FSIS Public Health Veterinarian Training Program

Weeks 1-2

Presented by the United States Department of Agriculture
Food Safety Inspection Service
Center for Learning

USDA

United States Department of Agriculture

Food Safety and Inspection Service

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

TO: Field Operations Attending Training

FROM: Soumaya Tohamy, Ph.D
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SUBJECT: Food Safety and Inspection Service (FSIS) Training Classes

Congratulations on being selected to attend FSIS training. This is an opportunity to gain significant knowledge about the skills and abilities needed to perform your job duties.

Please use these opportunities 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 and returned to their duty station.

Although FSIS does not have a formal dress code, the goal is to project a positive professional image at all times. Shorts, flip flops, short skirts, crop tops, tank tops, clothing with a message that may be offensive to others, are not neat, clean, and free from holes or tears, are examples of inappropriate clothing in an FSIS worksite.

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

Thank you for maintaining a positive and professional learning environment.

FSIS Public Health Veterinarian (PHV) Training Program: Module Descriptions and Objectives

FSIS Orientation

This module gives an overview with reference to the organization of the U.S. Department of Agriculture, Food Safety and Inspection Services (FSIS), and its mission in protecting the public health.

OBJECTIVES:

1. Defines USDA role within the Executive branch and its mission statement
2. Describes the role of FSIS within USDA and the food safety mission
3. Gives an overview of FSIS' authority as a public health regulatory agency
4. Describes FSIS vision to protect public health
5. Describes the functions of each office within FSIS

Essentials of a Public Health Regulatory Agency Module

This module covers an overview of the essentials of a public health regulatory agency. FSIS is 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.

Regulatory Framework Module

This module covers an overview of the regulatory framework that is used by the Food Safety and Inspection Service (FSIS). This module provides you with information about the context in which you work. It is an overview of the regulatory framework for the Food Safety and Inspection Service (FSIS). As an agent of the federal government, you need to understand your legal responsibilities and the consequences that result when establishments do not comply with the laws and regulations governing meat, poultry, and egg products.

OBJECTIVES:

1. Understand where FSIS derives its authority.
2. Identify what is covered by the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).
3. Understand what regulations are and where they come from.
4. Understand what Directives are and where they come from.
5. Understand what Notices are and where they come from.
6. Understand the relationship among statutes, regulations, directives, and notices.

Employee Safety Module (In-Plant Safety)

This module covers FSIS health and safety procedures and considerations, occupational zoonotic diseases of public health significance, and Lockout and Tagout procedures.

OBJECTIVES:

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

The Regulated Industries: *Characteristics and Manufacturing Processes (included for background only)*

The purpose of this module is to give a brief introduction to the meat and poultry industries. It will not be covering the details of how the industries are regulated by FSIS because this is addressed in other modules. This module will gives an overview of the processes used and the products produced by the industries that are regulated by FSIS.

OBJECTIVES:

1. Describe the characteristics of the regulated industry
2. Describe the processes used
3. Describe the manufacturing principles related to the meat and poultry industry

Ante Mortem Inspection

The module covers the following areas of ante mortem inspection: establishment responsibilities for facilities and conditions, supplies for performing Ante mortem inspection, observation, dispositions, and veterinary services.

OBJECTIVES:

1. Describe the various terms related to ante mortem inspection.
2. Identify the establishment's responsibilities
3. Identify the equipment and supplies that are needed to perform livestock Ante mortem inspection
4. Describe the appropriate methods for conducting Ante mortem inspection for livestock and poultry
5. Complete, given a list of information, a pen card, FSIS Form 6150-1, and FSIS Form 6200-16 in livestock inspection.
6. Given a list describing methods used to dispose of a livestock carcass condemned on Ante mortem, select those methods that are approved by FSIS.

Humane Handling of Livestock

This module covers the procedures and regulations involved in humane handling such as acceptable stunning methods, inspection actions, and humane handling of disabled animals.

OBJECTIVES:

1. Select from a list of definitions the one that best describes the terms:
    a. Surgical anesthesia.
    b. Ritual slaughter.
2. Describe the four approved methods for stunning animals as identified in the Humane Slaughter Act and the regulations.
3. Select from a list of general humane slaughter or handling responsibilities, those that are applicable to the establishment, to FSIS, or both.
4. Determine if a description of the way an animal Is stunned is in compliance with the federal humane slaughter law.
5. Describe a method of slaughter that is exempt from stunning.
6. Select, from a list describing various methods used to move a disabled, yet conscious, animal from one area to another area, those methods that are acceptable according to the Humane Slaughter Act.
7. Compare a description of the way an animal is handled to the federal humane slaughter law to determine if the handling is in compliance with the Humane Slaughter regulations.
8. Identify from descriptions of establishment conditions in or around the livestock holding pens, those that might cause injury to animals.
9. Describe the establishment's responsibilities for animals that are withheld from slaughter for longer than 24 hours.
10. Describe the action an inspector should take when he/she observes an incident of inhumane treatment in an official establishment as a result of:
    a. Facility deficiencies, disrepair, or equipment breakdown.
    b. Establishment employee actions in the handling or moving of the livestock.
    c. Improper stunning.

FSIS Directive 5000.1 Walk Through (included for background only)

This module is to help give direction on the public health veterinarian’s responsibilities to protect the public health through pathogen reduction, specifically *Salmonella* and *E. coli* as outlined in the FSIS directive.

OBJECTIVES:

1. Describe the inspection verification procedures performed to verify establishment compliance with the Sanitation Performance Standards.
2. Describe the inspection verification procedures performed to verify establishment compliance with Sanitation SOP regulations.
3. Describe the inspection verification procedures performed to verify establishment compliance with HACCP regulations.
4. Identify the procedure performed to verify compliance with generic *E*. *coli* requirements.
5. Describe the responsibility for inspection personnel to verify compliance with the *Salmonella* performance standards.

Labor Relations

This module provides information on the role of the field labor and employee relations specialists, Public Law 95-454, and the Labor-Management Agreement by presenting a general review of all agreement articles with emphasis on Governing Laws and Regulations, Management Rights, Union Rights, Employee Rights, Bargaining During the Term of Agreement, Hours of Work, Leave, Performance Management, Details, Overtime, Reassignments, Disciplinary and Adverse Actions, and Grievance Procedures.

OBJECTIVE:

1. Gain familiarity with the Labor-Management Agreement

Post Mortem Inspection Overview

This module covers performing inspection methods, making regulatory decisions, documenting findings, and taking enforcement actions when appropriate, in relation to post mortem inspection we are guided by the following statutes, regulations, directives, and notices.

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 procedures
5. Identify the establishment responsibilities with regard to conducting Post mortem inspection
6. Describe the process of conducting Post mortem inspection procedures
7. Define how the establishment must dispose of condemned product
8. Describe how to complete Post mortem reports

Multi Species Disposition

This module discusses the agency mission, regulatory basis for dispositions, professionalism in performing dispositions, and a systematic approach to the disposition thought process.

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 diseases 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

Reportable and Foreign Animal Diseases

This module covers reportable and foreign animal diseases, reporting procedures, the MOU between FSIS and APHIS, Bovine Tuberculosis Eradication Awards Program, and information about APHIS Veterinary Services.

OBJECTIVES:

1. From a list of animal diseases, be able to select those which are reportable.
2. Be able to recognize clinical signs and/or lesions suspicious of a reportable or foreign animal disease.
3. Know the appropriate procedures to follow when a reportable or foreign animal disease is suspected in an animal presented for slaughter.
4. Be able to properly identify and submit possible lesions of bovine tuberculosis for identification.
5. Be able to follow appropriate procedures when TB reactors, suspects, or exposed animals are presented for slaughter.

BSE

This module presents the new regulatory requirements that were developed and implemented as a result of the positive finding of BSE in the US.

OBJECTIVES:

1. Identify the policies related to non-ambulatory disabled cattle and the FSIS responsibilities related to implementing the policies.
2. Identify the policies related to specified risk materials (SRMs) and the FSIS responsibilities related to implementing the policies.
3. Define the FSIS policies related to mechanically separated (MS) beef.
4. Define the FSIS policies related to advanced meat recovery (AMR).
5. Explain the reason for the prohibition of air injection stunning.
6. Identify the key aspects of the BSE surveillance program.

Residue Detection Program

This module is an introduction to the FSIS National Residue Program, regulatory authority and residue in a HACCP environment, in-plant screening tests, residue testing procedures, animal identification and devices, KIS™ antimicrobial screen test, basic residue responsibilities for the pubic health veterinarian, the role of the Policy Development Division, residue violation cases and follow-up, residue terminology, Residue Violation Information System (RVIS), and residue dockets.

OBJECTIVES:

1. List the purpose for a residue program in FSIS.
2. List the names of the three federal agencies that are involved with residues in food animals.

3. Name and give the distribution of the forms used when the following types of samples have been collected and are ready to be mailed to the appropriate laboratory.
    a. Directed sample for monitoring phase
    b. Inspector generated suspected antibiotic residue
4. Name four tissues commonly requested on the FSIS Form 10, 210.3.
5. List three conditions which would lead to a decision by the PHV to perform an in-plant residue test.

Professionalism

This module discusses professionalism at all levels of the workforce, which is critical to support FSIS in achieving our vision of becoming the premier public health agency and improving the working environment.

OBJECTIVES:

1. Define “professionalism”- what does it look like.
2. Define how professionalism relates to, and impacts, food safety and biosecurity.
3. Identify appropriate and inappropriate behavior and explain how they affect employees, industry officials, consumers and others.
4. Define the Agency’s expectations and the role each employee has in supporting the Agency in achieving its public health mission.
5. Identify the Principles of Ethical Conduct in public service and your responsibility annually in completing the ethics training.

