Control (Swine and Poultry (other than Ratites))

Swine and poultry slaughter establishments are required to determine which microbial organisms will be effective in monitoring process control and implement their own written sampling plans. These establishments may test for generic *E. coli* if they determine such testing is effective for monitoring process control. These establishments may instead determine that another indicator organism (e.g., APC, *Enterobacteriaceae*, total coliforms) is effective for monitoring process control and test for that indicator organism. The regulations also require establishments to maintain daily records documenting the results of its sampling plan (9 CFR 310.18(d) and 381.65(h)).

Establishment Sampling as Validation and Support

Establishments may also conduct sampling and testing as part of their initial validation. For example, the FSIS Compliance Guideline: HACCP Systems Validation describes examples of when an establishment may or may not need to collect microbiological data during initial validation.

Whether or not an establishment needs to collect microbiological data during initial validation will vary depending on the situation. For example, if the establishment implements its actual process consistent with the critical operational parameters in its scientific support, and that scientific support contains microbiological data specifying the level of pathogen reduction to be achieved by the intervention strategy for the target pathogens identified in the hazard analysis, the establishment may not need to collect in-plant microbiological data. However, if the establishment's process is not implemented in a manner consistent with the critical operational parameters described in the scientific support (without justification) or if the scientific support does not contain microbiological data specifying the level of pathogen reduction achieved by the intervention for the target pathogen identified in the hazard analysis, the establishment will most likely need to collect in-plant microbiological data to demonstrate that the intervention's effectiveness under actual in-plant conditions is effective (or provide additional support).

Establishments may also use sampling and testing results as a method of ongoing verification. For example, the Industry Guideline for Minimizing the Risk of STEC in Raw Beef (including Veal) Processing Operations describes FSIS's recommendation that establishments which produce raw non-intact beef products and beef products intended for raw non-intact use utilize STEC sampling and testing as an ongoing verification activity to demonstrate their HACCP system is functioning as intended. In this guide, FSIS provides "safe harbors," which are recommended frequencies for establishments that conduct STEC sampling and testing as an ongoing verification activity, based on the volume of production.

If you have questions or concerns about how an establishment is utilizing sampling and testing results, you may contact your supervisor and askFSIS to request assistance with assessing the establishment's support.

Establishment Sampling and Testing Procedures and Pitfalls

As previously described, establishments are required by regulation to conduct microbial sampling to assess slaughter process control. Establishments may also sample for pathogens as part of support for their food safety system.

"Sampling" and "testing" are two distinct processes, and establishments should maintain adequate support for both their sampling and their testing protocols. "Sampling" is the technique by which a small portion of a lot is selected to represent the lot. "Testing" is the technique by which the sample is analyzed. The outcome of that analysis is the "result." A number of factors related to sampling and testing can affect or skew results.

FSIS has resources available that provide valuable information on pathogen sampling and testing that establishments may utilize as part of their support for their sampling and testing methods. For example, the Compliance Guideline for Establishments Sampling Beef Trimmings for STEC Organisms or Virulence Markers discusses the importance of taking thin, surface (from exterior tissues of carcass) tissue slices of meat when collecting N60 samples for STEC sampling. The guide also emphasizes that the method of lab analysis should be equivalent to that of the current method that FSIS laboratories use. In another example, the Controlling *Listeria monocytogenes* in Post-lethality Exposed RTE Meat and Poultry Products guide discusses the importance of proper collection technique to ensure low levels of *Lm* or *Listeria* spp. are detected (e.g., aseptic technique, sample size, sampling devices used as described, time of sample collection, avoid freezing sample). The guide also describes laboratory testing methods important to produce reliable and accurate results (e.g., an enrichment step, analysis of the entire sponge or sampling device, and using a validated screening method).

FSIS also has resources available that provide valuable information for establishments on sampling and testing to assess for process control. For example, the FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection – Microbiological Sampling of Raw Poultry and FSIS Guideline: Developing Microbiological Sampling Programs in Swine Slaughter Establishments. These guidelines discuss a number of factors important to sampling and testing, such as the importance of using a method of selecting carcasses that is random, using aseptic sampling techniques, and analyzing samples as soon after collection as possible.

FSIS also has available the Establishment Guidance for the Selection of Commercial or Private Microbiological Testing Laboratory and Foodborne Pathogen Test Kits Validated by Independent Organizations.

Note: The Foodborne Pathogen Test Kits Validated by Independent Organizations table only lists test kits that have been both validated by a recognized independent organization and the results have been submitted to be publicly available. If a sampling method or matrix for a particular kit is not listed, it may simply mean that this work has not been submitted to the validating organization to update the record. For example, FSIS previously validated the BAX method for environmental sponges. This has not been submitted as a listing by a third party, so it is not found in the Foodborne Pathogen Test Kits Validated by Independent Organizations table.

When considering the testing kits and laboratory analysis methods an establishment utilizes, in addition to using a validated test kit or method, establishments should also ensure the validated method is:

- Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen).
- Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results.

You should be alert to sampling factors that could impact the establishment's sampling results. For example:

- Improper sampling technique (e.g., for N60 sampling, not collecting from outside/exterior surfaces of the beef or collecting pieces thicker/smaller in size than described in the procedures).
- Lack of aseptic sampling.
- Using expired or leaking sampling broth.
- Not storing sampling broth/solutions according to manufacturer's recommendations.
- Freezing samples (may decrease bacterial counts).
- Applying additional interventions specifically to products to be sampled or increasing concentrations of antimicrobial interventions beyond what is used in the normal process.
- Improper storage of samples (typically, samples should be held under refrigeration).
- Delayed time to ship samples to the lab (typically, samples collected should be shipped the same day or next day).
- Not allowing adequate drip time after microbial interventions are applied (may result in the collection including a significant amount of residual antimicrobial).
- Collection method (non-destructive vs destructive methods, e.g., rinses and sponge samples are less likely than destructive methods to collect bacteria in feather follicles, crevices, or skin folds).

- Sample control methods (e.g., temperature abuse, sample leakage or other events that could impact sample integrity).
- Compositing samples.
- Equipment that is sampled was sanitized just prior to sampling.

Below is a list of examples of lab analysis related factors that could impact the results of the testing:

- Labs not using FSIS equivalent methods.
- Sample size used is below what methodology specifies.
- Sample remains chilled for a longer period than normal during incubation.
- In-house lab is not segregated from manufacturing areas and access to the laboratory is not limited to qualified personnel.
- In-house lab personnel not under the supervision of a qualified microbiologist or equivalent.
- In-house lab technicians not properly trained or not following written protocols.
- Lab did not properly document: date received, condition of the sample upon receipt (including sample temperature, if applicable), date the analysis was started and completed, and analytical result.

FSIS VERIFICATION

FSIS Verification of the HACCP System: Biological Hazards

You learned in Inspection Methods how IPP verify an establishment's food safety system, focusing on the overall effectiveness of the system. As described previously in this module, establishments may utilize antimicrobial interventions in their processes to address biological hazards identified in their hazard analysis. Slaughter establishments are required to conduct microbial sampling and testing to assess process control. Establishments may also test for pathogens as part of their validation and support. These are some of the many factors IPP must consider when assessing the establishment's food safety system.

Your role as a supervisor includes ensuring that IPP conduct HACCP inspection tasks according to FSIS policies. You will engage in discussion about IPP findings related to the establishment's HACCP system, including any trends or systemic concerns. You and your team will verify the establishment maintains adequate initial validation, which may include microbiological data. You will verify the establishment's antimicrobial interventions are validated. You will verify the establishment is implementing its HACCP system, including any antimicrobial interventions, as designed. You will observe the establishment's sampling procedures and review establishment testing records. You will consider the establishment's sampling programs and testing results in your thought process when assessing the adequacy of the establishment's HACCP system. FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" and FSIS Directive 5000.6 "Performance of the HAV Task" describe the verification activities IPP will conduct and your supervisory responsibilities related to those activities.

FSIS Verification of Establishment Sampling and Testing: General

For sampling and testing conducted by an establishment that may have an impact on the establishment's food safety system, you will ensure IPP review the results of the testing as described in FSIS Directive 5000.2 "Review of Establishment Testing Data by IPP." As you learned in Inspection Methods, the directive includes questions you are to seek answers to when reviewing establishment test results, such as:

- Are the results of the sampling indicative that a food safety concern may be developing?
- Is the establishment reacting to the situation?
- Are there operational results that correlate with the testing results?

Per FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System," IPP observe the establishment collecting samples, review sample results, and verify the establishment takes appropriate action in response to the results.

If you have concerns about the establishment's sampling and testing (e.g., support for the procedures, accuracy of the results, significance of the results), you may reach out to your supervisor, askFSIS, or request EIAO assistance in assessing the establishment's sampling and testing procedures.

FSIS Verification of Establishment Sampling and Testing: Process Control

For process control sampling and testing, IPP are to verify that establishments conduct microbial testing, that establishments document the results of microbial testing, and that establishments assess and respond appropriately to the results. As a supervisor, you will ensure that IPP verify by following the policies described in Agency issuances.

- For livestock (other than swine) and ratites - FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" (See "Pathogen Reduction Activities"). The directive provides IPP information on the regulations which require establishments that slaughter livestock (other than swine) and ratites to test carcasses of the species slaughtered in the greatest number for generic *E. coli* (9 CFR 310.25(a) and 381.94(a)). The directive also provides IPP with information on how to verify the establishment meets the regulatory requirements for generic *E. coli* sampling and testing, including the requirements for sample collection, frequency of collection, and sample analysis, as well as the requirements for analysis and recording of test results. IPP will also verify the establishment's response to the generic *E. coli* results. IPP will verify by directly observing the establishment collecting samples as well as reviewing establishment records. IPP document their findings in PHIS under the Generic *E. coli* verification task.
- For swine, FSIS Directive 6410.4 "Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens" and for poultry, FSIS Directive 6420.5 "Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens" provide IPP information on the regulations which require establishments that slaughter swine and poultry (other than ratites) to determine which microbial organisms will be effective in monitoring process control and for those establishments to implement their own sampling plans (9 CFR 310.18(c)) and 381.65(g)). The directives also provide information on how IPP verify the establishment meets the regulatory requirements for microbial sampling and testing. This includes:
    - Verifying that the establishment meets the requirements for sampling locations and frequency of collection.
    - Verifying that the establishment meets the requirements for analysis of its test results.
    - Verifying the establishment's response to the test results.

    IPP will verify by directly observing the establishment collecting samples as well as reviewing establishment records. IPP document their findings in PHIS under the applicable inspection task (task varies depending on where the establishment elects to incorporate their procedures to control contamination in their system).

As an SPHV, you may receive questions from IPP on your team about how an establishment evaluates its microbial test results for process control or how the establishment responds to these results.

When reviewing establishment test results, understand that a well-controlled process will normally show small to moderate variation around the desired result over time. A well-controlled process may occasionally produce results well outside the normal range through random statistical variation. IPP should look for trends that indicate increased variation or rising contamination levels, as these can be signs that the establishment is not maintaining process control. Attachment I at the end of this module provides examples of trends IPP should look for and what those trends could indicate.

Establishment microbial test results, by themselves, do not necessarily indicate noncompliance. IPP should consider if the establishment is taking effective action to maintain or restore process control when test results indicate a process control concern. IPP consider their findings regarding microbial testing for process control along with other findings (e.g., zero tolerance, sanitary dressing, pathogen testing) when evaluating whether the establishment is effectively implementing a HACCP system to ensure sanitary conditions during slaughter. You must notify your supervisor if you or IPP determine there may be systemic problems with the establishment's slaughter HACCP system, to determine if further enforcement action is warranted.

If you have questions about whether the establishment's sampling records indicate it is maintaining process control, you may consult your supervisor askFSIS, or request EIAO assistance in evaluating the food safety system.

FSIS SAMPLING PROJECTS OVERVIEW

Note: This section focuses on sampling conducted by FSIS.

FSIS conducts sampling and testing programs as part of its verification activities, including both microbiological and chemical residue sampling and testing. FSIS posts an Annual Sampling Plan to outline its strategy and identify changes from previous years. FSIS also maintains an Annual Catalog of Sampling Projects and posts summary reports of the data FSIS collects. All this information and more is located on the FSIS Website: Sampling Program page.

Supervisors should be aware of the FSIS sampling and testing projects, including which FSIS sampling may apply to the establishments within their assignments. Supervisors should ensure IPP are collecting samples to meet the frequency and timeframes provided in PHIS, unless there are no products available during the timeframe. As an SPHV, you will have access to PHIS reports which you may run to determine which samples are collected or not collected (including justification for why samples were not collected, if applicable). You may also review establishment profiles in PHIS to verify IPP are maintaining these accurately, as the establishment profile determines eligibility for sampling.

Specific information about each sampling project, including what products are eligible, how IPP are to collect the samples, and how IPP respond to the results of testing are located in the FSIS Directive 10000 series (e.g., FSIS sampling for *Salmonella*, STEC, and *Lm*) as well as other series of directives (e.g., FSIS Directive 7000 series for allergen verification and labeling claims sampling) depending on the sample project. FSIS may also issue notices to provide information on FSIS sampling projects, and IPP may also find sampling information on IPP Help: Sampling (VPN required).

For FSIS sampling, be sure to verify that you and your team are following the specific sampling, packaging, and shipping procedures provided within FSIS directives, notices, and IPP Help: Sampling. For example, FSIS Directive 10010.1 "Sampling Verification Activities for STEC in Raw Beef Products" describes how IPP using the cloth sampling procedures must use aseptic technique, pre-chill nBPW and shipping containers, vigorously massage the surface area of the product (including spaces and crevices between meat pieces) to ensure as much of the product surface area is sampled as possible, and avoid freezing the sample. FSIS Directive 10250.1 "*Salmonella* and *Campylobacter* Verification Program for Raw Poultry Products" describes how IPP collecting young chicken and turkey carcass samples should verify the broth is not expired or leaking and that the broth is pre-chilled upon receipt, collect samples using aseptic technique, allow a minimum of one minute drip time for poultry carcasses prior to rinsing or swabbing, and package the sample such that there is a barrier between the sample and the frozen gel pack to prevent freezing of the sample. These are just a few examples of the specific sampling procedures IPP must follow when conducting FSIS sampling.

ATTACHMENT I

Below are examples of trends in establishment microbial sampling results that may indicate that the establishment is not maintaining process control, as well as examples of how process control charts may be utilized to depict process control. See FSIS Directive 6410.4 "Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens," FSIS Directive 6420.5 "Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens," FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection – Microbiological Sampling of Raw Poultry and FSIS Guideline: Developing Microbiological Sampling Programs in Swine Slaughter Establishments for additional information.

Trends in Microbial Results

Trends in results that indicate increasing variation or rising contamination levels can be signs that the establishment is not maintaining process control. Look for trends such as:

- Sampling results exceed the establishment's normal variation or upper control limit by a relatively large amount several times in quick succession. This may indicate rare but significant variations from the normal performance of the establishment's system that overwhelm the control measures in place.
- Sampling results begin to regularly exceed the establishment's normal variation or upper control limit by a relatively small amount. This may indicate frequent or ongoing loss of control in one part of the establishment's slaughter system that is partially compensated for by controls in other parts of the system. Alternately, this could indicate systemic changes which reduce the overall effectiveness of the establishment's system.
- Sampling results show a trend of rising contamination over a relatively long period of time. Normal seasonal or weather-related changes can produce trends of more or less contamination on incoming animals, which may be reflected in establishment sampling results. However, if microbiological contamination increases from previous years or begins to deviate from an establishment's established seasonal pattern, this may indicate gradual decline of system effectiveness over time.
- Other sampling programs begin to show significantly worse results. These could include FSIS carcass sampling results or FSIS or establishment sampling results from downstream products (e.g., poultry parts and comminuted poultry products) that originate from the establishment's slaughtered carcasses. Abnormal results of these other sampling programs may indicate that increased contamination is occurring during slaughter.

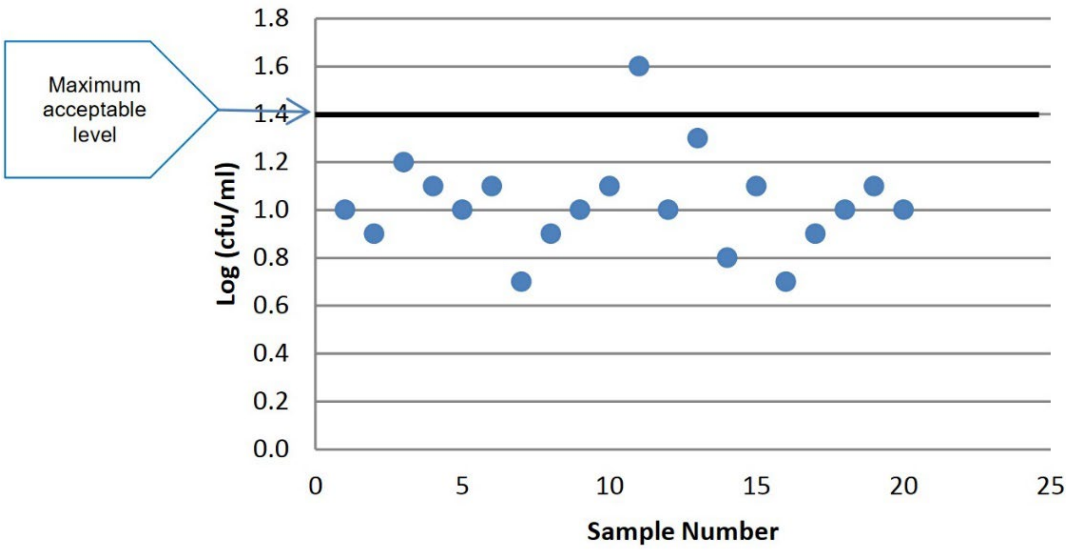
Process Control Charts

Establishments may use SPC methods that include the use of a control chart. These charts plot data over time and display an upper control limit for specific measurements and a centerline, above and below which there is an equal number of sample results. A sample result above the upper control limit would indicate the likely presence of a variation that should be addressed. Results within control limits would indicate the process is in control.

The following control charts provide hypothetical examples of when test results may indicate a process is under control or not under control.

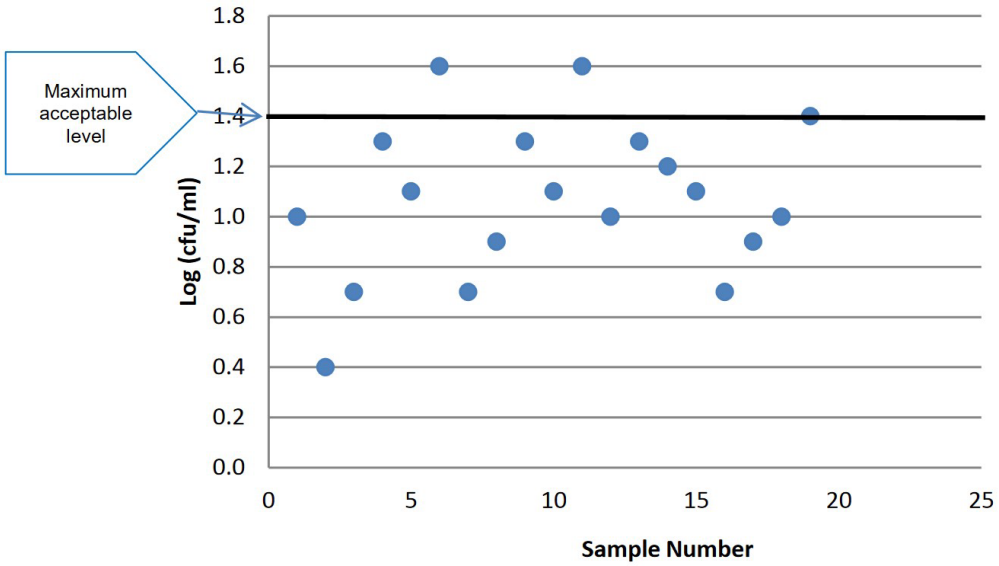
1. **Chart 1 – System under control**

   In a well-controlled system, most of the test results will be clustered around a central value. Even in a well-controlled system, there may be small to moderate variation around the desired result over time. There may occasionally be results well outside the normal range through random statistical variation. The chart below depicts a pattern of test results that would be seen in a well-controlled system.



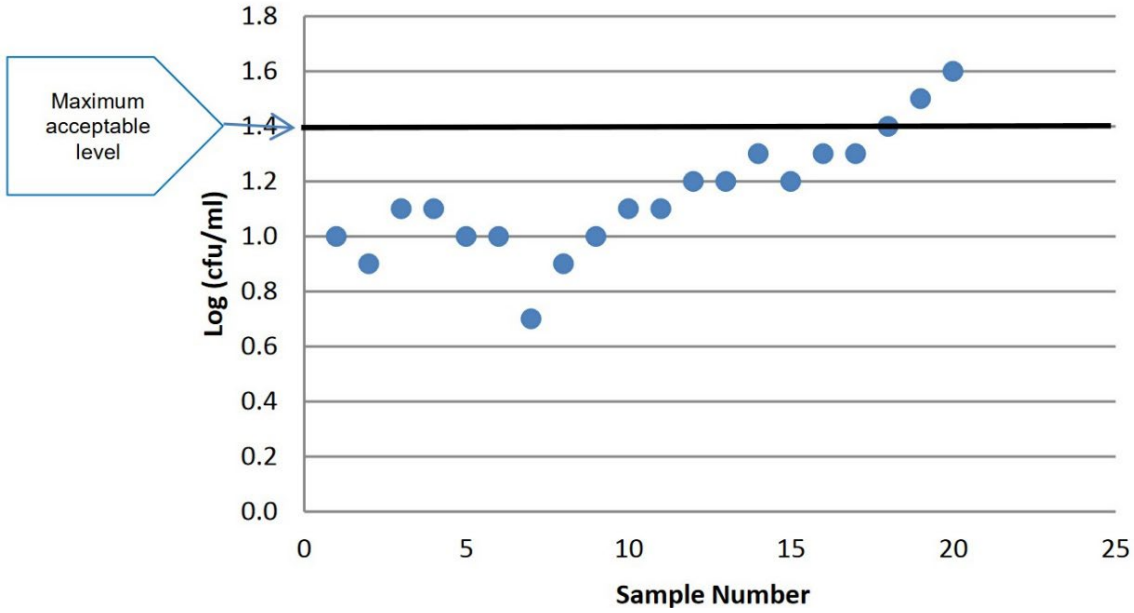
2. **Chart 2 – Lack of control due to excess variability**

   Chart 2 depicts a loss of process control due to excess variability. This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter points below the maximum acceptable level. This could suggest either a loss of control at a CCP or the existence of a CCP that has not been identified and controlled.



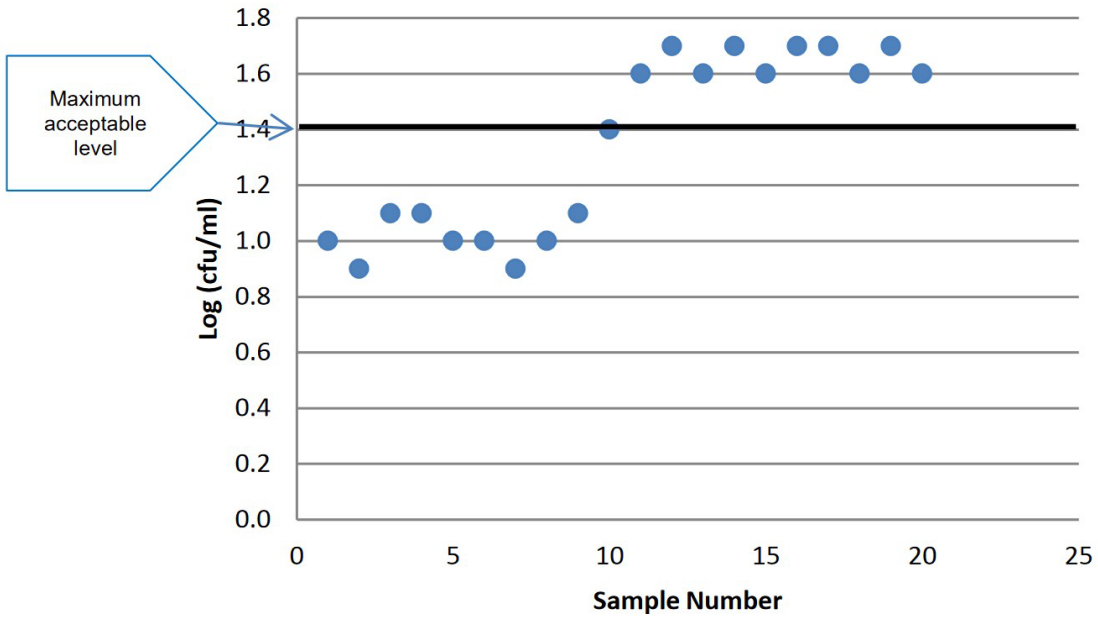
3. **Chart 3 – Loss of control due to gradual process failure**

Chart 3 depicts a loss of control as indicated by the upward trend in the data toward the maximum acceptable level. This suggests that a component of the process is losing its effectiveness over time.



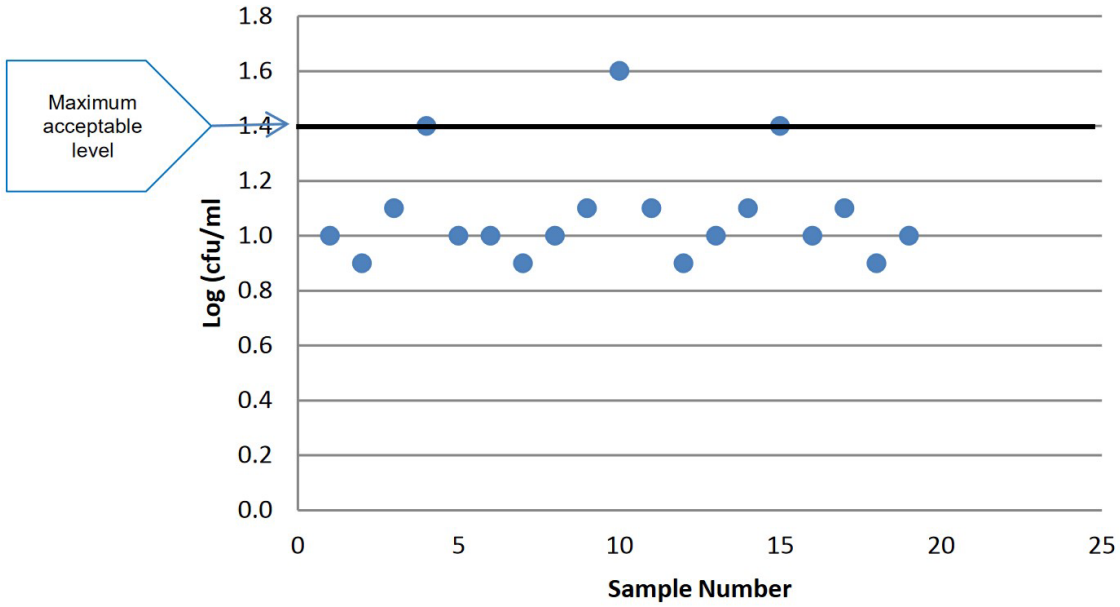
4. **Chart 4 – Loss of control due to abrupt process failure**

Chart 4 depicts a catastrophic loss of process control. This pattern of test results could be encountered in a situation such as an abrupt failure of a key piece of equipment, such as an antimicrobial wash cabinet.



5. Chart 5 – Loss of control due to reoccurring transitory process failure

Chart 5 depicts conditions where there is an intermittent but reoccurring problem within the process. Note the distinct periodicity of the test results over time. This pattern of test results could be observed in a situation where condensation is dripping onto product as it travels down a conveyor belt.



Small Business Regulatory Enforcement Fairness Act (SBREFA)

OBJECTIVES

1. Explain the PHV's role in meeting the Agency's SBREFA requirements.
2. Identify effective techniques and Agency resources that PHVs can use and provide when communicating with establishment management about assistance with establishment compliance.

RESOURCES

Small and Very Small Plant Guidance
FSIS News & Press Releases (see "FSIS Updates for Small Plants")
FSIS Policies on Regulatory Decisions

INTRODUCTION

SBREFA is a regulatory reform statute which was signed into law on March 29, 1996. SBREFA applies to all branches of government and gives small businesses a greater voice in the development and enforcement of federal regulations.

Under SBREFA, the Agency is responsible for being sensitive to the needs of small and very small establishments and, through the Agency's outreach program, small businesses are encouraged to participate in the rulemaking process. The FSIS FY2023-2026 Strategic Plan states that "FSIS will continue its outreach efforts focused on small and very small establishments to help ensure they have sound HACCP systems and food safety programs resulting in compliance with the regulations and improved food safety. To assist with outreach, FSIS has developed compliance guidelines focused on small and very small establishments in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the SBREFA."

Note: A small establishment is defined as an establishment with 10 or more employees but fewer than 500 employees. A very small establishment is defined as an establishment with fewer than 10 employees or annual sales of less than $2.5 million.

KEY AREAS OF EMPHASIS

There are key areas of emphasis regarding your role in SBREFA: advocacy and enforcement fairness.

Advocacy (Compliance Assistance or Outreach)

Agencies must assist small businesses in understanding and complying with the regulations. The goal of outreach is to provide technical guidance and assistance to small and very small establishments in the U.S. These establishments usually need technical guidance and assistance with the HACCP and food safety regulatory requirements. They may lack resources and knowledge, may have communication challenges due to different languages, may not belong to associations that provide resources, or may hold the belief that outdated methods result in safe products. This is why we devote time and attention to compliance assistance efforts, including outreach (conducted by EIAO trained employees).

Some common issues that arise with small establishments include the:

- Difficulty in finding scientific support for the hazard analysis.
- Difficulty in understanding how to reassess or address new issues as they arise in the establishment.
- Reliance upon literature without validating in the establishment's environment.
- Belief that "We've done it this way for years and no one has died from eating our product."
- Concern that new regulatory requirements are being applied to "put them out of business."
- Inability to attend training.

EIAOs are designated as the key position within OFO for conducting outreach to small and very small establishment owners. However, you as a SPHV also play a key role in outreach and advocacy to establishments.

Providing outreach involves helping small and very small establishment owners better understand regulatory requirements and identifying materials and resources that are available. Outreach is an opportunity to improve communication between industry and FSIS. As a SPHV, you may be involved in helping the small and very small establishment owners and operators gain access to information that the Agency supplies to assist them.

Be aware that, because you are a regulator, you cannot provide direct assistance to an establishment owner by suggesting how they design or validate their food safety systems. Instead, refer them to the list of contacts and coordinators. The contacts and coordinators can do what we cannot because of our regulatory role. Our job is to refer the small and very small establishments to these people so they can get the direct assistance they need (See Small & Very Small Plant Guidance: HACCP Directories & Resources).