Human Resources Basics

This module covers human resources topics specific to FSIS policies and procedures such as performance management, probationary employees, official personnel files, general pay schedules, staffing, merit promotions.

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
    -
    –
    – work unit meetings

Preparation for Mentoring

This module introduces the concept to the participants of the "New Hire" Mentoring program. Also, it provides the participants with a common language and understanding of what is expected throughout the mentoring process.

OBJECTIVES:
1. Become familiar with the concept of being a mentor
2. Become familiar with the requirements of mentees
3. Become familiar with the relationship aspect of a mentorship situation

Statues and Your Role

This module provides more detail about the regulatory framework and the statutory authority for day to day inspection and verification activities.

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.

Recalls

This module covers the Recall Management Division, the recall process, recall data systems, and the public health veterinarian's role in the recall process.

OBJECTIVES:
1. Explain why products are recalled.
2. Identify the classes of product recalls.
3. Identify the roles different groups play in product recalls.

Administrative Enforcement Reporting

This module covers the agency's Administrative Enforcement Report (AER) format and thought processes. The topics covered include:

-The use of critical thinking in developing an enforcement action.
-Different types of official documentation.
-The work methods and general process of building a case.
-The process behind recommending or taking an enforcement action.
-The basics of building a case and assembling an AER case file.
-How an establishment's response is verified by the agency.
-How to assess an establishment's corrective actions.

OBJECTIVES:
1. Explain and/or list the following concepts of critical thinking:
    a. What is critical thinking?
    b. The importance of critical thinking to the AER process

2. Explain the role of the PHV in the AER process:
    a. In-plant team leader
    b. Ensuring accurate supporting documentation
    c. Ensuring proper lines of communication
    d. Performing verification activities (verification plans)
3. Explain the role of the AER within the FSIS regulatory framework:
    a. Statutes and Rules of Practice as a framework of the AER case file
    b. Ensuring that the establishments receive due process
4. List and describe the main supporting components of the AER:
    a. NRs
    b. Memoranda
    c. MOI
    d. Signed Statements
    e. Other Agency Letters
5. Accurately document a Memorandum of Interview (MOI).
6. List two “other” sources of information pertinent to the AER process:
    a. Consumer Complaint Monitoring System (CCMS)
    b. Recall System

Food Microbiology

This module covers a brief overview of some of the basic principles of food microbiology; explains how those principles apply to meat, poultry, and egg products, and reviews the FSIS microbiological sampling programs.

OBJECTIVES:
1. Identify the sources and parameters affecting the growth of microorganism
2. Describe the pathogens of concerns that causes foodborne illnesses
3. Discuss the impact of pathogens in the in-plant environment.

Wellness and Resources/Networking

This module provides information about coping with stress and other health concerns in addition to providing useful resources that will help participants become more effective in performing their job duties as an FSIS Public Health Veterinarians.

OBJECTIVES:
1. Define different types of stress.
2. Generate a list of coping techniques for stressors.
3. Identify personal resources for dealing with stress.
4. To identify resources including professional organizations, web sites, and information useful in performing the job duties as an FSIS Public Health Veterinarian.

Animal Production Food Safety (included for background only)

This module covers animal foodborne hazards, high risk slaughter classes, quality assurance/certification, the role of FSIS veterinarians in collaboration and information sharing, and the current promising research areas.

OBJECTIVES:

1. Describe and explain why certain classes of livestock presented for slaughter are historically the highest risk for violative residues.
2. Be familiar with the dairy, pork, egg and beef producer HACCP-compatible, Quality Assurance or Good Production Practices Programs. Be able to describe the newest trends in verifiable, third party audited programs and the advantages to industry these programs bring.
3. Be able to describe the role of the in-plant Public Health Veterinarian when interacting with animal and egg production food safety partners.
4. Be familiar with promising research in preharvest food safety and why multiple interventions are believed to be more likely to succeed from farm to slaughter in reducing, controlling and/or eliminating public health hazards reasonably likely to occur in and on animals, poultry and eggs presented to processing.

IPPS Reviews

This module covers the purpose of an IPPS review, personnel involved in an IPPS review, the tools available to supervisors during an IPPS visit, preparation steps, the mechanics, filing, and sharing of IPPS worksheets, and the relationship of the IPPS Assessment worksheet to performance evaluations, and FOIA.

OBJECTIVES:

1. Identify 4 tools available to supervisors during IPPS visits.
2. Define who will conduct an IPPS review.
3. Describe the purpose of an IPPS review.
4. List 4 areas of evaluation for which the IPPS Supervisory Guideline provides information (e.g., for HACCP, Sanitation SOP, Sampling, etc.).
5. List what the supervisor must know/have in order to conduct an IPPS review.
6. State the minimum number of IPPS visits that must occur annually.
7. Describe how an IPPS assessment worksheet is used.
8. Describe where and how IPPS worksheets are filed.
9. Describe how the IPPS assessment worksheet is shared with the inspection program personnel.
10. Describe the relationship of the IPPS assessment worksheet to FSIS Form 4330-6 used to document progress reviews.
11. List the steps in preparing for an IPPS review visit.
12. List the performance elements for inspection program personnel addressed in the IPPS Supervisory Guideline.
13. State whether completed IPPS assessment worksheets are available under FOIA.

Homeland Food Security (included for background only)

This module will address food security activities in FSIS. First, the content covers an overview of what food security means and what activities FSIS has taken to ensure that meat, poultry, and egg products are protected from intentional harm. Then, information about the public health veterinarian's role and inspection activities that are related to food security is discussed.

OBJECTIVES:

1. Identify how FSIS has changed to meet the challenges of food security since "9/11." Be able to describe changes in the organization. Be familiar with various initiatives: planning, surveillance and monitoring, laboratories, Directives, continuity of operations, education and international areas.
2. Identify key weapons of mass destruction and biological threat agents that could be used to attack the food supply.
3. Identify the food security monitoring and reporting responsibilities of frontline supervisors when there is a Homeland Security threat condition.
4. Define how FSIS is promoting the adoption of preventive strategies for industry and consumers. Be familiar with the types of voluntary guidelines industry and consumers must consider in order to be better prepared to prevent and respond to terrorism.

Processing (7000 Directive)

This module covers the public health veterinarian's responsibilities related to the statutes, regulations, and directives that cover the regulatory requirements for what is called Non-Food Safety Consumer Protection, or NFSCP. These requirements relate to economic adulteration and misbranding of products.

OBJECTIVES:

1. Identify the statutes and regulations that relate to other consumer protection responsibilities.
2. Describe how to conduct the NFSCP procedures appropriately.
3. Describe how to conduct the Sampling procedures appropriately.
4. Explain what to do when noncompliance is observed.
5. Describe what to do when there are multiple noncompliances.

Small Plant Assistance

This module discusses the key provisions, the roles and responsibilities of Agency programs and personnel with respect to the Small Business Regulatory Enforcement Fairness Act (SBREFA).

OBJECTIVE:

1. To be able to identify FSIS activities related to Small Business Regulatory Enforcement Fairness Act (SBREFA).

Exports Overview

This module covers export certification and the references and directives pertaining to export certification, replacement certificates, and reinspection.

OBJECTIVE:
1. Conduct export certification duties according to Agency guidance.

Food Safety Education Program (included for background only)

This module will introduce you to the FSIS food safety education program.

OBJECTIVES
1. Explain the goal of the FSIS food safety education program.
2. Identify the highest risk populations for foodborne illnesses.

Inspection Methods (2-week training course)

Inspection Methods Training (IM) is based on FSIS Directive 5000.1, "Verifying an Establishment's Food Safety System". The directive outlines the full range of inspection responsibilities in relation to the HACCP/Pathogen Reduction regulation. In addition, it incorporates all recent Agency issuances (Directives, Notices) related to these topics. The purpose of the training is to reinforce understanding of how to perform food safety duties.

The Inspection Methods training is tailored to an inspector's assignment. All persons receiving the training get foundation training and customized training. The foundation training covers the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures. The customized training covers HACCP verification, Pathogen Reduction, and food safety sampling.

Inspectors assigned to establishments producing products in the Raw Non-Intact, Raw Intact, Slaughter, Ready-to-Eat/Not Ready-to-Eat, and Shelf Stable HACCP processing categories receive Sanitation, HACCP and Public Health Inspection System data entry training. Inspectors at establishments producing products in the Thermally Processed/ Commercially Sterile processing HACCP category receive training focused on thermally processed products.

FSIS New Employee Orientation

This module covers an overview of the U.S. Department of Agriculture, and the Food Safety and Inspection Service.

Objectives

After completing this module, you will be able to:

1. Identify USDA's role in government.
2. Identify FSIS' role in USDA, and where we get our authority.
3. Describe FSIS' workforce and offices, and the roles of each

Resource Materials

USDA web homepage
FSIS web homepage

Introduction

American consumers spend about $617 billion dollars annually on food. Of that amount, $500 billion dollars are spent on foods produced here in the United States. U.S. meat and poultry exports are America's top agricultural export.

Meat and poultry product purchases in the United States make up a large portion of the monies spent on U.S. produced products. Those product purchases equate to Americans consuming 236 pounds of meat and poultry products per person each year. 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 U.S. Department of Agriculture. Some examples of these front-line and behind the scenes professionals are In-plant Inspection Teams, Veterinarians, Chemists, Microbiologist, Analysts and Statisticians, Secretaries and Specialist, 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"?

Food Safety and Inspection Service 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 but 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:

Department of Agriculture (USDA)
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of the Treasury
Department of Veterans Affairs

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 positioned, and was created to ensure oversight of the entire Department. As head of a department of 113,000 employees, the Secretary oversees the nation's farm and food programs.

The current USDA Secretary of Agriculture is: _____.