FSIS has numerous resources available online for small and very small establishments. Be familiar with these resources and share them with establishments where applicable. Examples include:

- Small & Very Small Plant Guidance (includes example HACCP models and guidance; education and training; HACCP directories and resources; Small Plant Help Desk)
- FSIS Guidelines
- Small Plant Help Desk Form
- Food Safety Resources for Small and Very Small Plant Outreach: Order Form (includes resources in various languages)
- FSIS Webpage: News & Press Releases (see: Updates for Small Plants)

A good opportunity to share resources with small and very small establishments is during weekly meetings. FSIS Directive 5010.1 "Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management" includes as possible topics of discussion: policy clarifications published in askFSIS; new, revised, or amended FSIS directives, FSIS notices, FSIS compliance guides; and small and very small plant outreach information. Be sure to document what you shared and discussed with the establishment in your weekly meeting MOI.

Enforcement Fairness

Through the provisions of SBREFA, the Small Business Administration (SBA) appoints a National Ombudsman and creates Regulatory Fairness Boards, made up of small businesspersons.

A National Ombudsman is appointed to represent small businesses in their dealings with federal regulatory agencies. In addition, there are Regulatory Fairness Boards located throughout the U.S.

Members of the boards are small business owners who have been elected by other small business owners. Meetings of the Fairness Boards, called Fair Regulatory Enforcement Hearings, are open to the public. Attendance is generally made up of small businesses who want to air their concerns, and federal agency representatives. FSIS personnel (e.g., EIAOs, district management) may attend these meetings as part of their SBREFA responsibilities.

While the National Ombudsman and Fairness Boards may communicate small business concerns to the Agency and Congress, they cannot reverse Agency decisions. Small businesses may contact the National Ombudsman or Fairness Boards about their complaints regarding Agency regulatory, compliance, or enforcement decisions. The National Ombudsman and Fairness Boards also provide a venue for small businesses to participate in the Agency's regulatory process by providing comment through the SBA/Office of the National Ombudsman on new regulations before they can take effect. Through the SBA, companies can use their small business status to influence Congress.

FSIS personnel involved in inspection and enforcement activities should be aware that the National Ombudsman and the Fairness Boards provide, in a sense, an alternative avenue of appeal for the small businesses we regulate. In other words, in addition to appealing Agency actions through the FSIS chain of command and in addition to making their concerns known by other means, the owners or managers of small official establishments may also make their concerns known to the National Ombudsman or their regional Fairness Board. The National Ombudsman and the Fairness Boards provide an avenue of appeal for small entities, but they do not replace FSIS appeal processes and cannot overturn or adjudicate Agency decisions. Their focus is on "unfairness" in regulatory decisions or enforcement actions.

Find current information and FSIS SBREFA contacts on the FSIS Webpage: FSIS Policies on Regulatory Decisions. FSIS's role in enforcement fairness is to ensure non-retaliation for regulated establishments, to attend Fair Regulatory Enforcement Hearings, and to provide official responses to complaints and comments filed by industry through the Small Business Administration/Office of the National Ombudsman.

Wellness

OBJECTIVES

Scientific:

1. Recognize the causes and symptoms of job stress and isolation.
2. Identify remedies for job stress and isolation, such as networking to create a supportive work environment.
3. Recognize the causes and symptoms of the most common, repetitive stress injuries.
4. Identify ways to prevent or minimize repetitive stress injuries.

Regulatory/Administrative:

1. Identify and locate Agency resources available to help personnel, including supervisors, cope with stresses related to the in-plant environment that may lead to misconduct or workplace violence.

RESOURCES

FSIS Website: Understanding your Benefits
Worklife4you
Employee Assistance Program (EAP)
FOH4YOU
CDC NIOSH: Stress at work
IPP Help: Conflict Scenarios (VPN required)
IPP Help: Coaching Services (VPN required)
IPP Help: Employee Engagement Best Practices (VPN required)
IPP Help: Supervisor-Plant Relations (VPN required)

INTRODUCTION

Merriam-Webster dictionary defines “wellness” as “the quality or state of being in good health especially as an actively sought goal.” Whether at home or at work, your health and well-being are important. Starting a new job can be challenging, both physically and mentally. Job stress may pose a threat to the health of workers, leading to illness and injury. A job working in meat, poultry, and egg products establishments presents additional workplace hazards that are important to be aware of. This module will cover various types of stress and provide you with an overview of the benefits and tools available to you and your team to maintain and promote your health and wellness.

STRESS: OVERVIEW

The American Institute of Stress defines stress as a nonspecific response of the body to any demand – pleasant or unpleasant. The pioneers of stress research categorized all stress as negative or bad. Today, we understand that stress is anything in the environment that causes us to adapt, and that a "stressful" situation can be either happy/positive (like the birth of a baby) or sad/negative (like the death of a loved one).

We know that stress does not do the same thing to all people. One of the factors that is involved in this difference is how the impact of stress in situations is altered by how it is perceived by individuals who

are affected by the situation. American Institute of Stress former president Paul J. Rosch likened stress to a ride on a roller coaster. "There are those at the front of the car, hands over head, clapping, who can't wait to get on again," he pointed out, "and those at the back cringing, wondering how they got into this and how soon it's going to be over." Or, to put it another way, one roller coaster passenger "has his back stiffened, his knuckles are white, his eyes shut, jaws clenched, just waiting for it to be over. The wide-eyed thrill-seeker relishes every plunge, can't wait to do it again."

Rosch pointed out that differences in perception can cause some stress to be good stress (*eustress*) rather than bad stress (*distress*), and he used as an example symphony conductors. "They work long hours, travel frequently, deal with prima donnas and sensitive artists, yet they live long and productive lives. They've got positive vibes going. They enjoy what they're doing, have pride of accomplishment, the approbation of their peers, and the applause of the audience, all positive stresses."

In essence, some things that are stressful also promote curiosity and exploration. They are challenging, stimulating, and rewarding. Competitive sports are an excellent example. It's extremely stressful, both physically and emotionally, to gear up for a football game, worry about winning, and then pound across the field for three hours in an attempt to do it. But many believe the rewards and the thrill are well worth the stress, and millions of fans couldn't agree more. On the other hand, boredom and under-stimulation can also be distressful.

Below are three types of stress and how they are defined:

- **Physical stress:** involves stressors in the environment - factors such as extremes in temperature, environmental pollution, constant noise, or electric shock. Researchers also categorize physiological factors as physical stress. Examples include injury, surgery, hypoglycemia, prolonged exercise, or an inadequate supply of oxygen.
- **Psychological stress:** stems from the way we feel, the attitudes we have, and the way we react toward anything that is threatening us, whether the threat is real or imagined. As in the example of the roller coaster, one person may react calmly, while another may become extremely stressed.
- **Psychosocial stress:** involves stressors from interpersonal relationships, arguments or conflicts with family members, neighbors, employers, friends, or other people around us. Psychosocial stress may result from intense social interactions, but it can also occur when there is isolation as a result of inadequate social interactions.

Stress is costly. According to the American Institute of Stress, in addition to the toll stress takes on a person’s health, stress costs businesses and the economy billions of dollars. This includes costs related to absenteeism, decreased productivity, lower output, employee turnover, and healthcare costs.

Workplace stress is inevitable; therefore, it is important that you identify and utilize the stress management and wellness tools available to you and your team at FSIS.

IDENTIFY CAUSES AND SYMPTOMS OF STRESS AND ISOLATION

There are a variety of tools and guidance available to identify your stress levels and factors that may contribute to your stress, including the Workplace Stress Scale, the Holmes-Rahe Life Stress Inventory, and Early Warning Signs of Job Stress.

The CDC NIOSH describes job conditions that may lead to stress, such as heavy workload and long working hours, poor communication in the organization, lack of support or help from coworkers and

supervisors, conflicting or uncertain job expectations, lack of opportunity for growth, and dangerous working conditions.

The CDC describes how stress can cause feelings of fear, anger, sadness, worry; changes in appetite, energy, interests; trouble concentrating and making decisions; problems sleeping; physical reactions such as headaches, body pains, stomach problems; worsening of chronic health problems; and increased use of substances such as alcohol.

The CDC describes social isolation as not having relationships, contact with or support from others, which can pose a health risk.

Being aware of what may cause isolation and stress, as well as recognizing the symptoms of stress, can help you identify potential areas of concern with your own health and wellness. Understanding the common causes of workplace stress allows you to promote a work environment that encourages communication and minimizes or addresses potential negative stressors.

You may also identify situations where some of your team members could benefit from a reminder of the additional FSIS resources to support their wellness, such as reminding an employee of the Employee Assistance Program (see also: FOH4YOU) or WorkLife4You benefits (see below). Remember that FSIS has resources for you, as a supervisor, when you encounter employee performance or misconduct issues (e.g., FSIS Supervisor Help (VPN required) Addressing Poor Performance, Conduct vs. Performance, LERD@usda.gov, PerformanceManagement@usda.gov). If you identify an employee you believe is at risk of suicide or in immediate danger, OPM advises calling 911 and consulting the National Suicide Prevention Lifeline at 800-273-8255.

STRESS MANAGEMENT TOOLS

According to the American Institute of Stress, empathetic management practices at work can encourage communication and compassion amongst teams. This creates a safe environment for employees and can combat stress and prevent burnout. As an SPHV, what can you do to manage your own stress and promote a culture of wellness in your workplace? What resources and tools are available to you within FSIS that may help?

The Employee Assistance Program (see also: FOH4YOU) is a voluntary resources available to provide support, guidance, and referrals to helpful resources for many types of life challenges. No matter what the issue relates to – work, family relationships, health, finances or substance abuse, EAP has resources to help. EAP provides counseling, financial and legal services, and supervisory consultations. They provide resources for Stress Management, Self-Care & Resilience, Reducing Anxiety, and more.

FSIS employees have access to the Federal Occupational Health's WorkLife4You program, which provides employees and their family members with resources and tools to effectively manage life's milestones, transitions, and responsibilities at work and at home.

FSIS also has numerous options via AgLearn for continuous learning that may help you learn to manage stress, address conflict before it becomes a potential workplace violence situation, and improve your communication and emotional intelligence.

As a supervisor, lead by example. Promote safety in your workplace. Be aware of the FSIS resources available for Anti-Harassment and Workplace Violence Prevention and Response. Be aware of and promote the FSIS resources available for Civil Rights, including the mediation, team building, and

conflict resolution programs through the Mediation and Conflict Resolution Group (MCRG@usda.gov). You may also remind employees of the Agency's Reasonable Accommodation (ReasonableAccommodations@usda.gov) process. Encourage your team to utilize the resources available to them to prioritize their health and wellness.

As a leader, it is important to take care of your own health and wellness too. Doing so will benefit you personally and allow you to be engaged and present in your workplace. Remember that not all stress is bad, and that some stress can provide you with an opportunity for growth. Utilize the resources above as well as resources outside of FSIS that you find most helpful to maintain your health and wellness. Build a network of colleagues and friends that help support you in maintaining your well-being. Promoting your own health and wellness sets a good example for your team.

Take time to consider some of the ways you can manage stress. Examples of methods to manage stress from the CDC include:

- Take breaks from news stories and social media.
- Take care of your body (e.g., eat healthy, get enough sleep, move more and sit less).
- Limit alcohol intake and avoid using illegal drugs.
- Avoid smoking.
- Continue with regular health appointments, tests, screenings, and vaccinations.
- Make time to unwind (e.g., breathing exercises, stretching, meditating).
- Connect with others (e.g., community-based organizations).

PHYSICAL STRESS MANAGEMENT IN FSIS WORKPLACE

The FSIS "No Pain, Your Gain" video describes changes you and your team can make to minimize workplace injuries in meat and poultry slaughter establishments. Minimize injuries due to improper lifting, standing, and moving by:

- Standing close to the workstation (avoid leaning far over workstation).
- Keeping elbows close to body, shoulders back (not hunched).
- Standing with shoulders stacked over hips and hips over knees.
- Avoiding twisting or bending sideways when possible (turn with legs and feet instead).
- Moving around and change positions when possible.
- Putting one foot on a footrest when possible.
- Adjusting workstation when possible/necessary.

The video also describes cumulative trauma disorders that may occur with repetitive motion and the importance of paying attention to wrist motions and how IPP hold their knives.

There are also resources on the OSHA Website, including ergonomics in poultry facilities and Ergonomics Overview.

IPPS & STAR

OBJECTIVES

1. Use FSIS Directive 4430.3 to conduct IPPS and STAR assessments.
2. Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, and HACCP verification, etc. during IPPS assessments.
3. Create a follow-up plan to address an identified deficiency in employee knowledge or performance.

RESOURCES

FSIS Directive 4430.3 – In-Plant Performance System (IPPS)
Enterprise Performance Management Application (EPMA)
DR 4040-420 Employee Performance and Awards
IPP Help: Addressing Poor Performance (VPN required)
IPP Help: Conduct vs. Performance (VPN required)

INTRODUCTION TO IPPS

The In-Plant Performance System (IPPS) is a tool that supervisors use to assess employees' knowledge of job requirements, appropriate regulatory decision-making, and ability to execute inspection and verification procedures. IPPS covers non-supervisory in-plant inspection program personnel, including Food Inspectors, Consumer Safety Inspectors, and Public Health Veterinarians. An IPPS review is conducted by OFO supervisors, including Frontline Supervisors, Multi-IPPS Supervisors, Supervisory Public Health Veterinarians, and Supervisory Consumer Safety Inspectors, who determine how well non-supervisory in-plant program personnel conduct FSIS inspection and verification procedures.

In-plant supervisors are responsible for ensuring that the employees under their supervision know how to adequately perform their jobs and are aware of the impact that off-target performance might have on the health and welfare of consumers. IPPS encourages effective communication and correlation to ensure consistency in inspection methods. IPPS provides a tool to identify and address the need to improve employees' knowledge of their job requirements, recognize on-target or noteworthy performance, and assist in measuring organizational performance. FSIS Directive 4430.3 "In-Plant Performance System" provides procedures for supervisors who conduct, document, and report on IPPS assessments.

As a supervisor, you fulfill part of your critical Supervision and Mission Support performance elements when you conduct IPPS assessments. You play a key role in ensuring that decisions made by IPP are uniform, consistent, and in accordance with applicable statues, regulations, issuances and policies. You ensure duties performed by IPP are in accordance with prescribed inspection methods and procedures. You ensure IPP are using effective regulatory decision-making, documenting findings appropriately, and implementing regulatory enforcement actions properly.

PERFORMANCE MANAGEMENT

Every federal agency is required to have a performance management system that identifies and sets performance expectations for its employees, monitors their performance via progress reviews, and rates this performance by assigning a summary level rating. FSIS summary level ratings are expressed as Fully Successful or Unacceptable. Non-supervisory in-plant inspection program occupations have three performance elements: Mission Results-Oriented; Communication; and Fostering Customer Service, Collaboration and Partnership.

FSIS Rating Officials (including SPHVs who supervise IPP) have performance management responsibilities, including establishing performance plans, conducting quarterly conversations, conducting performance evaluations, addressing performance concerns and providing recognition. These requirements are set forth in DR 4040-430 "Employee Performance and Awards".

FSIS issues a notice at the start of each fiscal year (e.g., FSIS Notice 45-24 "Performance Management Instructions for FY 2025") to provide instructions on these requirements. This notice describes how performance feedback and ratings are recorded and acknowledged in the web-based Enterprise Performance Management Application (EPMA). FSIS also issues a notice at the end of each fiscal year (e.g., FSIS Notice 30-24 "End of Year Performance Management Instructions") to provide instructions on completing performance ratings of record.

USDA's official performance appraisal period is October 1 through September 30 of each calendar year. Rating Officials:

- Establish individual performance plans in EPMA and ensure employees have a clear understanding of their performance expectations and how their performance relates to the mission of the organization. Plans are issued to employees by the Rating Official in EPMA. Employees electronically acknowledge the plan in EPMA.
- Complete a formal evaluation and summary rating of an employee's performance based on the elements and standards for performance over the entire appraisal period (the rating of record/performance appraisal) by the end of the appraisal period. The Rating Official meets with the employee and delivers the rating of record. The rating of record is signed in EPMA by the employee and Rating Official.
- Conduct quarterly conversations to review progress towards performance goals with each employee no less than once each quarter. The Rating Official documents the conversations in EPMA and employees electronically acknowledge the quarterly conversation in EPMA.

Refer to the FSIS Performance Management notices issued each FY for timelines on when you must complete these responsibilities, as well as information on the various scenarios regarding performance ratings (e.g., inheriting current performance plans, providing interim ratings and advisory assessments).

Note: In FY2021 FSIS moved from a five-tier summary rating system to a two-tier system (Fully Successful or Unacceptable). FSIS also determined that all elements (rather than at least one) are critical. See Non-Executive Performance Management: Overview of Major Policy Changes Beginning in FY2021 and Non-Executive Performance Management: Frequently Asked Questions on Major Policy Changes for FY 2021.

IPPS AND PERFORMANCE MANAGEMENT

IPPS is designed to provide supervisors with a structured process for examining the elements of a job to identify, address, and correct areas where there is a need for performance improvement. IPPS also allows supervisors to provide feedback to the employees. Information is also extracted from the IPPS assessment sheets for use within the OFO's management control system. Even though IPPS measures individual performance while management control is focused on organizational performance, there is a link between the two. If individuals are not properly executing mission critical functions, an organization is less likely to successfully accomplish its mission as whole.

At least two IPPS assessments should be conducted for each covered employee during the rating cycle (October 1 – September 30). Typically, the first IPPS assessment is conducted between setting performance standards and the second quarterly conversation. The second IPPS assessment is usually conducted between the second quarterly conversation and the completion of the annual performance rating.

IPPS assessments are used in addition to quarterly conversations and the annual performance rating. Supervisors may conduct more than two IPPS assessments during the rating cycle. They should do so if they cannot thoroughly assess all the IPPS performance elements within two assessments, or if they need to follow-up on issues that were identified within previous IPPS assessments.

Supervisors will use the elements/sub-elements in the "IPPS Assessment Form" (Attachment 2 in FSIS Directive 4430.3 "In-plant Performance System") to assess the employees' knowledge of their job requirements. The sub-elements are categorized under the IPP performance elements described previously (Mission Results-Oriented; Communication; Fostering Customer Service, Collaboration and Partnership).

Note: This IPPS Assessment Form is distinct from the performance appraisal forms managed in EPMA. A performance rating (e.g., "Fully Successful") is not assigned or discussed during IPPS assessments. Supervisors use their judgement when combining data from IPPS assessments that are completed during the rating period and other information regarding an employee's performance. The performance rating reflects the employee's performance for the entire rating cycle.

OFO managers and supervisors review IPPS assessments and provide appropriate feedback as part of their management control system oversight. The SPHV reviews 25% of IPPS assessments conducted by the SCSI, with at least two of these reviews accomplished by direct observation. The FLS reviews 10% of the IPPS assessments conducted by the SPHV and SCSI, with 1% of these reviews accomplished by direct observation. The DM team and Executive Associate for Regulatory Operations (EARO) also review a certain portion of IPPS assessments.

PREPARING FOR THE IPPS ASSESSMENT

Preparation is an important aspect of the IPPS assessment. Before conducting the IPPS assessment, the supervisor must:

- Select the elements/sub-elements on the IPPS Form to cover during the IPPS assessment. You must ensure that all applicable elements are covered for the position before the end of the annual rating period (i.e., across two or more IPPS). You may want to print a copy of the IPPS Form to bring with you for the assessment.

- Be familiar with the processes and the FSIS verification activities that are conducted in the assignment and with how employees maintain electronic information as required by their positions.
- Review and assess PHIS data and reports, and other available data sources, to identify potential problem areas to focus on during the IPPS assessment (see "Reviewing Data Prior to IPPS" for more information).
- Review feedback from previous IPPS assessments to determine whether there are follow-up issues to cover during the visit. You will need to reassess the elements/sub-elements on which follow-up was indicated, after the employee has completed remedial assigned activities.
- Identify new FSIS directives and notices relevant to the employee's assignment and position. You will use the IPPS as an opportunity to ensure that the employee has followed the instructions and adhered to procedures in the new issuances.
- Ensure that employees have successfully completed required training. Training reports are available through AgLearn.

At the top of the IPPS form, you will document briefly how you prepared for the IPPS visit, including any data sources you used to prepare.

Note: The Labor Management Agreement Article 11 Section 7 states that employees will be provided all questions and topics, in writing, that will be asked/discussed of the Inspector(s) at least 5 working days prior to the IPPS review session and that IPPS will not take the place of progress reviews, nor will they be held simultaneously with a progress review. Consult with your supervisor prior to conducting IPPS reviews for more information on the expectations of this section of the LMA.

Reviewing Data Prior to IPPS

You will review and assess information in PHIS and other data prior to conducting the IPPS. FSIS Directive 4430.3 "In-plant Performance System" Attachment 3 outlines PHIS reports and other data sources you may use to prepare for an IPPS. More information on how to run PHIS reports is found on PHIS Help (VPN required) and in the How to View and Run PHIS Reports guide.

This data review allows you to verify IPP are keeping the information (e.g., establishment profile) current, are completing routine inspection tasks, and properly entering data. This data review provides you with insight into the decisions that IPP make regarding which procedures to perform and at what frequency. Using reports, you can determine whether trends are developing, which indicate whether the inspectors are on or off target in performing their verification duties.

Examples of data sources supervisors review in preparation for an IPPS visit include:

- Review MOIs to verify IPP followed instructions in new FSIS directives and notices for conducting and documenting awareness meetings with establishment management.
- Review NRs to determine whether NRs are being written in accordance with agency issuances (e.g., FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System").
- Review the Animal Disposition Report and HATS Summary Report to determine whether IPP are keeping the data current and performing the appropriate humane handling procedures (e.g., are IPP verifying all humane handling activities over time and recording proper times for each activity).
- Review food safety assessments and enforcement actions, if applicable at the IPP's assignment, to determine IPP's effectiveness in carrying out verification plan activities and documentation.

CONDUCTING THE IPPS ASSESSMENT

In general, supervisors use a combination of three methods to assess IPP during the IPPS: observation, records review, and discussion. More specifically, supervisors use the following methods singularly or in combination when conducting IPPS assessments:

- Observe the employee performing verification tasks.
- Review documentation, reports, and correspondence in the government files.
- Observe plant conditions and compare them to inspection results and noncompliance records on file.
- Ask questions about inspection methods, regulatory decision-making, documentation, and enforcement procedures as IPP perform inspection verification activities. Provide hypothetical situations or scenarios to get the employee to describe what they would do in response to the situation.

How you choose to gather information during the assessment is up to you. However, you should be consistent in applying standards during your visits to come away with a true assessment of what the employees know and how they apply that knowledge.

When conducting an IPPS assessment, verify that the employee is:

- Applying the appropriate inspection methodology, such as observing establishment employees conducting procedures, reviewing establishment records, and performing tasks.
- Utilizing effective decision-making to determine whether there is noncompliance.
- Documenting their findings appropriately, if required.
- Implementing enforcement actions properly (e.g., verification plans for suspensions and NOIEs), when authorized to do so.
- Implementing regulatory control actions.

Note: You don't have to conduct IPPS visits at all establishments on an employee's assignment. However, you should ensure that the employee can demonstrate an understanding of the methodology relevant to the whole assignment and an ability to execute it.

At the end of the assessment, meet with the employee and provide verbal feedback based on what you observed during the assessment.

Documentation

Complete the "IPPS Assessment Form" (Attachment 2 in FSIS Directive 4430.3 "In-plant Performance System") to document the IPPS. On this form, you will document:

- Whether the employee understanding of and ability to execute regulatory requirements was satisfactory (Yes/No).
- Positive performance briefly in the narrative boxes.
- Any deficiency in the employee's performance in a particular sub-element if you find that the performance is unsatisfactory.

You must provide a copy (hard copy or e-mailed PDF copy) of the assessment to the employee within two weeks of the assessment. When applicable, include recommended actions that the employee is to take to improve their knowledge and execution of inspection methods (e.g., review relevant directives, review IM training) and a timeframe for completion.

Keep the completed IPPS Assessment Form for one year following the termination of the previous rating cycle, in an electronic folder in your work files. Discard or delete the files at the appropriate time. IPPS Assessment Forms are not filed in the Human Resources Office's official personnel folder or the employee's performance file. You will find that your IPPS assessment files provide useful information at the end of the appraisal year. They will refresh your memory, help you to make rating decisions, and serve as a history of consistently executed assessments of employee performance. Use good judgment when combining data from the IPPS Assessment Sheets with any other information regarding employee's performance.

Any issues of misconduct that are identified during an IPPS visit should be addressed with your DO.

Follow-up

When a follow-up on any elements or sub-elements is required, supervisors are to make sure that the employee completes remedial assigned activities. You as the supervisor are to monitor follow-up items to ensure they are accomplished. On the next IPPS, you must follow up on any sub-elements for which performance was found to be unsatisfactory.

Note: Follow the directions in DR 4040-430 "Employee Performance and Awards" when an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle. When an employee is performing below the Fully Successful level as described in their performance plan, the Rating Official consults with the Performance Management team to discuss the development of a Demonstration Opportunity (DO).

Work Unit Meetings & IPPS

A benefit of IPPS reviews includes linking IPPS assessment results and work unit meeting topics to address common or group needs that are discovered during IPPS visits (e.g., matters on which supervisors find misunderstandings or lack of program execution among multiple inspection personnel).

INTRODUCTION TO STAR

The Supervisory Tool for Assessment Results (STAR) is a tool that supervisors use to assess the knowledge and proficiency of field level supervisory personnel. STAR assessments provide firsthand, onsite observations of how well field-level supervisors conduct and oversee the performance of FSIS inspection and verification procedures in federally inspected establishments. STAR does not replace the Performance Management System.

The positions covered by STAR include the following:

- Supervisory Public Health Veterinarians (SPHVs)
- Supervisory Consumer Safety Inspectors (SCSI)

When conducting the STAR, supervisory personnel determine whether in-plant, subordinate supervisors carry out both program activities and supervisory responsibilities, in accordance with applicable regulatory requirements and FSIS directives and notices. The STAR encourages effective communication between supervisors and subordinate supervisors through the assessment and feedback process. It allows supervisors to identify and address the need to improve field-level supervisors' knowledge of job requirements. The STAR encourages correlation with supervisors to ensure consistency in inspection methods and provides the opportunity to recognize and reward on-target or noteworthy supervisory performance. Group needs may be identified and addressed through

STAR assessments (e.g., areas in which multiple supervisors are having difficulty understanding or executing job requirements addressed in work unit or district meetings).

STAR AND PERFORMANCE MANAGEMENT

OFO uses STAR assessments, which apply to the supervisory in-plant occupations, to assess employees' knowledge of job requirements. STAR assessments are designed to provide supervisors with a structured process to look at specific elements of the job, provide feedback to employees, and to identify, address, and correct areas where there is a need for improvement in performance.

Supervisors will use the elements/sub-elements in the "Supervisory Tool for Assessment Results (STAR) Assessment Form" to assess the employees' knowledge of their job requirements. The sub-elements are categorized under the supervisory performance elements (Mission Results-Oriented; General Supervision and Leadership; Fostering Customer Service, Collaboration and Partnership).

Note: This STAR Assessment Form is distinct from the performance appraisal forms managed in EPMA. A performance rating (e.g., "Fully Successful") is not assigned at STAR assessments. Supervisors use their judgement when combining data from STAR assessments that are completed during the rating period and other information regarding an employee's performance when determining an employee's performance rating. The performance rating reflects the employee's performance for the entire rating cycle.

OFO field-level supervisory personnel must conduct at least one, in-person assessment for each covered employee during the rating cycle. Supervisors have flexibility in deciding when to conduct the assessment and whether to assess all the elements and sub-elements during a single visit or through multiple visits over the course of the rating cycle.

OFO executives, managers, and supervisors review STAR assessments and provide appropriate feedback as part of their management control system oversight. The FLS reviews 50% of STAR assessments conducted by the SPHV. The DM team reviews at least 1 STAR assessment per circuit performed by the FLS. The EARO reviews 5% of the DM reviews.

PREPARING FOR AND CONDUCTING THE STAR ASSESSMENT

Preparing for and conducting the STAR assessment is similar to what is described in the Preparing for the IPPS Assessment and Conducting the IPPS Assessment sections.

Supervisors can use the record review method, the discussion method, and the observation method, either singularly or in combination, while conducting the STAR assessment. Give verbal feedback to the employee upon completing the assessment and provide a copy of the STAR assessment to the employee within 2 weeks of the assessment. Supervisors maintain copies of the assessments in their supervisory files for one year.

Conduct any appropriate follow-up (for example, if an employee lacks essential knowledge of certain elements or sub-elements) and discuss the actions necessary for performance improvements, such as training. The supervisor is to follow-up on any sub-elements for which performance was found to be unsatisfactory during the next STAR assessment.

If an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle, follow the directions outlined in DR 4040-430 "Employee Performance and Awards." Any misconduct issues identified during the STAR visit should be addressed with the DO.

Non-Food Safety Consumer Protection

OBJECTIVES

1. Given a scenario in the poultry slaughter context, apply prescribed NFSCP criteria to score poultry pre-chill and post-chill to verify the establishment's process control.
2. Using reference material provided, apply pre- and post-chill criteria to a 10-bird sample in the field/establishment setting.
3. Explain the establishment's responsibility when pre-chill or post-chill tests exceed established limits.
4. Given a scenario involving verification tasks in the Processing context, apply labeling regulations, FSIS Directive 7000.1, the NIST Handbooks, and the Calculation Aid to verify NFSCP compliance.
5. Given a scenario in the Processing context, provide appropriate feedback and guidance to an IPP when they incorrectly perform a non-food safety consumer protection task.
6. Given a scenario in the Processing context, identify the NFSCP noncompliance and the task to document the NR in, whether a recall is likely, and select the appropriate action regarding the product involved.
7. Given a scenario in the Processing context, apply post-chill finished product standards (FPS) criteria to poultry samples, i.e., sampling of 10 birds at least twice per line per shift.

RESOURCES

FSIS Directive 7000.1 – Verification of Non-Food Safety Consumer Protection Regulatory Requirements
FSIS Directive 6100.3 – Ante-mortem and Post-mortem Poultry Inspection
FSIS Directive 6120.1 – Finished Product Standards Program for the New Line Speed Inspection System and the Streamlined Inspection System
FSIS Directive 7620.3 – Processing Inspectors' Calculations Handbook
FSIS Guideline for Label Approval
A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products
Food Standards and Labeling Policy Book
NIST Handbook 133
Further Processing and Labeling Inspection Course Student Handout
FSIS Applications: Calculation Aid
Further Processing and Labeling Training 9500 Series (request to register through supervisor)

INTRODUCTION

This module provides an overview of inspection responsibilities that cover the regulatory requirements for non-food safety consumer protection. FSIS's highest priority is protecting public health and food safety. FSIS also verifies other protections extended by the Acts, including verifying compliance with requirements that provide non-food safety consumer protection.