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 current Deputy Secretary of Agriculture is: _____.

USDA'S Mission

USDA's mission statement reads:

"Provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management. "

That is, USDA provides leadership in agriculture issues. Those 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 which operate over 200 programs. These Areas include:

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, 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, and others).

An Under Secretary heads each mission area and oversees the policies and programs of the area. Food Safety and Inspection Service (FSIS) is in the Food Safety mission area. The Under Secretary for Food Safety also oversees the U.S. Codex Steering Committee, which provides guidance to U.S. Delegations to the Codex Alimentarius Commission.

The current Under Secretary for Food Safety is:_____.

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 as well as chairing the U.S. Codex Steering Committee.

The current Deputy Under Secretary for Food Safety is: _____.

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 assure 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, poultry, and egg products sold in interstate commerce, including imported products. We also enforce, and 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 the Food Safety and Inspection Service 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' 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".

The current FSIS Administrator is: _____.

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 current FSIS Deputy Administrator is: _____.

USDA Headquarters

USDA's Headquarters complex buildings are located in Washington, D.C.; on the National Mall at 1400 Independence Avenue, SW. The Jamie L. Whitten Building houses about 1000 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, block-long 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; it has 7 miles of corridors, 4292 offices, 4746 windows, and houses approximately 6500 employees. Within the South Building, we find the headquarters office of FSIS' Offices and Program Areas. The South Building connects to the Whitten Building by an underground tunnel running under Independence Avenue and by two walkways formed 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

The Food Safety and Inspection Service 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:

FMIA – The Federal Meat Inspection Act
PPIA – The Poultry Products Inspection Act
EPIA – The Egg Products Inspection Act

As part of the Executive Branch, it is FSIS’ responsibility to implement these laws. We regulate meat, 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 — the sanitation and so forth — 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 his or her role, recognize that we all play a part in achieving our common vision to be:

A trusted public health regulatory agency committed to preventing foodborne illness.

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 becoming “a trusted public health regulatory agency”.

FSIS: The Organization

Now that we’ve answered the “What is FSIS” question, let’s shift gears a little before we go into more detail explaining the “Who is FSIS”. 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 over 10,000 employees housed throughout the nation.

We will visit each of these units and see how we work together to accomplish our food safety activities.

Program Areas

- 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' major programs. The Office of the Administrator oversees the emergency Coordination function, and the food defense assessment function.

Office of Field Operations (OFO)

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 the FSIS, managing about 85% of the Agency's resources and about 90% of its human resources. Field Operations employs about 7,200 field inspection personnel including Food Inspectors, Consumer Safety Inspectors, Public Health Veterinarians, Veterinary Medical Specialists, 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. The Office of Field Operation 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 and to whom about 150 field supervisors report. OFO overseas FSIS outreach function.

Field Operations manages a nationwide program of public health protection through inspection and verification of HACCP systems. This Office is also responsible for enforcing the Humane Methods of Slaughter Act for livestock. It also verifies that other consumer protection requirements (OCP) 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. Some specific inspection activities that inspection personnel perform is antemortem inspection on the live animals brought to the establishment including livestock (cattle, swine, sheep, goat, and equine) and poultry. Each animal also receives postmortem inspection (carcass and parts of carcasses) 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 know as the 2008 Farm Bill), FSIS was mandated to inspect catfish. Catfish inspection program manage a nationwide program of regulatory oversight to ensure the safety, security and wholesomeness of domestic and imported catfish. Some of their responsibilities include planning and formulating domestic and international catfish policies, establishing Agency policies and procedures for conducting catfish equivalence evaluations and foreign catfish inspection system audits, conducting audits of foreign country catfish inspection systems, and conducting regulatory compliance activities pertinent to federally inspected establishments and ports of entry. However, the primary function of OFO is within the assurance component of the Public Health Model (assessment, policy development, assurance), and maintain computerized inspection databases on the food safety, food security, and consumer protection programs.

Office of Planning, Analysis and Risk Management (OPARM)

On August 11, 2002, FSIS created the Office of Food Security and Emergency Preparedness (OFSEP). The primary function of this office was to coordinate an Agency response to terrorist threats or deliberate acts of terrorism affecting the supply of meat, poultry, and egg products.

In June 2005, the name of this program area was changed to the Office of Data Integration and Food Protection (ODIFP) which better communicates the comprehensive nature of the program area's mission. In 2018 the name of this program area was changed to Office of Planning, Analysis and Risk Management (OPARM)

Quite often, the terms food safety is confused with food security. Although both are necessary for public health, they require different expertise and experiences along with varying management and prevention methods. These terms are defined as follows:

- **Food safety** involves preventing the accidental or unintentional contamination of food during processing, production, operational deficits, or improper handling.

- **Food security**, on the other hand, focuses on the prevention of acts of deliberately and intentionally introducing dangerous substances into food.

Some of OPARM's activities and functions are:

Data integration and analysis and predictive analytics activities
Management control function
Strategic planning and evaluation function

Office of Investigation, Enforcement and Audit (OIEA)

OIEA supports the Agency's mission and function through investigation, review, assessment, enforcement and audit capacity to improve management effectiveness, efficiency and decision making. It is through this proactive structure that OIEA alerts the Under Secretary and Administrator of any potential or harmful compromise, or failure, of FSIS programs or operations. In many ways, OIEA serves as the ears and eyes of the Agency.

OIEA activities extend to all areas ranging from field inspection effectiveness and efficiency to food safety policy; involving all matters, ranging from Import surveillance, fiscal accountability , human resource policy, hearing , appeals and to all domestic and international inspection function For example:

Ensures that reviews of establishments for compliance and food safety investigations are carried out in a way most conductive to protecting the public health;
Is the Agency's liaison with the Office of Inspector General and the General Accountability Office. This uniquely positions OIEA to focus on key areas in need of improvement.

Hearings and appeals
Detain product in commerce and requests that a seizure action be filed against such product.

The work of the field Program Investigators in OIEA places them on a daily basis in close proximity to performance and compliance problems and concerns at the in-plant level, which affords the agency the ability to deal with necessary adjustments and problems in a much more immediate and direct fashion than in the past.

OIEA also provides oversight of Federal/State cooperative agreements. Establishments have the option to apply for Federal or State Inspection. Although most of the Nation's meat and poultry is produced under Federal Inspection, there are about 28 states that have established meat and poultry inspection programs for products produce and sold within their jurisdictions. These states must enforce requirements at least equivalent to those of FSIS Federal inspection and operate under a cooperative agreement with FSIS. The Agency provides up to 50% of the State's operating funds, as well as training and other assistance. Additionally, OIEA provides oversight for the Interstate Shipment Cooperative Agreement, whereby some State-inspected facilities can produce and ship products across state lines.

Office of Public Affairs and Consumer Education (OPACE)

OPACE plays a critical role in promoting the Agency's public health mission by conveying a single, unified and consistent message to external audiences, and to all FSIS employees. They are also responsible for conducting public communication programs to inform and educate a variety of audiences about Food Safety and Inspection Service activities, food safety policies, foodborne illness, and safe food handling. These audiences include Congress, Media, Industry, Government, Academia and Consumers.

While the Executive Correspondence and Issues Management Staff prepare the Agency's written responses to food safety correspondence, the Congressional and Public Affairs Office also has a Congressional liaison staff within OPACE. They also are the liaison to the media and other constituents.

OPACE's Food Safety and Education Staff conduct communication activities. These are carried out through a variety of means such as public meetings, the USDA Meat and Poultry Hotline, print and video news releases, media tours, visits to members of Congress and their staffs, speeches, testimony, correspondence, publications, internal memoranda, internal and external news-letters, the FSIS website, and responses to Freedom of Information Act request. OPACE is responsible about the record management function in FSIS.

The Agency's consumer and food handler food safety education campaigns and programs are also handled by OPACE.

Office of Public Health and Science (OPHS)

OPHS provides leadership to FSIS and USDA, and assures the establishment and support of scientifically sound food safety programs and policies to reduce or eliminate foodborne illness.

The OPHS staff (Biologists, Chemists, Computer Specialists, Engineers, Epidemiologists, Food Technologists, Microbiologists, Nurses, Physicians, Public Health Specialists, Risk Analysts, Statisticians, Toxicologists, Veterinary Medical Officers, Veterinary Pathologists and other professionals) develop scientific and public health information related to meat, poultry, and egg products from their conception to consumption; and, uses that information to assess potential human health risks throughout the farm-to-table continuum. This includes the development of scientifically based risk assessments that evaluate the occurrence of foodborne contaminants and the probability of human illness upon exposure to such contaminants. In addition, OPHS scientific experts monitor and analyze production processes, identify and evaluate potential foodborne hazards. They also conduct trace-back or trace-forward investigations to identify product disposition and/or the origin of hazards, as well as participate in the recall of adulterated products.

OPHS operates three FSIS Field Service Laboratories (Eastern Laboratory, Midwestern Laboratory and Western Laboratory) that provide support in the areas of microbiology, pathology, food chemistry, species identification, entomology, extraneous materials, and other scientific disciplines. This Office also manages the Accredited Laboratory Program, which grants accreditation to non-federal analytical chemistry laboratories for food chemistry, and several classes of chemical and drug residue. Another component is the Food Emergency Response Network Division (FERN), housed within the Eastern Laboratory. FERN's role is to assist in the development and oversight of an integrated network of laboratories that can quickly respond to food-related emergencies. Through laboratory results, and other function work within OPHS, Agency initiated regulatory issues and policies (e.g. performance standards) have sound science based support.