NFSCP in the Acts

There are sections related to NFSCP requirements in the FMIA, PPIA, and EPIA. For example, the FMIA (21 U.S.C. 601(n)) defines "misbranded" in twelve parts, including meat product that:

- Has labeling which is false or misleading.

- Is offered for sale under the name of another food.
- Is an imitation of another food.
- Has a container that is misleading.
- Has a label that fails to show the name and place of business that produced the product or fails to contain an accurate statement of the quantity of the contents of the meat product.
- Contains a label that is missing required information.
- Has a label that purports that it was produced in a manner that follows a standard of identity, but the product does not conform to those standards.
- The amount of product in the container falls below the fill standard.
- Contains ingredients that are not represented on the label by common names of the food.
- Makes special dietary claims but does not list the corresponding dietary properties and information required on the label.
- Contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label.
- Requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information.

The Acts also have sections regarding labeling, such as Section 457 of the PPIA, which describes how poultry products shall bear legible labels, comply with the definitions and standards of identity, must not be sold under false labeling or misleading size, and that labels may be withheld until modified so that they are not misleading or false. See also the FMIA Section 607 and the EPIA Section 1036.

NFSCP Regulations

The regulations related to the NFSCP requirements are extensive and detailed. Below is an overview of some of these regulations. Depending on the activities of establishments within your assignment, you may need to be familiar with additional NFSCP requirements to conduct inspection verification activities.

General labeling requirements include:

- 9 CFR 412.1: Contains the requirements related to labeling approval, including that no final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS Labeling and Program Delivery Staff (LPDS) (except for generically approved labels authorized for use in 9 CFR 412.2). Labels that require LPDS approval include those for religious exempt products, labels with special statements and claims, and labels for temporary approval. More information on the label approval process can be found on the FSIS Webpage: Labeling and Label Approval.
- 9 CFR 412.2: Covers generically approved labels. Neither IPP nor the establishment generically approve labels. Generically approved labels are approved by FSIS if the label meets the criteria listed in 9 CFR 412.2(b). Therefore, a label that meets one of the conditions of being generically approved does not have to be submitted to FSIS for further approval. For examples of labels that are generically approved, see the appendices in the FSIS Guideline for Label Approval.

General labeling requirements for meat products include:

- 9 CFR 317.1: Describes that labels are required for containers of meat products (some exceptions are outlined in the regulation).
- 9 CFR 317.2: Describes required features of labels including: name of product and ingredients used in the production of the product; name and place of business of the manufacturer must be shown; must contain accurate statement of net quantity of the contents of the product; must not be false or misleading; must list any handling of the product required in order to maintain the product in a wholesome condition; specific requirements for safe handling instructions; inspection legend.

- 9 CFR 312 and 316: Cover marks applied directly to the carcass and that the type of ink used is legible and of harmless material.
- 9 CFR 317.300 – 317.400: Cover nutritional labeling requirements and exemptions for meat products.

General labeling requirements for poultry products are found in 9 CFR Subpart N from 381.115 – 381.144 and include:

- 9 CFR 381.115 – Require the containers of poultry products to be labeled.
- 9 CFR 381.116 – Covers wording on labels of immediate containers.
- 9 CFR 381.117 – Covers the name of product and other label terminology (e.g., light or white meat).
- 9 CFR 381.118 – Covers the requirement for ingredients statements for poultry products.
- 9 CFR 381.119 – States that artificial flavoring or coloring must be declared on labels of poultry products.
- 9 CFR 381.120 – States that antioxidants, chemical preservatives, and other additives must be declared on the labels of poultry products.
- 9 CFR 381.121 – Requires that the label shows the quantity of the contents of the product.
- 9 CFR 381.122 – Requires that the label identifies the product manufacturer, packer or distributor.
- 9 CFR 381.123 – Covers the official inspection mark.
- 9 CFR381.124 – States that dietary food claims must be matched with appropriate details on the label.
- 9 CFR 381.125 – Requires that if poultry products require special handling to maintain a wholesome condition, these handling requirements must be listed on the label.
- 9 CFR 381.130 – States that false or misleading label are not permitted for poultry products.

In addition to the regulations above, there are regulatory requirements for products that are subject to standards of identity. The “Definitions and Standards of Identity or Composition” regulations for meat and poultry products are found in 9 CFR 319 and 9 CFR 381 Subpart P, respectively.

The requirements in 9 CFR 319.1 cover the general labeling and preparation of standardized meat products. This regulation states that products for which standards of identity exist must have a label showing the products name and ingredients statement and other information as appropriate. The 9 CFR 319.15-319.881 (Subparts B through U) cover the specific requirements for various meat products – from raw products that have very few, if any ingredients or preparation, to products such as cooked sausage that may have a number of ingredients and may go through a variety of steps in preparation.

Outline of the 9 CFR 319.1 regulations covering the definitions and standards of identity or composition for meat products:

- Subpart A − General
- Subpart B – Raw meat products
- Subpart C – Cooked meats
- Subpart D – Cured meat, unsmoked and smoked
- Subpart E – Sausage generally: fresh sausage
- Subpart F – Uncooked, smoked sausage
- Subpart G – Cooked sausage
- Subpart K – Luncheon meat, loaves, jellied products
- Subpart L – Meat specialties, puddings, nonspecific loaves
- Subpart M – Canned, frozen, dehydrated meat food products

- Subpart N – Meat food entrée products, pies, and turnovers
- Subpart O – Meat snacks, hors d'oeuvres, pizza, and specialty items
- Subpart P – Fats, oils, shortenings
- Subpart Q – Meat soups, soup mixes, broths, stocks, extracts
- Subpart R – Meat salads and meat spreads
- Subpart U – Miscellaneous (breaded and liver meat products)

9 CFR 381 Subpart P covers the labeling requirements for poultry products that have standards of identity. Outline of the regulations covering the standards of identity for poultry products:

- 381.155 – General
- 381.156 – Poultry meat content standards for certain poultry products
- 381.157 – Canned boned poultry and baby or geriatric food
- 381.158 – Poultry dinners (frozen) and pies
- 381.159 – Poultry rolls
- 381.160 – (Kind) burgers; (Kind) patties
- 381.161 – "(Kind) A La Kiev"
- 381.162 – "(Kind) steak or fillet"
- 381.163 – "(Kind) baked" or "(Kind) roasted"
- 381.164 – "(Kind) barbecued"
- 381.165 – "(Kind) barbecued prepared with moist heat
- 381.166 – Breaded products
- 381.167 – Other poultry dishes and specialty items
- 381.168 – Maximum percent of skin in certain poultry products
- 381.169 – Ready-to-cook poultry products to which solutions are added
- 381.170 – Standards for kind and classes, and for cuts of raw poultry
- 381.171 – Definitions and standards for "Turkey Ham"
- 381.172 – Requirements for substitute standardized poultry products named by use of an expressed nutrient content claim and a standardized term
- 381.173 – Mechanically Separated (Kind of Poultry)
- 381.174 – Limitations with respect to use of Mechanically Separated (Kind of Poultry)

VERIFICATION METHODOLOGY FOR NFSCP TASKS: OVERVIEW

There are many inspection tasks in PHIS that IPP perform to verify the establishments are complying with NFSCP requirements. IPP perform these tasks by:

- Observing establishment product formulation.
- Verifying the accuracy of labeling.
- Observing preparation or processing procedures.
- Reviewing establishment records, examining product.
- Checking product identification, condition, and temperature.
- Performing a variety of other in-plant measurements, testing, and calculations.
- Observing slaughter practices.

When conducting verification activities related to product formulation, IPP:

- Verify that the product meets requirements that are specified in the applicable standards of identity.
- Verify that all ingredients have been added in amounts that come within the maximum or minimum level specified in the applicable standard.

- Verify all ingredients used in formulating the product are accurately declared on the label in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredient statement.
- Verify that the product defect levels are consistent with applicable standards.
- Observe establishment activities.
- Review establishment records.

When conducting verification activities related to labeling, IPP:

- Review the establishment's labeling records including any supporting documentation such as letters from FSIS, temporary approvals, etc.
- Determine whether labeling is approved in accordance with appropriate regulations, i.e., either approved as a sketch by the FSIS LPDS, or generically approved in accordance 9 CFR 412.2.
- Verify that the required features are present on the labels.
- Verify that the net weight of the product is accurately reflected on its label.
- Verify that the labels are not false or misleading.
- Verify that the correct labels are applied to products.

FSIS Directive 7000.1 "Verification of Non-food Safety Consumer Protection Regulatory Requirements" instructs inspection personnel on how to verify that establishments comply with the regulatory requirements designed to protect the consumer in ways other than ensuring food safety. This directive also references numerous other agency issuances related to specific NFSCP requirements and inspection activities.

Inspection program personnel are not to perform directed NFSCP verification tasks unless, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements. If, following a preliminary assessment of such information, you have reason to believe that non-compliant product is being or has been produced, perform a directed verification task and a thorough evaluation.

There are no designated sampling plans or sample sizes that IPP are to use when examining products to assure that the products meet non-food safety regulatory requirements, nor are IPP to examine all products. They examine product to determine whether the product complies with regulatory requirements, such as product standards, net weight standards, regulatory maximum or minimum limits of ingredients or components, or product defects.

When you verify the condition of inspected and passed product, verify product identification and evaluate the product condition. That includes the product temperature and storage. After such an assessment, you should be able to determine the extent of the verification tasks that you may need to perform. Where effective establishment processing controls are evident, only limited verification activity may be necessary. You should, in these cases, direct the inspection to those parts of the processing operation that are not covered by an establishment's control procedures. You do not need to count individual defects to make a judgment on a finished production lot. The condition of product should be clearly evident and sufficient to allow inspection personnel to render a judgment that the product is not adulterated.

Note: While performing NFSCP tasks, it is possible that you may uncover concerns related to an establishment's food safety systems, such as the Sanitation SOP or HACCP plan. When this occurs, you should perform the appropriate directed food safety task and take any necessary enforcement actions. For example, if you are performing a routine labeling verification task and discover that the establishment has issued an ingredient of public health concern without properly declaring the

ingredient, you should pursue the food safety aspects of the findings and perform any warranted, directed food safety task as instructed in FSIS Directive 5000.1 “Verifying an Establishment’s Food Safety System.”

SPECIFIC NFSCP VERIFICATION TASKS

Poultry Finished Product Standards Task

In Streamlined Inspection Systems (SIS), New Line Speed Inspection Systems (NELS) and New Turkey Inspection (NTI) establishments, IPP verify compliance with poultry finished product standards (FPS). In these establishments, online IPP focus their post-mortem inspection decisions on whole carcass dispositions. The online inspector determines which carcasses will be salvaged, reprocessed, condemned, or retained for veterinary disposition and which carcasses will be allowed to proceed down the line as passed carcasses that are subject to trim and re-inspection (9 CFR 381.76(b)(3)(iii)(c)). Carcasses with certain trim and processing defects that do not require whole carcass condemnation are allowed to continue through the dressing process, but establishments must ensure these defects are adequately removed, so that the resulting carcasses are not adulterated. IPP perform pre-chill processing and trim nonconformance tests to verify adequate removal of these defects (9 CFR 381.76(b)(3)(iv)). FSIS verifies the FPS requirements for SIS to determine whether establishments that operate under the NELS and NTI inspection systems meet the reinspection requirements in 9 CFR 381.76(b)(4) in NELS and 9 CFR 381.76(b)(5) in NTI systems.

FPS are criteria applied to processed birds before and after chill to ensure that the product being produced is consistently wholesome and unadulterated (9 CFR 381.76(b)(3)(iv)(*c*)). These criteria consist of nonconformances (Table 1 in 9 CFR 381.76), the incidence of which is determined from 10 bird subgroup samples, reduced to a Cumulative Sum (CUSUM) number, and measured against the standards (Table 2 in 9 CFR 381.76). The standards are applied to permit the Agency to estimate when the production process is in control and when it is out of control. FPS uses the CUSUM statistical concept to measure process effectiveness. CUSUM represents the accumulated number of weighted nonconformances that exceed the tolerance in a series of consecutive subgroups. These nonconformances and weighted factors are listed on FSIS Forms 6500-1, 6500-2, and 6500-3.

Regulatory definitions relevant to FPS include:

- **Cumulative sum (CUSUM):** A statistical concept used by the establishment and monitored by the inspector whereby compliance is determined based on sample results collected over a period of time. For purposes of determining compliance with the FPS, the CUSUM is equal to the sum of prior test results plus the weighted result of the current test minus the tolerance, with the condition that the resulting CUSUM cannot go below zero.
- **Tolerance number:** A weighted measure that equates to product being produced at a national product quality level.
- **Action number:** A level reached by the CUSUM where the process is out of control and product action is required by the establishment or the inspector.
- **Start number:** A value halfway between zero and the action number. The start number is used to determine the starting CUSUM for the first subgroup of a shift and to reset the CUSUM value if the CUSUM is equal to or greater than the action number.
- **Subgroup:** A 10-bird sample collected before product enters the chiller and after product leaves the chiller.
- **Subgroup absolute limit:** The tolerance number plus 5.

- **Pre-chill testing:** Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system.
- **Post-chill testing:** Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected as the product leaves the chilling system.
- **Rework:** Reprocessing the product to correct the condition or conditions causing the nonconformances listed in Table 1 of 9 CFR 381.76.

The establishment is responsible for maintaining FPS, which, in turn, is monitored by the inspector. FPS is applied in two separate parts. The first is called pre-chill testing. It is designed to ensure that the slaughter and evisceration procedures are in control. The second part of the FPS is called post-chill testing. It is designed to monitor the production through the chill system to ensure that it meets the post-chill FPS. The pre-chill and post-chill tests are independent of one another.

IPP verify poultry slaughter establishments comply with finished product standards by performing the Poultry Finished Product Standards task. When completing this task, IPP perform activities at the frequencies described in 9 CFR 381.76 and in FSIS Directive 6120.1 "Finished Product Standards Program for the NELS and SIS." For example, the regulations state that IPP conduct pre-chill tests once per line per each half-shift at random times. IPP conduct post-chill tests twice per shift (once each half shift for each chilling system at random times. The directive also describes correlation between FSIS and the establishment monitoring personnel at least twice weekly to ensure that all establishment and inspection personnel are applying the standards correctly and uniformly.

When IPP perform the Poultry FPS tasks they:

1. Review the establishment's application of Poultry FPS;
2. Perform the FPS pre-chill tests twice per line per shift (once each half-shift) for each evisceration line at the pre-chill reinspection station;
3. Perform the post-chill FPS tests twice per shift (once each half-shift) for each chilling system at the post-chill inspection station;
4. Record the results in PHIS each time they perform the task; and
5. Perform additional directed Poultry FPS tasks when it is necessary, as directed by the PHV or IIC. An example of when a directed Poultry FPS task is necessary is when observations indicate the establishment appears to have lost process control, such as persistent defects on carcasses, and the establishment does not implement effective measures to remove the defects.

Pre-chill Testing

9 CFR 381.76(b)(3)(iv)(*d*) describes how pre-chill FPS are divided into processing and trim categories. The processing category is designed to monitor the output of the dressing and evisceration procedures. The trim category monitors the establishment's ability to remove unwholesome lesions and conditions from inspected and passed carcasses. Each category is monitored independently of the other category using a separate CUSUM for each category. Pre-chill tests are conducted prior to the product entering the chilling system.