Office of Management (OM)

The Office of Management (OM) is a support organization made up of a group of over 400 employees who work in Washington, D.C. and Beltsville, MD. In addition to the offices in DC, there are also field offices, including the Human Resource Field Office in Minneapolis, MN. They serve in a variety of administrative, technical, professional occupations. These folks provide a full range of centralized administrative and support services; in addition to assisting in the day-to-day management of FSIS. FSIS personnel cannot do their jobs without the people in OM.

OM provides a full range of administrative and support services to FSIS including:

Business systems improvement;
Personal and real property;
Health and safety;
Labor and employee relations;

Contracting;
Procurement;
Workforce violence prevention; and
Management improvement and internal controls.

At FSIS, our Human Resources Division (HRD) within the Office of Management, supports and enhances the Agency's food safety mission by providing our employees with human resource services that are customer focused and timely. HRD provides services in the areas of:

Employee benefits and workers compensation
Position classification and position management
Personnel processing

Office of Policy and Program Development (OPPD)

The Office of Policy and Program Development (OPPD) is responsible for developing and recommending all domestic and international agency policy for the Food Safety and Inspection Service. This includes:

Gathering information and conducting analyses necessary to set policy for domestic inspection, export, and equivalency function**.**
Developing regulations,
Establishing new programs and systems,
Establish general labeling, food additives, labeling and product composition aspects,
Modifying existing standards and programs, and
Providing technical support.
Managing small plant help desk.

OPPD collaborates with other offices within FSIS to ensure statutory mandates are met. They also work closely with the Office of Field Operations in developing procedures and methods for conducting inspections of livestock, poultry, processed products, and egg products. It also establishes and modifies product standards, inspection systems methodologies, and enforcement strategies.

OPPD reviews new technologies that companies employ to ensure that their use is consistent with Agency regulations and will not adversely affect product safety, inspection procedures, or the safety of FSIS inspectors. It also serves as the Agency’s center for technical assistance, advice, and guidance for OFO personnel and the industry. This includes technical guidance and assistance in the implementation of national policies, programs, systems, and procedures.

Office of Employee Experience and Development (OEED)

This program area ensures that all FSIS personnel have the necessary training to effectively carry out their assigned duties. OEED has three branches; the Center for Learning branch, Training Transformation and Distance Learning Staff, and The Employee Engagement and Recognition Staff

OEED provides leadership in implementing training and development policies by assessing, planning, developing, and conducting various technical and non- technical programs, activities, and resources for the Agency's workforce.

Summary

So, now you have a closer look at Food Safety and Inspection Service and our many food safety activities.

We started with about 10,000 employees. That number has increased. You have joined us, and together we can accomplish our mission. As we conclude this part of your orientation, let's work daily toward supporting our mission:

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Essentials of a Public Health Regulatory Agency

This module covers an overview of the essentials of a public health regulatory agency. FSIS is a public health regulatory agency.

OBJECTIVES

After completing this module, you will be able to:

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

RESOURCE MATERIALS

- Veterinary Recruiting video
- Enhancing Public Health: Strategies for the Future 2003 FSIS Food Safety Vision
- A Description of the U.S. Food Safety System
- Food Safety: A Team Approach
- Milestones in U.S. Food and Drug Law History

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 enacted first, 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 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. We will not be covering the EPIA because of the small number of plants and the large volume of material we must cover.

The Acts provide for the basis for FSIS's ability to perform as a public health agency. In Section 602 of the FMIA, Congressional statement of findings, the first sentence reads:

"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 are wholesome, not adulterated and properly marked, labeled, and packaged. It is hereby in 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 (1) wholesome, (2) not adulterated, (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 things.

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

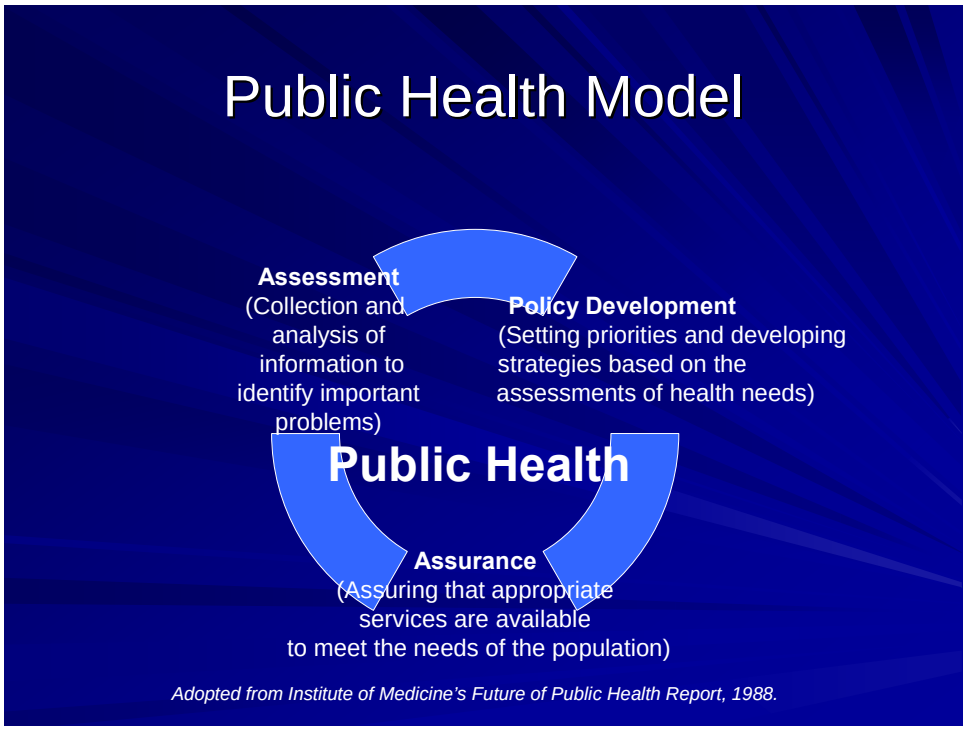
Another foundation principle is outlined in Section 452 of the PPIA which indicates that inspection is authorized to prevent products from entering commerce that are adulterated or misbranded. Remember, ***all the things you do or you supervise as part of your job that can be traced back to the statutes 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; and
- 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. Assessment is carried out using the latest surveillance and testing methods to gather data for conducting the analyses, including quantitative risk assessments, forecasting models, data-mining, and trend analysis. The assessment component is focused on gathering, analyzing, and interpreting data about public health problems using science. Some examples of the activities in FSIS related to assessment include surveillance, identifying needs, analyzing the causes of problems, collecting and interpreting data, case-finding, monitoring and forecasting trends, research, and evaluation of outcomes.

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. Some examples of policy development activities include planning and priority-setting, the development of regulations, directives

and other policy vehicles, mobilizing resources, training, constituency building and distribution of public information, and encouragement of public and private sector cooperation.

The Office of Policy and Program Development has the major responsibility for policy development in FSIS. Some examples of policy documents and policy guidance include regulations, Directives, and Notices. When there is an emerging issue affecting public health, such as the discovery of a cow that tested positive for BSE in January of 2004, FSIS must develop a policy that responds to that issue. Therefore, FSIS policies are dynamic and change to meet the challenges facing public health. You will be responsible for carrying out the policies in your day to day activities. You can provide input into policy development by commenting on interim regulations.

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.

Vision and Goals for FSIS as a Public Health Regulatory Agency

As part of the U.S. Department of Agriculture, FSIS reports to the Undersecretary for Food Safety. The Undersecretary has identified 3 themes incorporating 8 goals for FSIS to achieve. These goals are outlined in the FSIS Strategic Plan FY 2011-2016, which can be found on the FSIS website.

The vision is for FSIS to become a trusted public health regulatory agency committed to preventing foodborne illness.

Theme number one: Prevent Foodborne Illness. Preventing foodborne illness and protecting public health is FSIS' primary purpose. FSIS continually strives to become more adaptable to changing food safety risks, educates consumers on food handling best practices, and works closely with other public health partners to present a comprehensive approach to preventing illness.

- Goal 1 – Ensure that food safety inspection aligns with existing and emerging risks
- Goal 2 – Maximize domestic and international compliance with food safety policies
- Goal 3 – Enhance public education and outreach to improve food-handling practices

- Goal 4 – Strengthen collaboration among internal and external stakeholders to prevent foodborne illness

Theme number two: Understand and Influence the Farm-to-Table Continuum. FSIS cannot improve its ability to prevent foodborne illness, develop new policy or regulation, or effectively collaborate with other food safety organizations without first understanding the epidemiology of foodborne illness outbreaks and factors influencing food safety issues. To gain this insight, FSIS optimizes its use of science and data to fully understand the environment in which FSIS operates.

- Goal 5 – Effectively use science to understand foodborne illness and emerging trends
- Goal 6 – Implement effective policies to respond to existing and emerging risks

Theme number three: Empower People and Strengthen Infrastructure. All FSIS employees deserve to take pride in the fact that what they do helps prevent foodborne illness. FSIS hires the appropriate people, trains them correctly, and ensures that they have the right tools and technology to perform their jobs. Each FSIS employee contributes to the success of the entire Agency.

- Goal 7 – Empower employees with the training, resources, and tools to enable success in protecting public health
- Goal 8 – Based on the defined Agency business needs, develop, maintain, and use innovative methodologies, processes, and tools, including PHIS, to protect public health efficiently and effectively and to support defined public health needs and goals

FSIS: Part of the Food Safety System

In the Appendix of this handout, the last attachment covers the food safety system. This document identifies FSIS, along with FDA. APHIS and EPA as 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.

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.

Enhancing Public Health: Strategies for the Future
2003 FSIS Food Safety Vision

PDF version, best for printing*(17 pp.)

ABSTRACT

On March 19, 2003, Agriculture Secretary Ann Veneman challenged the Food Safety and Inspection Service (FSIS) to reach the next level of food safety. Secretary Veneman's challenge called for creative and effective ways to modernize the FSIS' ability to continue to improve the safety of U.S. meat, poultry, and egg products to better protect public health. This vision document identifies goals and strategies to be pursued by FSIS.

Americans enjoy the safest food supply in the world. This is due in part to efforts by the U.S. Department of Agriculture (USDA) to follow a scientific approach in administering its food safety programs. This approach has resulted in tangible public health benefits for consumers, as seen by the 16 percent decline in foodborne illness over the last 6 years. The Centers for Disease Control and Prevention (CDC) attributes these results in part to the implementation of the Hazard Analysis Critical Control Point (HACCP) system in all meat and poultry plants in the United States.

Over the past two years, the Food Safety and Inspection Service (FSIS) has been implementing a 5-point strategy to further reduce the incidences of foodborne illness using HACCP as the foundation. This strategy includes: improved management of inspectors, application of science in crafting regulations, better coordination with other agencies, an aggressive education campaign for food handlers, and protection of the food supply against terrorist attack.

In this document, FSIS presents a list of accomplishments achieved over the past two years that further enhance the safety of the food supply. In order to continue on the road to improving public health, FSIS will be implementing several new initiatives. These new initiatives, which are outlined in this document, are focused on improved training for inspectors, the use of effective technologies in processing plants to address harmful bacteria, and on scientific research directed and applied to address food safety from the farm to the table.

In addition to these ongoing efforts, the Agency must examine how it can best utilize its resources and authorities to further enhance its systems while providing incentives for compliance. A brief description of these challenges is also presented in this document, laying the groundwork for directions that FSIS may take in the future. The Agency welcomes the input of all interested parties, and encourages the free exchange of ideas, as it continues to work to enhance the safety of the food supply.

Introduction:

Americans enjoy the safest food supply in the world, and it is getting safer. This is evidenced by an overall 16 percent decline in foodborne illnesses from 1996 to 2002, as reported by the Centers for Disease Control and Prevention (CDC). Preliminary FoodNet data for that 6-year period were released April 18, 2003. The preliminary data demonstrate a sustained decrease in major bacterial foodborne illnesses caused by *Campylobacter* and *Listeria*, indicating progress toward meeting the Agency's health objectives of reducing the incidence of foodborne infections. In addition, data from FSIS show a continuing decline in the prevalence of *Salmonella* in regulatory samples of meat and poultry.

In spite of these positive trends towards a safer food supply, FSIS recognizes that intensified efforts are needed to further reduce the incidence of foodborne illnesses related to meat, poultry, and egg products in

the United States. For example, preliminary FoodNet data do not show a sustained decline in foodborne infections caused by *E. coli* O157:H7 and *Salmonella*. Eradicating foodborne illness is an evolving challenge affected by many factors. These factors include changes in food distribution and preparation habits, increases in the average lifespan and the number of immune-compromised individuals, and the emergence and virulence of new pathogens. As the Institute of Food Technologists states in its report titled, "Implications for Control in the 21st Century," food safety issues change over time and so too must the management strategies and regulatory framework.

FSIS is committed to anticipating the changes by incorporating into policymaking the many advances that have been made in food safety research and technologies. These advances will enable FSIS to predict trends in food contamination, and in hazard survivability and growth, thereby enabling the Agency to protect the public's health to the greatest extent possible. An added benefit to such a preventive and anticipatory approach to food safety is the impact that various management practices can have on risk mitigation. Applying risk assessment can enable us to focus efforts on the highest-risk problems, resulting in a more efficient use of resources.

The continued mission of FSIS is to ensure that consumers have the safest possible food supply. To fulfill this vision, FSIS must use science-based practices to diminish the incidence of foodborne illness associated with meat, poultry and egg products. This document outlines recent FSIS accomplishments in combating foodborne illness, describes new initiatives FSIS is undertaking in pursuing its mission, and presents the challenges that must be overcome in order to realize the FSIS vision for food safety. Input from all interested parties on ideas presented in this document is encouraged.

Goals in Pursuit of the FSIS Mission:

The following five core goals best articulate the road map for FSIS' food safety mission:

Goal #1: Improve the management and effectiveness of regulatory programs. In order for policies and programs to be successful, they must be uniformly and correctly applied. Thus, proper training of the workforce is essential. In addition, communication to field personnel needs to be timely and accurate, with proper supervision from the district and from headquarters in order to foster accountability in the system.

Goal #2: Ensure that policy decisions are based on science. Science allows for policy decisions to be continually updated based on technological advances and to respond to emerging threats to public health. Science-based decision-making is objective and preventive in nature, and thus, it offers the best foundation for the development of policies that will achieve the desired result of improving public health, both in the short term and the long term. In terms of developing science-based policies, the threats to public health need to be understood and addressed within the context of the best available research and risk analysis. With input from the scientific community, FSIS can develop practical policies that allow the industry to implement new technologies as food safety interventions.

Goal #3: Improve coordination of food safety activities with other public health agencies. This coordination includes all Federal, State, and other food safety agencies to better utilize resources. All of these agencies share the same mission and their activities and programs should be complementary, so that the maximum benefit can be realized without duplication of efforts.

Goal #4: Enhance public education efforts. Everyone has a responsibility for food safety. Food preparers must know clearly and understand basic food-handling practices. Therefore, FSIS needs to enhance public education efforts. These efforts must be broad enough to ensure that no segment of the public is uninformed about safe food handling practices. Communicating with the public about food safety must be accomplished in a manner that is easily understandable so that it is useful to every segment of the population. The food safety messages must also be targeted to various segments of the population to

improve receptivity, and messages should be focused on positively influencing those behaviors that pose the greatest potential risk. These messages must be distributed to as broad an audience as possible to ensure an effective use of resources. Thus, FSIS must consider innovative and collaborative methods for delivering the food safety message.

Goal #5: Protect meat, poultry, and egg products against intentional contamination. In the aftermath of September 11, 2001, there is recognition that threats to the well being of the Nation's citizens can come in the form of terrorist attacks, including the intentional contamination of food. Thus, FSIS must do everything possible to protect meat, poultry, and egg products against such threats. As with food safety, protection of the food supply against intentional contamination must be coordinated with all relevant agencies.

Accomplishments Within Each Goal:

FSIS has made great strides in achieving its vision through the pursuit of its five stated goals. The following is a summary of some of the most significant efforts made since 2001.

Goal #1: Improve the management and effectiveness of regulatory programs.

FSIS field employees are in every meat, poultry, and egg products plant, ensuring that the plants are producing products that are safe, wholesome, and accurately labeled. These frontline employees are responsible for making the critical determination that products are not adulterated and therefore are safe to eat. Therefore, it is essential to have a scientifically and technically trained workforce that is dedicated to ensuring a safe supply of meat, poultry, and egg products.

A key to improving the management and effectiveness of food safety regulatory programs is having a workforce that understands the scientific basis behind its programs. Having a workforce more grounded in science enables the Agency to better assess the soundness of food safety programs implemented at slaughter and processing establishments, and to enhance its ability to conduct epidemiological investigations. Therefore, the agency created the Consumer Safety Officer (CSO) series to reflect increasing reliance on science and technology. CSOs have a scientific and technical background and receive additional Agency training that enables them to use a disciplined methodology to assess and verify the design of food safety systems. FSIS has trained 107 employees as CSOs in FY 2002, and plans to train almost 200 additional employees in the CSO methodology in FY 2003. In addition, the agency is extending CSO training to its Veterinary Medical Officers.

Because accountability is crucial in delivering programs in a consistent and effective manner, FSIS implemented the In-Plant Performance System (IPPS). This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities, encourage correlation with employees to ensure consistency in methods and applications of methods, help identify and address performance problems, and recognize and reward on-target employee performance.

In addition to these efforts, FSIS is finalizing a plan for reorganization to prepare the Agency to better meet its public health and food safety goals. The specific objectives of this reorganization are to increase accountability, enhance communication, strengthen appropriate agency action on HACCP issues as they occur, and improve overall efficiency at FSIS. The changes have strengthened the bonds between the FSIS offices and have made operations more coherent and responsive.

To improve efficiency, the reorganization includes four new offices with cross-cutting purposes. For example, the assistant administrator for Food Security and Emergency Preparedness ties together all

Homeland Security activities within the Agency, so that FSIS policy makers, scientists, field staff, and management are all working together to ensure that FSIS is prepared to prevent and respond to any bioterrorist attack.

The reorganization also includes an Office of Program Evaluation, Enforcement and Review (PEER) to serve as the Agency's quality control team. This office's mission is to ensure that effectiveness, efficiency, consistency, and accountability become the rule at FSIS. The PEER quality assurance program ensures that FSIS functions, such as reviews of plants for compliance and food safety investigations, are carried out in a way most conducive to protecting the public health. This office also conducts audits of foreign country inspection systems, reviews, assessments, and program evaluations in an effort to ensure that the programs are performing as needed. PEER is the Agency's liaison with the General Accounting Office and the Office of the Inspector General; this uniquely positions PEER to focus on key areas in need of improvement. PEER retains the role of ensuring prompt and appropriate enforcement of the inspection laws. The work of the field Program Investigators in PEER places them on a daily basis in close proximity to performance and compliance problems and concerns at the in-plant level, which affords the Agency the ability to deal with necessary adjustments and problems in a much more immediate and direct fashion than in the past. PEER was formed because a strong quality assurance program that uses reviews, evaluations, and audits as its tools can have a significant impact on management effectiveness, efficiency and policy development.