When IPP review the establishment's application of pre-chill FPS they are to review the establishment's records to determine whether:

1. The establishment randomly selected and recorded subgroup sampling times before product reached the pre-chill inspection station on the evisceration line, and performed the pre-chill tests at those times (9 CFR 381.76(b)(3)(iv)(d)(1)(i)(A);

2. The time between random time subgroup pre-chill tests exceeds one hour of production time (9 CFR 381.76(b)(3)(iv)(d)(1)(i)(A));

Note: The actual time elapsed between pre-chill subgroup tests could exceed 1 hour and still meet the regulatory requirement. For example, the establishment could schedule and perform a pre-chill test at a random time within the first hour of production (i.e., at 7:12 am) and perform additional tests at random times within each hour of production (i.e., 8:33 am, 9:52 am).

3. Any of the establishment's subgroup test results exceeded the absolute limit.
4. The establishment implemented the actions described in 9 CFR 381.76(b)(3)(iv)(d)(2), if the pre-chill subgroup absolute limit was exceeded;
5. The CUSUM value met or exceeded the action number;
6. The establishment implemented the actions described in 9 CFR 381.76(b)(3)(iv)(d)(4), if the pre-chill CUSUM reached or exceeded the action number;
7. The establishment identified a trimmable lesion or condition during a subgroup test; and
8. The establishment implemented the actions described in 9 CFR 381.76(b)(3)(iv)(d)(3), if a trimmable lesion or condition was found during a pre-chill subgroup trim nonconformance test.

To perform a 10-bird pre-chill subgroup tests, IPP select random times to perform both the processing and trim nonconformance tests on the same 10 carcasses for each evisceration line, twice per shift. IPP select an unbiased 10-carcass sample for the test at the random time selected. An unbiased sample means that certain carcasses are not selected over others. An example of how to select an unbiased sample is to select the first 10 carcasses or every other carcass or every third carcass that arrives at the pre-chill re-inspection station. An example of a biased sample is when IPP select carcasses based on visible trim or processing or other types of defects.

Use the following procedure to uniformly examine carcasses:

a. Hold the carcass with the back of the carcass towards them and the hocks pointing upwards;
b. Observe the hocks, back parts of the legs, tail area, back of the carcass, and top sides of the wings;
c. Turn the carcass to observe the outside front including the bottom sides of the wings, breast and front parts of the legs;
d. Observe the inside surface of the carcass and the abdominal flaps and fat; and
e. Observe the neck flap and thoracic inlet.

IPP use FSIS Forms 6500-1 (processing) and 6500-2 (trim) and the factor values in Table 1 of 9 CFR 381.76 to calculate pre-chill nonconformance. FSIS Forms 6500-1 and 6500-2 list and describe the specific nonconformances and include a factor for each nonconformance. The 10-bird nonconformance total for each nonconformance listed is multiplied by the factor to score the subgroup total for each nonconformance. IPP add the total scores for each nonconformance line to determine the subgroup total. IPP compare the subgroup total to the absolute limit. For example, IPP select a 10-bird subgroup and examine the birds for processing (e.g., oil gland remnant, crop, trachea, feathers) and trim (e.g., bruises, trimmable lesions, fractures, scabs) nonconformance. IPP determine the subgroup nonconformance total and compare that subgroup total to the subgroup absolute limit (Table 2 in 9 CFR 381.76).

IPP also verify the establishment is conducting pre-chill FPS testing and taking appropriate actions as described in 9 CFR 381.76 when:

- **The process is in control.** The establishment randomly selects subgroup sampling times not to exceed 1 hour between tests and conducts 10-bird subgroup tests on each line; obtains weighted value of each nonconformance by multiplying the number of each nonconformance by the factor in Table 1, sum the total of all the nonconformances, and calculate CUSUM for that test.
- **The subgroup absolute limit is exceeded.** If either the inspector or establishment determines the limit is exceeded, the establishment must determine if any of the immediate past 5 plant pre-chill subgroups for that category – processing or trim – resulted in a CUSUM above the start number.
    - If all of the past 5 plant pre-chill subgroups are at or below the start number, the establishment immediately conducts a retest on that category of pre-chill. If the retest subgroup total equals tolerance or less, the establishment resumes random time testing. If the retest exceeds tolerance, the establishment proceeds as if CUSUM reaches action number.
    - If any of the past 5 plant pre-chill subgroups resulted in a CUSUM above the start number, establishment proceeds as if CUSUM reaches action number.
- **A trimmable lesion/condition is found** (by either inspector or establishment). Establishment must immediately conduct an additional pre-chill subgroup test for the same trimmable lesion/condition category.
    - If no additional item in the same category is found on retest, the establishment resumes random time sampling.
    - If an additional item in the same category is found on retest, the establishment proceeds as if CUSUM reaches action number.
- **The CUSUM reaches the action number.** The process is not in control and the establishment shall immediately notify the inspector in charge and production supervisor of the affected line. The establishment follows the 9 CFR 381.76(b)(3)(iv)(*d*)(*4*) regulations, which include suspending random time pre-chill testing, conducting subgroup retests, and identifying product for rework.

Post-chill Testing

9 CFR 381.76(b)(3)(iv)(*e*) describes how post-chill subgroups are collected after the product leaves the chiller but before the product is divided into separate processes.

IPP select a 10-bird subgroup and examine the birds for nonconformances (extraneous material). IPP use FSIS Form 6500-3 and the factor values in Table 1 of 9 CFR 381.76 to calculate post-chill nonconformance subgroup total and compare that subgroup total to the subgroup absolute limit (Table 2 in 9 CFR 381.76).

IPP also verify the establishment is conducting post-chill FPS testing and taking appropriate actions as described in 9 CFR 381.76 when:

- **The process is in control.** The establishment randomly selects subgroup sampling times not to exceed 2 hours between tests and conducts 10-bird subgroup tests for each chiller system.

- **The subgroup absolute limit is exceeded.** If either the inspector or establishment determines the limit is exceeded, the establishment must determine if any of the immediate past 5 plant post-chill subgroups resulted in a CUSUM above the start number.
    - If all of the past 5 plant post-chill subgroups are at or below the start number, the establishment immediately conducts a retest. If the retest subgroup total equals tolerance or less, the establishment resumes random time testing. If the retest exceeds tolerance, the establishment proceeds as if CUSUM reaches action number.
    - If any of the past 5 plant post-chill subgroups resulted in a CUSUM above the start number, the establishment proceeds as if CUSUM reaches action number.
- **The CUSUM reaches the action number.** The process is not in control and the establishment shall immediately notify the inspector in charge and production supervisor of the affected chiller. The establishment follows the 9 CFR 381.76(b)(3)(iv)(*e*)(*3*) regulations, which include suspending random time post-chill subgroup testing, conducting additional post-chill subgroup testing, and identifying product for rework.

When pre-chill or post-chill product has been identified as having been produced when the process was not in control, additional online subgroup testing by the establishment is required to determine its conformance to the standard. If any of the additional plant subgroup testing results in a subgroup total exceeding tolerance, offline product corrective actions must take place. The responsibilities of the establishment and the inspector change depending on the CUSUM.

All corrective actions such as identifying affected product, segregating product, and maintaining control through rework actions are the establishment's responsibility. Corrective actions by the inspector depends upon the establishment's ability to control rework of affected product. If the establishment fails in its responsibilities, the inspector will identify, segregate, and retain affected product to prevent adulterated product from reaching consumers. See 9 CFR 381.76(b)(3)(v) for detailed information on both establishment and inspector responsibilities related to offline product and reworked product.

FSIS does not verify the FPS requirements of 9 CFR 381.76(b) in Traditional Inspection systems or in New Poultry Inspection Systems (NPIS). Under Traditional Inspection, the inspector requires the establishment to remove trim and processing defects during post-mortem inspection. Establishments operating under the NPIS are required to maintain records documenting that the products resulting from their slaughter operations meet the ready-to-cook definition in 9 CFR 381.1 (9 CFR 381.76(b)(6)(ii)(D)).

Livestock Finished Product Standards Task

IPP conduct the Livestock Finished Product Standards task to verify the establishment complies with 9 CFR 318.2, 318.5, and 318.6. This task applies to carcasses, boneless meat, returned products, product reconditioning, reinspection, retention, and disposal of meat products at official establishments; and to requirements concerning procedures, ingredients, and other articles used in preparation of products.

IPP perform this task by reviewing establishment records and making observations. IPP examine product that may have undergone a significant change after it was inspected and passed (e.g., chilled in the cooler or boned). An example of noncompliance would be finding that after the boning process, the boneless product does not represent “boneless meat” because of the number of bone fragments, and the establishment has failed to address the situation. More information and examples are found in FSIS Directive 7000.1 “Verification of Non-food Safety Consumer Protection Regulatory Requirements.”

Percent Yield/Shrink Task

IPP conduct the Percent Yield/Shrink task to verify the establishment complies with a number of regulations (9 CFR 319.80; 319.81; 319.100; 319.101; 319.102; 319.103; 319.106; 319.107; 424.21 (c)). This task applies to products such as bacon, BBQ meats, roast beef, corned beef, cured beef tongue, and country ham.

IPP review establishment records and labels, calculate the % yield or shrink, and compare the result with the appropriate regulatory requirement. IPP also verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, cooking, chilling, curing, drying, etc.), calculating the % yield, shrink or gain, and comparing the result with the appropriate regulatory requirement. See FSIS Directive 7620.3 "Processing Inspectors' Calculations Handbook" for instructions on relevant calculations.

X Percent Solution Task (applies only to X% labeled products)

IPP conduct the X Percent Solution task to verify the establishment complies with a number of regulations (9 CFR 317.2(c); 317.8; 381.129, 319.104, and 319.105 (in these regulations, the sections that apply are those covering X% label products)). This task applies to products such as cured pork products, ham patties, chopped ham, ready-to-cook poultry products, turkey ham, corned beef, and beef brisket.

IPP select an appropriate product and verify compliance with X% labeling requirements by reviewing establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration. IPP also verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration. See FSIS Directive 7620.3 "Processing Inspectors' Calculations Handbook" for instructions on relevant calculations.

MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS Task

IPP conduct the MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task to verify the establishment complies with a number of regulations (9 CFR 319.5; 319.15; 319.29; 318.24; 381.173). This task applies to Mechanically Separated Species other than from beef including veal (MSS), Mechanically Separated Pork (MSP), Mechanically Separated Kind of Poultry (MSKP), Partially Defatted Beef Fatty Tissue (PDBFT), Partially Defatted Pork Fatty Tissue (PDPFT), Partially Defatted Chopped Beef (PDCB), Partially Defatted Chopped Pork (PDCP), and Advanced Meat Recovery Systems (AMRS) products.

IPP select an appropriate product and verify compliance by reviewing establishment records and labels, or by observing the preparation of products. IPP check product identification, condition, temperature, and holding time/temperature. IPP examine bones before and after meat recovery systems to observe condition and conformation. IPP review establishment laboratory results and compare findings with the appropriate regulatory standard and collect samples as directed. See FSIS Directive 7160.3 "Verification Activities for Advanced Meat Recovery Systems" for specific details on verification activities related to AMRS products.

Batter/Breading Task

IPP conduct the Batter/Breading task to verify compliance with 9 CFR 319.880 and 381.166. This task applies to products such as breaded products, breaded patties, breaded meat cuts, and fritters. IPP

select an appropriate product and review establishment records to calculate final % batter/breading and compare the findings to the standards listed in the regulations. IPP also verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the establishment's QC programs) or batches of the product. See FSIS Directive 7620.3 "Processing Inspectors' Calculations Handbook" for instructions on relevant calculations.

Labeling - Product Standards Task

IPP conduct the Labeling – Product Standards task to verify compliance with regulations in 9 CFR 319.1 (livestock) and 9 CFR 381 Subpart P (poultry). This task applies to products such as sausage, frankfurters, luncheon meats, chili con carne, meat stews, and tamales.

IPP select an appropriate product and verify compliance by reviewing establishment records and labels or by observing the preparation of products and comparing the findings to the appropriate regulatory standards. To verify some regulatory requirements, calculations will need to be performed to determine specified components, such as % fat, or % water. FSIS Directive 7620.3 "Processing Inspectors' Calculations Handbook" for instructions on relevant calculations.

Child Nutrition/Grade Labeling/Declared Count/Vignette Task

IPP conduct the Child Nutrition/Grade Labeling/Declared Count/Vignette task to verify compliance with 9 CFR 317.2, 317.8 and 381.116.

IPP select product and verify that the labeling is used on appropriate product and that there is a label approval on file.

Labeling - Net Weights Task

IPP conduct the Labeling – Net Weights task to verify compliance with 9 CFR 317.18-22 and 381.121 (a-c). IPP select an appropriate retail-sized packaged product and verify net weight regulatory requirements by reviewing establishment records and conducting net weight/drained weight checks, scale calibration checks (certification and accuracy), and calculating average tare weights. For QC inspection verification, follow the QC program requirements after first evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements. See NIST Handbook 133 and NIST Handbook 44 as references on how to determine net weight compliance. See also the "Further Processing and Labeling Inspection Course Student Handout" on how to calculate net weight.

General Labeling

IPP conduct the General Labeling task to verify compliance with a number of regulations (9 CFR 316; 317; 318; 319; 381; 412; 424.21; 441.10). IPP select an appropriate product and verify that the label contains all required information. This includes the ingredients statement is accurate (i.e., that all ingredients are listed in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredients statement), restricted ingredients are used as per regulatory requirements, the label is used on appropriate product, and that there is a label approval on file. When verifying restricted ingredient requirements or ingredients statement compliance, observe the establishment formulating product and compare to the approved label.

Note: Proteinaceous substances can cause adverse reactions (i.e., allergic and non- allergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement. See also FSIS Directive 7230.1 "Ongoing Verification of Product Formulation

and Labeling Targeting the Nine Most Common ("Big 9") Food Allergens" and "The 'Big 9' Verification" section.

See FSIS Directive 7120.1 "Safe and suitable Ingredients Used in the Production of Meat, Poultry and Egg Products," FSIS Directive 7130.1 "Verifying Nutrition Labeling for the Major Cuts of Single-ingredient, Raw Meat and Poultry Products and Ground or Chopped Meat and Poultry Products," and FSIS Website: Basics of Labeling as resources for conducting this task.

Misbranding/Economic Adulteration Sampling

Refer to the specific Agency issuance on how to conduct specific sampling tasks (e.g., FSIS Directive 7000.5 "FSIS Sampling for Labeling Claims Verification").

NFSCP ENFORCEMENT

Product compliance determinations are made based on NFSCP regulatory requirements (see Attachment 1 in FSIS Directive 7000.1 "Verification of Non-food Safety Consumer Protection Regulatory Requirements").

If product is found to exceed any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other NFSCP regulatory requirements, there may be regulatory noncompliance. Inspection program personnel are to issue NRs when they determine the process is out of control, resulting in economically adulterated or misbranded product.

Determinations of noncompliance should be based on production lots or process controls rather than on individual units of product. For example, if one package of product exceeds its net weight, IPP are to investigate whether there have been problems in the process that will cause all packages to exceed the net weight requirements. Use professional judgment and consult with your FLS for assistance when necessary.

When noncompliance is found, take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a)), if it is determined that misbranded or economically adulterated product (e.g., under-weight product, the product does not meet requirements that are specified in the applicable standard of identity for the product, etc.), would otherwise enter commerce (be shipped from the establishment). Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes, or forms of any container for use with any meat or poultry product per 9 CFR 500.8.

The DO may notify the establishment in writing that the repeat noncompliances may lead to a regulatory control action (9 CFR 500.1-3) that would affect the entire production of the product in question because product may be economically adulterated or misbranded. More information on NFSCP enforcement is found in FSIS Directive 7000.1 "Verification of Non-food Safety Consumer Protection Regulatory Requirements."

HACCP

OBJECTIVES

1. Given a scenario, use the verification methods in FSIS Directive 5000.1 to determine whether an establishment meets HACCP regulatory requirements for a specific production.
2. Given a scenario, use the verification methods in FSIS Directive 5000.6 to determine whether an establishment's HACCP prerequisite program adequately prevents identified hazards.
3. Given a scenario, use the verification methods in FSIS Directive 5000.6 to determine whether an establishment's records for its HACCP prerequisite programs support decisions made during the establishment's hazard analysis to designate particular hazards as Not Reasonably Likely to Occur (NRLTO).
4. Given a scenario, use the verification methods in FSIS Directive 5000.6 and the Meat and Poultry Hazards and Controls Guide to analyze the adequacy of an establishment's hazard analysis.
5. Given a scenario, use the verification methods in FSIS Directive 5000.1 to verify that an establishment's corrective actions meet regulatory requirements when a deviation from a critical limit occurs at a critical control point (CCP).
6. Given a scenario, use the verification methods in FSIS Directive 5000.1 to verify that an establishment's corrective actions meet regulatory requirements when an unforeseen hazard occurs.

RESOURCES

FSIS Directive 5000.1 – Verifying an Establishment's Food Safety System
FSIS Directive 5000.6 – Performance of the Hazard Analysis Verification Task
Meat and Poultry Hazards and Controls Guide
FSIS Website: HACCP Validation
FSIS Website: HACCP Guidebook and Models

INTRODUCTION

This module reviews key concepts you learned in Inspection Methods regarding HACCP inspection verification activities. As a supervisor of IPP performing HACCP inspection tasks, you play a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority (FMIA Section 608; PPIA Section 456; EPIA Section 1035) and Agency policy (9 CFR 417), and that IPP duties are performed in accordance with prescribed inspection methods and procedures in FSIS directives.

Supervisors verify IPP are scheduling and completing HACCP inspection tasks in a timely and complete manner. Supervisors are to engage in discussion with IPP about their findings related to the establishment's HACCP system. Supervisors are to ensure IPP understand and apply the gather-assess-determine (GAD) process, including that IPP are correctly applying inspection methodology, making informed decisions, properly documenting findings, and taking appropriate enforcement actions.

Supervisors are to discuss how establishment testing results and other data that may not explicitly be part of the establishment's CCPs or PRPs might influence IPP's thought process regarding the effectiveness of an establishment's HACCP system. Supervisors assist IPP in considering an establishment's hazard analysis, PRPs, HACCP plans, Sanitation SOPs, and other program areas in

an integrated way and discuss ways in which findings in one area may impact other parts of the establishment's HACCP system.

Supervisors are to actively engage with IPP when IPP obtain additional information from askFSIS or other resources. Together, IPP and the supervisor review the information. The supervisor assists IPP in the process of making a final decision of HACCP compliance or noncompliance. If IPP have concerns with PRPs, scientific support, or in-plant validation data, the supervisor must address these questions and concerns. If needed, you as the supervisor may request assistance (e.g., EIAO) through your chain of command.

REVIEW OF HACCP

The following is a brief review of key HACCP concepts you learned during Inspection Methods training. FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System" and FSIS Directive 5000.6 "Performance of the Hazard Analysis Verification Task" provide comprehensive instructions to IPP and supervisors on verifying an establishment's compliance with the HACCP regulations.

- **HACCP inspection tasks**
    - The Hazard Analysis Verification (HAV) task directs IPP to review the establishment's flow chart and hazard analysis for one HACCP plan, the HACCP plan itself, any PRPs or other documentation used to support the decision that a food safety hazard is not reasonably likely to occur in the process, initial validation and reassessment (i.e., **design** of the establishment's HACCP system).
    - The HACCP verification task focuses the attention of IPP on the execution or implementation of the establishment's HACCP plans, PRPs and other supporting programs, including verifying corrective action and pre-shipment review requirements are met (i.e., **implementation** of the establishment's HACCP system).
- **HACCP system:** The HACCP plan in operation, including the HACCP plan itself.
    - The HACCP plan in operation includes the hazard analysis, HACCP plan, supporting documentation (including any Sanitation SOP or other PRPs used to make decisions in the HA) and the HACCP records generated on an ongoing basis.
- **Food safety hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- **Critical control point:** A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

  Note: The location of the CCP does not have to be at the point where the hazard is identified. CCPs may be at any location that is adequate to prevent, eliminate, or reduce to an acceptable level the identified food safety hazard.
- **Critical limit:** The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- **Prerequisite program:** A procedure or set of procedures designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. IPP consider the following questions when reviewing documentation used to support a prerequisite program and the decision that a hazard is NRLTO:

    - Is the program written, and if so, does it describe procedures implemented by the establishment to support that a hazard is NRLTO?
    - Does the program describe the records that the establishment keeps to show the program is implemented as written?
    - Does the establishment maintain records showing that the implementation of the prerequisite program continually supports that a hazard is prevented from becoming RLTO?
    - Does the program describe activities the establishment conducts if it fails to implement the program, or if it finds that implementation of the program failed to prevent a hazard from becoming RLTO?
- **Supporting documentation:** Documentation the establishment maintains to meet 9 CFR 417.4 and 417.5(a), including initial validation data, decision-making documents for the selection and development of CCPs and CLs, documents supporting the selection of monitoring and verification procedures and frequencies, scientific and technical documents, and other documents to support decisions in the HA (e.g., journal articles, letters of guarantee, certificate of analyses (COAs), historical records, etc.).
- **Corrective action:** Procedures to be followed when a deviation occurs.
    - See 9 CFR 417.3(a) for HACCP corrective actions required in response to a deviation from a critical limit:
        - The cause of the deviation is identified and eliminated.
        - The CCP will be under control after the corrective action is taken.
        - Measures to prevent recurrence are established.
        - No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
    - See 9 CFR 417.3(b) for HACCP corrective actions required if a deviation is not covered by a specified corrective action or if another unforeseen hazard arises:
        - Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met.
        - Perform a review to determine the acceptability of the affected product for distribution.
        - Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
        - Perform or obtain a reassessment by an individual trained in accordance with 9 CFR 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
- **Initial validation:** 9 CFR 417.4 requires that each establishment validate the adequacy of its HACCP system in controlling the food safety hazards identified in its hazard analysis. Establishments are required to assemble two types of supporting documentation to demonstrate a HACCP system has been validated:
    - The scientific or technical support for the HACCP system design (design).
    - The in-plant implementation (validation) data (execution).
- **Ongoing verification:** 9 CFR 417.4 describes ongoing verification activity requirements that include, but are not limited to, the calibration of process-monitoring instruments; the direct observations of monitoring activities and corrective action; and the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3).

Export Certification

OBJECTIVES

1. Demonstrate using the Export Library, FSIS Directive 9000.1 and FSIS Directive 13000.5 for the following:
   - Locating requirements of individual countries.
   - Locating instructions for export certification.
   - Locating documents used in export certification.
2. Identify the appropriate export circumstances for the following:
   - Letterhead certificate
   - Replacement certificate
   - Transit certificate
   - Continuation form
   - Export certificates that cannot be certified
3. Recognize CSI inspection activities for export certification, evaluate the accuracy and completeness of sample applications and certificates, and distinguish the CSI's role from the PHV's role in export certification when the country requires PHV certification.
4. Describe some circumstances where you are justified in your refusal to sign an export certificate and the follow-up actions you would take in documenting this.
5. Recognize accountable items in export certification, such as stamps, logs, and other documents.

RESOURCES

FSIS Directive 9000.1 – Export Certification
FSIS Directive 9000 Series (e.g., 9000.2, 9000.6, 9000.9, 9010.1)
FSIS Directive 13000.5 – Public Health Information System Export Certification
FSIS Notices (e.g., 22-24 "Export Module of the PHIS – China", 16-24 "Export Module of the PHIS – Phase Nine")
FSIS Website: Export Guidance
FSIS Website: Export Library
IPP Help: Exports (VPN required)
PHIS Help: Export Tutorials (VPN required)
Electronic Export Course 9000 Series

INTRODUCTION

This module reviews key concepts you learned in Inspection Methods regarding Export Certification verification activities. As an FSIS veterinarian, you may be responsible for signing export certificates. As a supervisor of IPP performing export verification activities, you play a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority (e.g., FMIA Sections 615-618) and Agency policy (see below) and that IPP duties are performed in accordance with prescribed inspection methods and procedures in FSIS directives. These activities provide assurance that the U.S. meat and poultry products are in compliance with the importing country's requirements.

Note: As a supervisor, you must verify that IPP are appropriately trained prior to performing export verification and certification activities. In addition to reviewing FSIS directives and completing Inspection Methods, IPP may take additional export training offered by the Agency and on the PHIS Help button.

All federally inspected and passed meat, poultry, and egg products are eligible to receive an Export Certificate of Wholesomeness (Meat and Poultry Export Certificate of Wholesomeness-FSIS Form 9060-5, Siluriformes Fish and Fish Products Export Certificate of Wholesomeness-FSIS Form 9060-5S, or Egg Products Export Certificate of Wholesomeness-FSIS Form 9060-5EP) hereafter referred to as an "export certificate," to accompany the products intended for export. Many foreign countries maintain additional eligibility requirements and certification statements which are accessed in the FSIS Export Library.

When an application for export certification (FSIS Form 9060-6, Application for Export, for all meat, poultry, and egg product exports) is submitted to IPP, IPP verify the application is complete, correct, and the product is eligible for export before they sign the application, issue the USDA export mark, and issue (but not sign) an export certificate. IPP perform export verification activities and, if required, product re-inspection. IPP review the export certificate and required supplemental export documents for accuracy and completeness based on the application and FSIS Export Library requirements for the receiving country. IPP sign and date export certificates and any required supplemental export documents if there are no issues or concerns.

Livestock Regulations (includes Siluriformes)

- 9 CFR 312.8 – Export inspection marks
- 9 CFR 317.7 – Products for foreign commerce; printing labels in foreign language permissible
- 9 CFR 322 – Marking products for export; export certification; transferring products for export

Poultry Regulations

- 9 CFR 381.104 – 107 – Marking products for export; export certification; special procedures as to certification of poultry products for export to certain countries
- 9 CFR 381.128 – Labels in foreign languages

Egg Products Regulations

- 9 CFR 590.407 – Export certification and marking of containers with export inspection mark
- 9 CFR 592.20(d) – Kinds of services available, export certification

Note: FSIS provides export certification service at the request of an exporter. This service is reimbursable when the exporter is not an official establishment or when the export involves requirements or certifications beyond those provided for in the FMIA, PPIA, or EPIA in all facilities. See FSIS Directive 12600.1 "Voluntary and Other Reimbursable Inspection Services" and coordinate with your supervisor on how you and IPP are to charge for the time required to perform certain export verification activities.

REVIEW OF EXPORT CERTIFICATION

The following is a review of key Export Certification concepts you learned during Inspection Methods training. FSIS Directive 9000.1 "Export Certification" and FSIS Directive 13000.5 "Public Health Information System Export Certification" provide instructions to IPP for performing export certification of

meat and poultry products. The directives state the importance of reviewing the importing country's requirements in the FSIS Export Library prior to signing documents and certificates. FSIS also issues notices to inform IPP on changes in the PHIS export module, including when countries are added into the PHIS export module.

Forms and Documentation

- **Application for Export Certification (FSIS Form 9060-6)**: The form submitted to IPP by export applicants (e.g., the establishment).
- **Establishment Application for Export (FSIS Form 9080-3)**: Some countries require pre-approval or registration of eligible establishments before they can be included on an "eligible plants list." Establishments complete the FSIS Form 9080-3 in PHIS to accomplish registration or pre-approval.
- **Meat and Poultry Export Certificate of Wholesomeness (FSIS Form 9060-5)**: The "export certificate." IPP have the authority to issue an export certificate provided an application has been submitted by the export applicant, after IPP verify it is complete, correct, and that the requirements of the receiving country have been met. FSIS Form 9060-5S is used for Siluriformes fish. FSIS Form 9060-5EP is used for egg products. IPP review the certificate and required supplemental documents, perform export verification activities and if required, product reinspection, prior to signing the export certificate.
- **Meat and Poultry Export Certificate of Wholesomeness Continuation Sheet (FSIS Form 9060-5A)**: A product continuation sheet prepared if the items in the shipment exceed the space available in the product grid on the face of the export certificate.
- **Remarks Continuation Page (FSIS Form 9060-5B)**: A continuation of the remarks section of the export certificate. This form may contain attestations, other information, or replacement certificate information that will not fit in the remarks section of the associated export certificate.
- **Supplemental export documents**: Additional documents required by the FSIS Export Library to meet the importing country requirements (e.g., letterhead certificate, transit certificate, foreign country certificate). The establishment is responsible for submitting supplemental export documentation and IPP verify the documentation.

Application for Export (FSIS Form 9060-6)

Upon receiving a completed application for export, IPP review the application to verify, using documentation and evidence provided by the applicant, that it is complete, correct, and that the requirements of the receiving country as listed in the FSIS Export Library have been met. IPP verify the accuracy of statements on the application and supplemental export documents (e.g., letterhead certificate) requiring FSIS signature, when necessary, by requesting supporting documentation from the applicant.

Note: Not all countries that import U.S. meat and poultry products have additional requirements listed in the FSIS Export Library. If a country is not listed in the FSIS Export Library or a product is not included (as eligible or ineligible) on a specific country's webpage in the Export Library, IPP are to issue the export certificate with no additional supplemental certificates, statements, or attestations.

When IPP verify product eligibility and that all export requirements are met, IPP (for paper-based export applications and certificates) will sign the paper application, retain a copy, provide the unsigned export certificate for completion by the exporter and permit the establishment to apply the USDA export mark. For countries in the PHIS export module, IPP refer to FSIS Directive 13000.5 "Public Health Information

System Export Certification" the PHIS Help button for guidance on issuing export certificates through PHIS.

If IPP have concerns that the products listed on the application are ineligible for export to the designated country (e.g., the product is adulterated, unwholesome, or does not meet FSIS Export Library requirements), they are not to sign the application. Instead, they follow the procedures in FSIS Directive 9000.1 "Export Certification" to raise concerns with the applicant and document the discussion in an MOI.

Stamping

Export applicants may apply the export mark through various methods, including by the use of the FSIS rubber export stamp, the use of a computer-generated export mark (pressure-sensitive one-time use stickers), or the application of an export mark by direct printing (i.e., inkjet application) to the box. Computer-generated export marks and direct inkjet printing of the export mark to the carton or container are allowed. IPP follow the procedures in FSIS Directive 9000.1 "Export Certification" to verify the applicant is using these methods appropriately (e.g., mark is equal in size and an exact impression of the FSIS rubber export stamp, is not printed until authorized by IPP, etc.).