In addition, FSIS recently consolidated all of the communication functions under the Office of Public Affairs, Education and Outreach to increase the efficiency and strength of FSIS' internal and external communications, outreach, and partnerships. This is a cross-cutting office that combines traditional communications activities, such as those conducted by the Agency's Congressional and Public Affairs, Food Safety Education, and Executive Management Staff, with outreach conducted by the Strategic Initiatives, Partnerships and Outreach Staff (SIPOS). SIPOS includes the Meat and Poultry Advisory Committee Staff, the Planning Staff, small and very small plant outreach, and works with members of Federal, State and local governments.

The new Office of International Affairs centralizes the Agency's activities related to regulation of imported meat, poultry and egg products and certification of exports. This includes representation in international settings where FSIS influences and directs activities that establish food safety standards and promotes improved food safety practices worldwide.

In addition to the new offices, FSIS has instituted new information systems to assist in achieving its mission. In FY 2002, FSIS introduced the new Automated Import Information System (AIIS), which directs port-of-entry sampling of imported shipments. The new AIIS system focuses on a foreign country's inspection system as a whole, rather than on individual plants. The system randomly selects shipments of meat and poultry imports for reinspection based on the annual volume of shipments from the exporting country. Previously, reinspection was based only on an establishment's compliance history. The new system is user-friendly for inspectors, provides managers with instant access to inspection reports, and permits better tracking of shipments once they enter the United States. The next step is for FSIS to integrate its system with other key systems in order to further protect the food safety system against intentional attacks. Such systems include those of USDA's Animal and Plant Health Inspection Service and the Bureau of Immigration and Customs Enforcement within the U.S. Department of Homeland Security.

Goal #2: Ensure that policy decisions are based on science.

The food safety system employed by FSIS to accomplish its mission has evolved from a purely inspection program, in which visual and other organoleptic examination was the cornerstone, to one in which a science-based framework is used to identify and prevent food safety problems. This framework is known as

the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) system. PR/HACCP allows for the use of science, research, technology, and data disclosure in the development of improved food safety. HACCP identifies hazards for the purpose of establishing critical control points. It is a preventive approach.

PR/HACCP is working. Evidenced by a 16 percent overall decrease in foodborne illnesses between 1996 and 2002, and by a decrease from 5.0 percent to 4.3 percent in the prevalence of *Salmonella* in regulatory samples (from 2001 to 2002), this system has become an effective tool to minimize the entry of pathogens into the food supply.

In addition, a strong system of checks and balances is essential to continued improvements in food safety. In the last two years, FSIS has taken decisive and concrete actions to modernize this system. For example, FSIS has used its authority to issue regulations for specific pathogens to impose additional data requirements on establishments producing ready-to-eat products where the pathogen *Listeria monocytogenes* is a concern. New audit initiatives have produced significant improvements to HACCP controls in raw beef product producing plants. In-depth reviews of establishments failing to meet *Salmonella* performance standards are also producing results, including increased use of suspension authorities pending correction.

As stated above, FSIS continuously reviews its existing authorities and regulations to ensure that emerging food safety challenges are adequately addressed. In addition, FSIS is committed to continuing its emphasis on the use of science, research, and technology in the development of improved food safety policies, focused on prevention whenever possible. Risk assessment is one tool that can provide FSIS with the solid scientific foundation on which to base regulatory and policy decisions. In fact, the Agency has used risk assessment to estimate the likelihood of exposure to various hazards, and to estimate the resulting public health impact. For example, in February 2003, FSIS released a draft of a quantitative risk assessment conducted on *Listeria* in ready-to-eat (RTE) meat and poultry products. On February 26, 2003, FSIS held a public meeting to discuss the design of the risk assessment, the results, and conclusions that could be drawn from it regarding the risk of contamination of RTE products with this pathogen during processing.

The risk assessment, in conjunction with a previously released Food and Drug Administration (FDA)/FSIS risk ranking, peer review and public comment, provided important data enabling FSIS on June 6 to publish a final *Listeria* rule proposed in early 2001. This risk-based regulation will serve as the cornerstone of the FSIS efforts to prevent listeriosis from RTE meat and poultry products. The rule requires all establishments that produce RTE products that are exposed to the environment after cooking to develop written programs to control *Listeria monocytogenes* and to verify the effectiveness of those programs through testing. Establishments must share testing data and plant generated information relevant to their controls with FSIS. The rule also encourages all establishments to employ additional and more effective *Listeria monocytogenes* control measures. The new rule is accompanied by a verification testing program under which intensified testing is conducted at high-risk plants that produce high-risk products, as identified by the previously released FDA/FSIS risk ranking.

In addition to the new *Listeria* regulation, additional policies that have been implemented include:

***Salmonella* Notice.**

In August 2002, FSIS issued new procedures emphasizing the use of *Salmonella* testing. Establishment failure to meet the *Salmonella* performance standard triggers an immediate review of an establishment's entire food safety system.

Establishments that do not meet food safety requirements, as determined during these in-depth reviews, are subject to enforcement actions. In fact, in-depth reviews have resulted in an increase in suspensions of

inspection from 2.3 percent in 1998 to 4.8 percent in 2002. The new procedures also emphasize coordination between consumer safety officers, district managers, circuit supervisors, compliance officers and inspection personnel to ensure that plants identify and correct problems in their food safety systems that are resulting in noncompliance. Increased coordination also helps FSIS ensure that it addresses performance problems regarding inconsistent inspection and related issues. These can be measured through audits of verification activities carried out by FSIS inspectors.

E. coli O157:H7 Reassessment.

Data from the Agricultural Research Service (ARS) as well as FSIS' draft risk assessment for *E. coli* O157:H7, indicate that *E. coli* O157:H7 is more prevalent in cattle than previously believed. Based on this data, in October 2002, FSIS announced a series of new measures to further prevent contamination in ground beef with the pathogen *E. coli* O157:H7.

In an October 7, 2002, *Federal Register* Notice, FSIS informed manufacturers of beef products of the Agency's views about the application of the HACCP system regulations to contamination with *E. coli* O157:H7. The Notice informed all establishments producing raw beef products that they must reassess their food safety plans, based on evidence indicating that *E. coli* O157:H7 is a hazard reasonably likely to occur at all stages of the process (unless they had already reassessed their plans in light of this data). If establishments determine from these reassessments that *E. coli* O157:H7 is a hazard reasonably likely to occur, they (or for grinders, their suppliers) must incorporate one or more critical control points designed to prevent or eliminate contamination with this pathogen.

FSIS is in the process of reviewing these establishment reassessments, through audits being conducted by CSOs. As of mid-May, 63 percent of all plants reviewed, and 87 percent of large plants reviewed, have revised their HACCP plans to include better controls for *E. coli* O157:H7, in an effort to prevent contamination of products with this pathogen.

E. coli O157:H7 Testing.

In April 2003, FSIS issued an FSIS Notice to clarify that FSIS will now collect a sample of ground beef for *E. coli* O157:H7 analysis regardless of the measures that plants take to reduce or eliminate this pathogen. FSIS announced this new procedure in order not to exempt any processor and to recognize that the prevalence of this pathogen begins to rise in April and May of each year. FSIS is in the process of developing a risk-based verification testing program for *E. coli* O157:H7, and expects to issue a revised Directive 10,010.1 in August 2003.

AMR Sampling Program.

On March 3, 2003, FSIS released the results of a blind survey of beef products produced using Advanced Meat Recovery (AMR) systems. The survey of 34 establishments was conducted to determine the frequency of products containing central nervous system (CNS) tissue, including spinal cord tissue, produced with this equipment. The results showed that approximately 35 percent of the final product samples tested positive for CNS tissue (spinal cord) and CNS-associated tissues.

As a result of the survey, FSIS began implementing a verification program to verify that establishments using AMR systems to produce beef are following regulations designed to prevent spinal cord from entering the food supply. The sampling program specifically requires inspection personnel to take samples of AMR product on a routine basis. If the tests identify the presence of spinal cord tissue in the product, then inspection personnel are to withhold marks of inspection from the establishment's AMR product and tag the AMR system itself. This means that neither the product nor the equipment can be used until

satisfactory corrective action has been taken and verified.

In response to the survey results and the sampling program, establishments with beef AMR systems have implemented numerous changes to reduce the likelihood of spinal cord tissue entering the final product. The changes range from discontinuing the use of their AMR systems altogether, to retraining employees and employing new equipment and procedures to ensure that spinal cord is fully removed from the vertebral column prior to entry into the AMR system for processing. As a result, the percent of samples testing positive for CNS tissue has decreased by over 50 percent.

As a means to consider possible strategies for addressing food safety issues, FSIS has aggressively sought the input of the scientific community and others. The Agency has sponsored many public meetings and scientific symposia that allow the agency to share information with, and gather input from, stakeholders on food safety and public health topics.

A public meeting entitled "Applied Epidemiology – A Public Health Tool to Inform Food Safety Inspection," was held on January 29-30, 2002, to discuss the Agency's use of epidemiological data, scientific principles and techniques, and the use of other public health tools. The meeting was designed to help develop a framework for how FSIS will conduct public health investigations and integrate the scientific principles of applied epidemiology into in-plant activities.

FSIS also sponsored a major symposium entitled "Pathogen Reduction: A Scientific Dialogue," in May 2002. The symposium brought together leading experts from government and academia to discuss scientific data and issues associated with pathogen reduction and HACCP. From this meeting, FSIS has been able to gather information on how pathogens enter the food chain, options for constructing statistically sound performance sampling strategies, new trends in microbiology and microbial ecology, and new technologies to remove or inactivate pathogens on carcasses.

The Second National Conference for Food Safety Educators, "Thinking Globally--Working Locally: A Conference on Food Safety Education," was held in Orlando, Florida, from September 18-20, 2002. More than 600 food safety educators from across the United States and around the world attended the conference. This conference enabled the exchange of successful educational approaches among the participants.

On November 18, 2002 FSIS held a "*Listeria* Summit." This forum allowed government, academia, industry, advocacy groups and the public to present the Agency with up-to-date research data as well as comments on actions that best address *Listeria monocytogenes*. This summit was helpful in obtaining additional scientific analysis, information and public input to finalize a proposed rule on *Listeria* to enhance current policies.

FSIS also held a public meeting December 12, 2002, to discuss improving the process for recalls of meat, poultry and egg products. This public meeting provided an opportunity for public input on how to further improve the recall process. Suggestions and ideas derived from this meeting are currently being considered by the Agency, as it seeks to enhance these systems to better protect public health.

On February 26, 2003, FSIS held a public meeting to discuss and gather input on the draft risk assessment for *Listeria*. The draft risk assessment was an important step in finalizing regulations for addressing *Listeria* monocytogenes. Comments and discussions held at this meeting aided the Agency in determining how the risk assessment could be improved, and was the first step towards seeking further input through a peer review conducted by university experts soon thereafter.

FSIS held a public meeting on March 27, 2003, to share perspectives and discuss strategies for improving global food safety. The meeting allowed discussion of the challenges faced by the international food safety

community, and provided an opportunity to share ideas and perspectives on food safety issues, discuss strategies to improve food safety worldwide, and foster relationships to promote food safety.

Finally, a second public meeting on applied epidemiology was held on April 29, 2003, to discuss the use of epidemiological data, principles, techniques and other tools to help it achieve its public health goals. This meeting was designed as a follow-up to a meeting held in early 2002, with the purpose of helping FSIS develop a framework for how the Agency will conduct public health investigations and integrate the scientific principles of applied epidemiology into its in-plant activities.

On April 28, 2003, FSIS implemented the Food Safety Regulatory Essentials Training Program under which FSIS will retrain the entire workforce in HACCP. The training is based on revised Directive 5000.1, issued May 21. Directive 5000.1 serves as a handbook that contains instructions for FSIS field personnel on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations. It guides the consumer safety inspector (CSI) and the CSO on the verification procedures, documentation instructions and enforcement actions for specific food safety activities. It provides a framework to assist the CSI in understanding the thorough process to be followed in performing the inspection methodology and making regulatory decisions.

Goal #3: Improve coordination of food safety activities with other public health agencies.

An example of the progress in coordinating efforts was an unprecedented investigation conducted with the CDC and State and local public health agencies on the Northeastern listeriosis outbreak that occurred in 2002. FSIS dispatched seven teams beginning in early September to affected Northeastern States and used information provided by CDC to test products and visit plants that were suspected of being linked to the outbreak. FSIS collected more than 400 samples of product and the environment for analysis in the course of the investigation. When it was first suspected that a turkey product caused the outbreak, FSIS took immediate, focused steps to identify the plant. After identifying the plant, FSIS immediately requested a recall and sent a team of specialists to the establishment to help identify any problems in the plant. Functioning as a true public health agency, FSIS spent an enormous amount of time and resources investigating this outbreak, including creating a team of more than 50 laboratory scientists, regional epidemiologists, CSOs, compliance officers, field personnel and headquarters management to work closely with CDC and State and local public health officials to locate the source. CDC has publicly commended FSIS for its successful public health role in identifying and addressing the source of the outbreak.

In addition, the cadre of FSIS epidemiologists, including several who are Public Health Service (PHS) Commissioned Officers, enhanced public health agency coordination. The ability of FSIS to utilize these PHS Officers results from a Memorandum of Agreement (MOA) with the U.S. Department of Health and Human Services' PHS Commissioned Corps signed on April 17, 2003. The addition of these PHS Commissioned Officers will enhance FSIS capabilities for rapid response during heightened security alerts or in the event of an actual threat to food security.

Another area in which FSIS is making strides involves cooperation with States through the sharing of product recall information. In July 2002, FSIS published a final rule allowing the Agency to share a firm's distribution list with State and Federal agencies in the event of a meat or poultry recall through a Memorandum of Understanding. This change allows for better communication and coordination between FSIS and the numerous State and Federal agencies that are involved in product recalls.

Goal #4: Enhance public education efforts.

Food safety education is a critical element of the risk analysis framework, which includes risk assessment, risk management, and risk communication. It is a risk management strategy because educating food

preparers – in the home, in institutions, and in food service -- is an important way to reduce the risk of foodborne illness. Education is also a risk communication function because it serves to alert the public about a hazard that exists and can be addressed by safe food handling and food selection.

FSIS has been conducting an aggressive educational campaign of public events and media interviews with national and regional media organizations in order to reach more of the population with important public health messages. Recent events were held in Atlanta, Miami, Detroit, Austin, and Nashville. National television interviews have been conducted with major television networks, including *Fox News*, *Telemundo* and *Univision*. National celebrities, such as former Miss America Heather Whitestone and country singer Wynonna Judd, have also been recruited to help FSIS reach even larger audiences with food safety messages through special events and the filming of Public Service Announcements.

FSIS is developing a comprehensive and sustainable mass media campaign that leverages traditional and non-traditional media outlets throughout the country to get this important message out.

FSIS is sending the *USDA Food Safety Mobile* to strategic locations throughout the country to research and develop this important food safety education campaign. Through a partnership with university extension agents and private industry, the Mobile has hosted numerous demonstrations for food handlers of all ages. While delivering important food safety messages to the public, the Mobile is providing valuable first hand insight on how future mass media messages and education campaigns should be constructed and delivered.

Keeping in mind the changing demographics of the Nation, FSIS has also taken important steps to provide food safety education to citizens whose first language is not English. The Agency has translated its most popular consumer publications into Spanish and this year the FSIS Meat and Poultry Hotline is answering – in Spanish – the food safety questions of Spanish-speaking Americans. FSIS is making progress on translating key materials into other languages as well.

Goal #5: Protect meat, poultry, and egg products against intentional contamination.

Close coordination with other public health agencies is important in protecting the food supply against intentional harm. Since the attacks on September 11, 2001, FSIS has strengthened coordination and preparation efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism, and ensure the safety of meat, poultry, and egg products that come to us from other countries. With a strong food safety infrastructure already in place, FSIS has been able to focus on strengthening existing programs and improving lines of communication, both internally and externally.

Also, the formation of PEER provides FSIS with a strong enforcement program with significant surveillance capacity. While much of the Agency's focus is properly at the in-plant level, strong surveillance is critical to the ability to control product at retail, in distribution and in transit. The FSIS enforcement program also addresses intentional contamination of products.

FSIS has made important progress on the scientific front. FSIS laboratories have enhanced analytical capability for compounds of concern, and developed surge capacity. FSIS is represented on the interagency Laboratory Response Network and worked to develop the Food Emergency Response Network for potential foodborne contamination incidents. FSIS has hosted a laboratory workshop for food and drug officials on integrating laboratory resources for national food security. The Agency has also begun construction of a Bio Security Level 3 facility. In order to respond rapidly to possible intentional contamination, field employees must diligently monitor all plants and other facilities where products are stored, handled and transported to ensure that there is no intentional biosecurity breach that could harm the Nation's food supply. Coordination with other agencies is one of the Agency's goals.

FSIS has strengthened its controls to protect the public from the entry of contaminated product from abroad. FSIS continually assesses foreign country inspection systems to ensure that they maintain food safety standards and operations equivalent to the U.S. inspection system. These assessments include in-country audits and port-of-entry reinspection of all shipments entering the country.

To augment the efforts of traditional FSIS import inspectors, FSIS has also added 20 new import surveillance liaison inspectors who are on duty at ports of entry. Where traditional FSIS import inspectors examine each shipment and conduct reinspection activities, these new import surveillance liaison inspectors conduct a broader range of surveillance activities at each import facility and serve as liaisons to improve coordination with other agencies concerned with the safety of imported food products, such as the Department of Homeland Security.

Besides initiatives to screen imported products, FSIS has conducted a vulnerability assessment to be used as a tool for determining the most vulnerable products, likely agents, and potential sites for deliberate adulteration of domestically produced meat, poultry, and egg products. The assessment was conducted using a farm-to-table approach based on current knowledge of the industrial processes used in the production of these products and the potential biological and chemical agents that could be introduced. The assessment was concluded in June 2002, and the information obtained is being used to develop risk management strategies, including ensuring that FSIS laboratories are equipped with the methods and personnel necessary for detecting agents of concern.

FSIS has also developed a vulnerability assessment of the import system to identify points in the production of imported products where biological, chemical, and radiological contaminants could be intentionally added to foods being brought into the United States. FSIS used the risk analysis framework to conduct a relative risk ranking to be used to allocate resources to monitor U.S. ports of entry for those food commodities that pose the greatest risk, examine different intervention strategies for preventing or reducing risks, develop biohazard identification protocols, and target training of personnel and develop educational campaigns to increase awareness. This assessment is expected to be completed in September 2003.

FSIS has taken preparation for food safety emergencies to a higher level with simulation exercises. Earlier this year, an exercise known as “Crimson Winter” was conducted to familiarize managers and staff with the operating environment that would exist during an outbreak of foodborne disease – the cause being intentional or unintentional. This exercise was very constructive for FSIS’ senior management, its emergency response team, its partners in the Food Threat Preparedness Network, and other relevant Federal and State agencies.

New Initiatives for 2003:

FSIS is implementing several new initiatives in order to continue toward its vision for food safety.

Train to the Vision.

FSIS recognizes that to successfully implement consistent enforcement of its regulations, it needs to support the most critical component of FSIS effectiveness -- its workforce. Thus, one of the Agency’s top priorities is to aggressively address the training and education of its workforce. The Agency must ensure it is training employees to fulfill its vision. In order to ensure consistent and accurate inspection, FSIS has made a strong commitment to recruiting scientifically educated employees and retooling its entire training and education programs for all employees.