Note: IPP may permit pre-stamping (applying the export mark and completing the export certificate when IPP is on duty but not present at the establishment), provided that the applicant has prior approval from FSIS. IPP verify the export pre-stamping program meets the requirements described in FSIS Directive 9000.1 "Export Certification" (e.g., the program is written and identifies how the controlled stamping of product will be accomplished, the export mark is applied in a uniform, clear, legible manner, accountable items are controlled by designated establishment personnel, etc.). IPP follow the instructions in the directive if the establishment fails to follow its pre-stamping program, which include suspending the pre-stamping operations.

Export Certificate (FSIS Form 9060-5)

Before issuing a signed export certificate, IPP are to perform export verification activities on the export consignment. IPP use good judgement to determine the amount of product to perform export verification activities on. These activities include verifying the:

- Export mark is equal in size and an exact impression of the FSIS export stamp.
- Correct export mark number is applied, legible, and links the certificate to the shipment.
- Export mark stickers are tightly adhered and applied in such a manner that prevents the possibility of reuse.
- Any excess export mark stickers are returned to IPP.
- Excess boxes containing the inkjet export mark are destroyed or the export mark is removed or permanently and completely covered or defaced.

IPP record the amount of product they verified on the FSIS copy of the FSIS Form 9060-6 (Application for Export) for paper-based exports and in the "findings" tab of the associated export task for exports processed in PHIS.

IPP are to consult the FSIS Export Library prior to certifying each export certificate to ensure there are no new product restrictions or updates to previous country requirements. IPP are to review the certificate and required supplemental export documents for accuracy and completeness. This includes:

- Verifying that only the required information or statements from the FSIS Export Library are entered in the remarks section of the export certificate or on any accompanying letterhead certificate or other required supplemental document.
- Verifying the appropriate box is checked indicating that the animals received ante- and post-mortem inspection.
- Verifying that any unused space in the product grid and in the remarks section of the export certificate are lined out.
- Verifying that the certificate number, applicant name and address, exporting plant number, product as labeled, shipping marks (if any), weights and package counts (for individual lots and totals), and establishment number on the product listed on the application match those listed on the export certificate.
- Verifying the establishment number on the shipping cartons of the product is a U.S. establishment, which may be the establishment number of the official import establishment, and that it corresponds with the "Est. No. on Product" listed on the export certificate.
- Verifying letterhead certificates used are the most current version found in the FSIS Export Library, that no statements on the letterhead certificate have been changed from the most current version, that no additional statements have been added and that any certification required by another USDA agency (e.g., AMS) is provided along with the completed letterhead.
- Conducting product re-inspection, if required.

Note: At times, verification may require re-inspection of products prior to issuing an export certificate. Re-inspection is **not** to be confused with export verification activities. The purpose of re-inspection of product intended for export is to verify the product's safety, wholesomeness, identity, and eligibility of export. Refer to FSIS Directive 9000.1 "Export Certification" for detailed instructions on when re-inspection may be required (e.g., when an applicant applies for an export certificate after a consignment has moved from the producing establishment to a non-producing establishment, such as an ID warehouse or cold storage facility) and how to perform re-inspection.

IPP sign and date (with the current date) the export certificate and any required supplemental export documents if there are no issues or concerns. For paper-based exports, IPP sign using other than black ink. If the FSIS Export Library requires a PHV signature, the PHV includes their professional degree and, if not already typed by the applicant, enter the district name or number. For exports processed in PHIS, IPP will digitally sign the certificate in PHIS. If a PHV signature is required, PHIS will generate an export task in the task list for the PHV after IPP approve the export application. PHIS will automatically apply "DVM" behind the printed name of the certifying PHV on the export certificate.

Refusal to Sign Export Certificates

If IPP have questions about the information on the application, the export certificate, or other supplemental documents, IPP are not to sign the certificate until they have contacted the IPP who signed the application (if applicable) or the exporter for clarification. If this does not resolve the concerns about signing the export certificate, IPP follow instructions in FSIS Directive 9000.1 "Export Certification" to discuss their concerns with the applicant, document the discussion in an MOI, and notify their supervisor.

IPP are not to sign the export application or certificate if product is found to be unsound or unwholesome, or if the products do not meet the eligibility requirements found in the FSIS Export Library. IPP are not to sign the export certificate if the weight and package amounts on the application do not match those on the export certificate.

If IPP refuse to sign an export certificate, the applicant may appeal IPP's refusal to the next in line FSIS supervisor. Based on the review of the appeal and associated information, the supervisor may uphold the refusal or may decide that the signature is justified and sign the certificate.

Replacement Certificates

A certificate replacing an original export certificate is a re-certification of the product's condition **at the time of the initial export certification**. A replacement certificate for a lot **does not** represent that lot's current condition. IPP may issue a replacement certificate without further re-inspection of the product, provided that the exporter makes the request within the timeframes outlined in FSIS Directive 9000.1 "Export Certification." IPP re-inspect the product before issuing a replacement certificate if IPP suspect the product is unwholesome, unsafe, or improperly labeled. **Note:** All requests for replacement certificates are to be accompanied by the original export certificate and all copies of the original certificate. If the original certificate is lost, the applicant is to provide a letter stating that the original certificate will be returned to FSIS if it is found.

FSIS Directive 9000.1 "Export Certification" outlines five specific reasons a replacement certificate may be issued. If the applicant requests a replacement certificate and provides a new export application, IPP verify that the request is consistent with at least one of the five reasons in the directive. The directive includes specific procedures for issuing replacement certificates, including required information to appear in the "Remarks" section of the most current certificate.

Inventory and Accountable Items

Official export stamps must be controlled at all times. Export certificates, stamps, and pertinent inventory records must be maintained under official government lock or seal when not in use. The inspection program employee does not have to be present in order for the establishment to apply the export stamp to boxes. However, when the stamp is not in use, it must be secured by FSIS personnel. The inspection program employee at each establishment must maintain an accurate inventory record of export certificates issued and voided certificates.

IPP also are to verify the destruction of excess pre-printed computer-generated export mark stickers and unused boxes containing the inkjet printed export mark when applicable.

Certifying Products under Export Verification and Quality System Assessment (EV/QSA) Programs

A foreign country may require products to be produced under an APHIS or AMS Process Verified Program (PVP) or EV/QSA program. IPP are to be familiar with the establishment's written program and be able to attest that the program is being implemented as required. If IPP have reason to believe the establishment is not properly executing the program, IPP are not to sign the export application or certificate. Instead, IPP follow instructions in FSIS Directive 9000.1 "Export Certification" to document an MOI and notify AMS and the IPP's supervisor. IPP verification procedures for EV/QSA programs are described in much further detail in the directive.

Questions Regarding the Export Library

If there are any questions regarding the importing countries requirements, visit the Export Library or call the Import/Export Coordination and Policy Development Staff, OPPD, at 800-233-3935 (importexport@usda.gov). You may also visit askFSIS and select "export" form the inquiry type drop down menu.

Modernization of Inspection

OVERVIEW

This training focused on the regulations, issuances, and inspection methodologies that concern establishments which choose not to operate under the new swine or new poultry inspection systems (NSIS, NPIS). You will receive additional training if your assignment includes establishments that operate under NSIS or NPIS.

RESOURCES

Below are some NSIS and NPIS resources that are not specifically covered in this training but are useful to be aware of.

FSIS Website: Modernization of Swine Slaughter Inspection

FSIS Website: Modernization of Poultry Slaughter Inspection

FSIS Directive 6600.1 – New Swine Slaughter Inspection System: Ante-Mortem and Post-Mortem Inspection and Verification of Food Safety and Ready-to-Cook Requirements

FSIS Directive 6500.1 – New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-to-Cook Requirement

IPP Help: NSIS Student Materials (VPN Required)

AgLearn: FSIS New Poultry Inspection System Training

Acronyms

AA	Assistant Administrator
AI	Avian Influenza
AD	Assistant Director
ADR	Animal Disposition Reporting
AER	Administrative Enforcement Report
AM	Ante-mortem Inspection
AMR	Advanced Meat Recovery
AMRS	Advanced Meat Recovery Systems
AMS	Agricultural Marketing Service
APC	Aerobic Plate Count
APHIS-VS	Animal and Plant Health Inspection Service – Veterinary Services
APM	Adulterated Product Monitoring
AMR	Advanced Meat Recovery
ASF	African Swine Fever
AVIC	Area Veterinarian-in-Chage
A_w	Water Activity
BEI	Behavioral Event Interviewing
BSE	Bovine Spongiform Encephalopathy
CA	Corrective Actions
CBPP	Contagious Bovine Pleuropneumonia
CCMS	Consumer Complaint Monitoring System
CCP	Critical Control Point
CCT	Comparative Cervical Tuberculin
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CFSPH	Center for Food Security and Public Health
CFT	Caudal Fold Tuberculin

CFU	Colony Forming Units
CID	Compliance and Investigations Division (OIEA)
CJD	Creutzfeldt-Jakob Disease
CL	Critical Limit
CLA	Caseous Lymphadenitis
CNS	Central Nervous System
COA	Certificate of Analysis
CSF	Classical Swine Fever
CSI	Consumer Safety Inspector
CUSUM	Cumulative Sum
DM	District Manager
DDM	Deputy District Manager
DCS	District Case Specialist
DO	District Office
DOA	Dead on Arrival
DR	Departmental Regulation
DRG	Dorsal Root Ganglia
DVMO	District Veterinary Medical Officer
DVMS	District Veterinary Medical Specialist
EAP	Employee Assistance Program
EARO	Executive Associate for Regulatory Operations
EIAO	Enforcement Investigations and Analysis Officer
EM	Eosinophilic Myositis
eOPF	Electronic Official Personnel Folder
EOS	Enforcement Operations Staff (OIEA)
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
EPMA	Enterprise Performance Management Application
EV/QSA	Export Verification and Quality System Assessment

FAD	Foreign Animal Disease
FCS	Food Contact Surface
FDA	Food and Drug Administration
FI	Food Inspector
FLS	Frontline Supervisor
FMD	Foot and Mouth Disease
FMIA	Federal Meat Inspection Act
FPS	Finished Product Standard
FR	Federal Register
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
GAD	Gather Assess Determine
GCP	Good Commercial Practices
GI	Gastrointestinal
GMP	Good Manufacturing Practice
GS	General Schedule
HA	Hazard Analysis
HACCP	Hazard Analysis and Critical Control Point
HATS	Humane Activities Tracking System
HAV	Hazard Analysis Verification
HCG	Hazards Control Guide
HEP	High Event Period (with regard to STECs)
HH	Humane Handling
HIKE	Humane Interactive Knowledge Exchange
HIMP	HACCP-based Inspection Models Project
HMSA	Humane Methods of Slaughter Act
HPAI	Highly Pathogenic Avian Influenza
HPP	High Pressure Processing
HR	Human Resources

HRI	Hotels, Restaurants, and Institutions
ID	Identification
IIC	Inspector in Charge
IM	Inspection Methods
IP	Inflammatory Process
IPP	Inspection Program Personnel
IPPS	In-Plant Performance System
IVT	Intensified Verification Testing
KIS™	Kidney Inhibition Swab
LERD	Labor and Employee Relations Division
LIMS	Laboratory Information Management System Direct
Lm	*Listeria monocytogenes*
LOD	Letter of Deferral
LOG	Letter of Guarantee
LOI	Letter of Information (or Instruction)
LOW	Letter of Warning
LPAI	Low Pathogenicity Avian Influenza
LPDS	Labeling and Program Delivery Staff
MOI	Memorandum of Interview
MOU	Memorandum of Understanding
MS	Mechanically Separated
MSKP	Mechanically Separated Kind of Poultry
MSP	Mechanically Separated Pork
MSS	Mechanically Separated Species
NAFV	National Association of Federal Veterinarians
NARMS	National Antimicrobial Resistance Monitoring System
NELS	New Line Speed (inspection system)
NFCS	Non Food Contact Surface
NFSCP	Non-Food Safety Consumer Protection

NIST	National Institute of Standards and Technology
NJC	National Joint Council
NOIE	Notice of Intended Enforcement
NOL	No Objection Letter
NOS	Notice of Suspension
NOSA	Notice of Suspension Held in Abeyance
NPIS	New Poultry Inspection System
NPN	Nonprotein Nitrogen
NR	Noncompliance Record
NRLTO	Not Reasonably Likely to Occur
NROS	Notice of Reinstatement of Suspension
NRP	National Residue Program
NRTE	Not Ready to Eat
NSAID	Non-steroidal Anti-inflammatory Drug
NSIS	New Swine Inspection System
NSLP	National School Lunch Program
NTIS	New Turkey Inspection System
NVAP	National Veterinary Accreditation Program
NVSL	National Veterinary Services Laboratory (Ames, IA)
OA	Office of the Administrator
OCP	Other Consumer Protection
OEED	Office of Employee Experience and Development
OFLR	Offline Reprocessing
OFO	Office of Field Operations
OIE	Office International des Epizooties
OIEA	Office of Investigation, Enforcement, and Audit
OIG	Office of Inspector General
OLR	Online Reprocessing
OM	Office of Management

OP	Organophosphate
OPF	Official Personnel Folder
OPM	Office of Personnel Management
OPACE	Office of Public Affairs and Consumer Education
OPARM	Office of Planning, Analysis, and Risk Management
OPHS	Office of Public Health Science
OPPD	Office of Policy and Program Development
OSHA	Occupational Safety and Health Administration/Act
PDBFT	Partially Defatted Beef Fatty Tissue
PDCB	Partially Defatted Chopped Beef
PDCP	Partially Defatted Chopped Pork
PDS	Policy Development Staff
PHV	Public Health Veterinarian
PHIS	Public Health Information System
PLE	Post Lethality Exposed
PM	Post-mortem Inspection
PPIA	Poultry Products Inspection Act
PRP	Pre-Requisite Program
PSE	Pale Soft Exudative Pork
PSS	Porcine Stress Syndrome
PVP	Process Verified Program
QA	Quality Assurance
QC	Quality Control
RA	Reasonable Accommodation
RAD	Reportable Animal Disease
RCA	Regulatory Control Action
RD	Regional Director (OIEA)
REC	Recall Effectiveness Check
RMIS	Risk Management and Innovation Staff

RLTO	Reasonably Likely to Occur
RMA	Resource Management Analyst
RMS	Resource Management Specialist
RMTAS	Recall Management and Technical Analysis Staff
RO	Recall Officer
ROP	Rules of Practice
RTE	Ready to Eat
SAHO	State Animal Health Official
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SCSI	Supervisory Consumer Safety Inspector
SEIAO	Supervisory Enforcement Investigations and Analysis Officer
SIPRS	Significant Incident Preparedness and Response Staff
SIS	Streamlined Inspection System
SOP	Standard Operating Procedures
SPC	Statistical Process Control or Standard Plate Count
SPHV	Supervisory Public Health Veterinarian
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures
STAR	Supervisory Tool for Assessment Results
STEC	Shiga toxin-producing *E. coli*
STEPS	System Tracking *E. coli* Positive Suppliers
SVD	Swine Vesicular Disease
SVMO	Supervisory Veterinary Medical Officer
TA	Talmadge-Aiken Act
TB	Tuberculosis
TCOE	Training as a Condition of Employment
TOC	Turkey Osteomyelitis Complex

TSE	Transmissible Spongiform Encephalopathy
UMR	Uniform Methods and Rules
USC	United States Code
USDA	United States Department of Agriculture
vCJD	Variant Creutzfeldt-Jakob disease
VMO	Veterinary Medical Officer
VP	Verification Plan
VPN	Virtual Private Network
VS	Vesicular Stomatitis (or Veterinary Services in regards to APHIS)
WAE	When Actually Employed
WGI	Within Grade Increase