FSIS has crafted a two-fold plan on how it will enhance its workforce training capability. First, all training programs for all employees will be updated to incorporate a public health focus by integrating scientific and technical principles, including HACCP validation, with training on technical and regulatory approaches to inspection, and use of enforcement responses, such as suspension of inspection, where appropriate.

Second, FSIS is moving to a system of delivering training that is as close to the employee's worksite as possible. This will involve regional training and regional trainers, as well as interactive sessions near the employee's work site and on-site training programs. Training and education programs must be easily accessible for both headquarters and field personnel.

FSIS is developing long-term strategies to build a more knowledgeable and empowered workforce. The program will incorporate both technical and managerial aspects so that FSIS has employees who can function well in a science-based environment. In addition, some of the training, particularly training involving new technologies and methodologies, must be carried out in conjunction with the regulated industry, so that both processors and inspectors share in the knowledge gained about the science behind the FSIS regulations, and how they must be applied to improve public health.

Food Safety Technologies.

The Agency is working to encourage the regulated industry to target microbial interventions at appropriate control points to best protect public health. FSIS is establishing a technology review staff that will review interventions in order to expedite the implementation of safe interventions at slaughter and processing establishments. The Agency is refining guidance documents for industry on how to seek review of new technologies under an expedited review process. These enhancements follow earlier steps to facilitate the review process, including implementing a simultaneous review process (with FDA) for new ingredients. On April 29, 2003, FSIS issued a direct final rule to permit the use of any safe and suitable binder or antimicrobial agent in the production of meat and poultry products that are subject to a standard of identity or composition that provides for the use of such ingredients. This rule, effective June 30, will provide food processors with much more flexibility in using antimicrobial agents in standardized meat and poultry products.

Risk Assessment Coordination.

In order to better focus its resources in food safety risk assessment activities, FSIS is planning the establishment of a risk assessment coordination team with USDA-wide membership. The goals are to strategically plan these activities and to improve coordination with researchers within and outside FSIS so that risk assessments are conducted more efficiently and utilizing the best science. As an added benefit, the Agency anticipates that such a focused approach will better enable use of risk assessments as tools to help identify future research needs.

Research Agenda.

FSIS is working with the Research, Education, and Extension mission area at USDA to coordinate food safety research priorities and needs, including elucidating the ecology of various pathogens from farm to table. This research agenda will include a mechanism by which research needs in food safety are prioritized and conducted by the Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CSREES), with input from other government agencies, academia, and stakeholders, in order to improve efficiency in the use of resources, and effectiveness in application of research results to better improve food safety.

In order to improve coordination with ongoing research efforts in food safety, the Research, Education, and

Economics (REE) mission area of USDA is planning to host a food safety research agenda symposium. The symposium will help initiate the development of a unified research agenda to complement industry and academic research as well as encourage external research directed toward this unified agenda. FSIS has created a new position of Strategic Manager for Research and Technology Transfer. The Agency has also recruited and hired a senior ARS scientist-veterinarian into this position. This new FSIS scientist will greatly facilitate FSIS communication and coordination with its USDA and other research partners.

Best Practices for Animal Production.

In consultation with livestock producers, researchers, and other stakeholders, FSIS is developing a list of best management practices for animal production facilities such as feedlots to provide guidance in reducing pathogen loads before slaughter. FSIS is planning a symposium in coming months as a foundation for the development of guidelines that can be followed at the feedlot by producers to minimize carriage of human pathogens by food animals.

Baseline Studies.

FSIS is making plans to conduct continuous baseline studies to determine the nationwide prevalence and levels of various pathogenic microorganisms in raw meat and poultry. In the past, limited baseline studies have been used to establish performance standards. While these performance standards have not been directly correlated with public health outcomes, they are an important part of verifying the sanitary operation of meat and poultry establishments.

The new baseline studies will take into account regional variation, seasonality and other critical factors. The continual nature of the baseline studies will provide both benchmark information on the national trends and a tool to assess performance of initiatives designed to reduce the level and prevalence of pathogens in meat and poultry products. These baseline studies will also provide important information for conducting risk assessments that support regulatory initiatives for reducing foodborne illness. These surveys will be important in establishing the link between foodborne disease and ecological niches, as well as levels and incidence of pathogens in meat and poultry. The net result will be more targeted interventions and effective elimination of sources of foodborne microorganisms.

Modernization of Enforcement Activities.

A strong system of checks and balances is important to an effective food safety system. FSIS will continue to review authorities and regulations and will continue to work with interested parties to modernize and further enhance its compliance efforts.

Achieving the Next Level of the Food Safety Vision:

Emergence of previously unrecognized human pathogens, as well as new trends in food distribution and consumption, have prompted FSIS to consider the need for novel strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry, and egg products. Although great strides have been made in accomplishing FSIS' vision for food safety, it is necessary for us to pursue a course of action that will help us attain the next level of prevention, which is to predict, or anticipate, problems as much as possible before they arise. Toward this effort, FSIS intends to identify hazards early by analyzing prevalence and enforcement data, coupled with ensuring that the right corrective actions are taken promptly to minimize risks to public health.

Through analysis and discussions with stakeholders, FSIS has identified three issues that need to be addressed if FSIS is to attain this next level of public health protection.

Issue #1: Anticipate/Predict risk through enhanced data integration.

To anticipate hazards involving meat and poultry products, FSIS must have the best available data to clearly identify the extent and nature of these hazards, in order to determine and calibrate an effective response. These data consist of FSIS' regulatory samples, as well as samples collected by food processing establishments. Thus, there is a need to improve access to, and analysis of food safety data from all reliable sources. This must be achieved in a responsible manner that serves public health.

Issue #2: Improved application of risk into regulatory and enforcement activities.

FSIS recognizes the need to better document food safety problems as they occur, in order to analyze conditions that should be corrected in its science-based approach to pathogen reduction. For example, a better understanding of the prevalence and causes of food safety failures could allow FSIS to assess how best to address them. Data regarding the causes of food safety violations, either within a specific establishment, or within a class, can be utilized in order to better focus prevention and regulatory enforcement strategies.

Issue #3: Better association of program outcomes to public health surveillance data.

FSIS has made great strides in preventing foodborne illness, which CDC has attributed in part to the implementation of HACCP. For example, the preliminary FoodNet report for 1996-2002 notes that the decline in the rate of *S. Typhimurium* infections in humans coincided with a decline in the prevalence of *Salmonella* isolated from FSIS regulated products to levels below baseline levels before HACCP was implemented.

However, there still is a need to determine how specific policies affect public health. In order to accomplish this, data that links foodborne illness outbreaks with specific foods needs to be obtained and documented, so that it may be linked with prevalence data of specific pathogens in specific foods. The latter activity can be best accomplished through an ongoing commitment to conducting baseline studies for various foodborne hazards. As previously mentioned in this document, such an activity is one of the initiatives currently being pursued by FSIS. However, to complete the linkage with public health outcomes, a strong connection with human health surveillance data is needed.

Accomplishing this task will help point FSIS regulatory efforts towards focusing its inspection and enforcement on those practices where risk is deemed to be highest, resulting in a more efficient use of government resources. Toward this goal, FSIS is working with CDC's National Center for Infectious Diseases to design and support studies that enable definite connections to be made between occurrence of specific pathogens in specific foods and the occurrence of human foodborne illness.

The Agency intends to engage the scientific community, public health experts and all interested parties in an effort to identify science-based solutions with public health outcomes. It is FSIS' intention to pursue such a course of action in the coming months, in as transparent a manner as possible. The resulting strategies should help FSIS continue to pursue its goals and achieve its mission of reducing foodborne illness.

U.S. Food and Drug Administration
U.S. Department of Agriculture
March 3, 2000

A Description Of The U.S. Food Safety System

The following interagency paper was prepared as the U.S.'s March 2, 2000 submission to the Organization for Economic Cooperation and Development (OECD), which requested descriptions of member countries' food safety systems. The documents will be used to prepare an international food safety paper for OECD use.

- This page is a mirror of the page at http://www.foodsafety.gov/~fsg/fssyst2.html
- **Annex 1** and **Annex 2** are now available at http://www.foodsafety.gov/~fsg/fssystem.html.
- Any updates or additional information will be posted on the U.S. Codex Office "What's New?" page .

I. Synthesis: The United States Food Safety System

The United States Constitution prescribes the responsibilities of the government's three branches: executive, legislative and judicial, which all have roles that underpin the nation's food safety system. Congress, the legislative branch, enacts statutes designed to ensure the safety of the food supply. Congress also authorizes executive branch agencies to implement statutes, and they may 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. General U.S. laws and statutes and Presidential Executive Orders establish procedures to ensure that regulations are developed in a transparent and interactive manner with the public. Characteristics of the U.S. food safety system include the separation of powers among these three branches and transparent, science-based decision-making, and public participation.

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and industry's legal responsibility to produce safe foods. Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The system is guided by the following principles: (1) only safe and wholesome foods may be marketed; (2) regulatory decision-making in food safety is science-based; (3) the government has enforcement responsibility; (4) manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and (5) the regulatory process is transparent and accessible to the public. As a result, the U.S. system has high levels of public confidence.

Precaution and science-based risk analyses are long-standing and important traditions of U.S. food safety policy and decision-making. U.S. food safety statutes, regulations, and policies are risk-based and have precautionary approaches embedded in them.

The agencies' well-qualified science and public health experts work cooperatively to ensure the safety of U.S. food. Scientists from outside government are regularly consulted to provide additional recommendations regarding technical and scientific methods, processes, and analyses used by regulators. The cutting-edge science that informs U.S. regulators is routinely shared internationally through interactions with organizations like the Codex Alimentarius Commission, World Health Organization, and the Food and Agriculture Organization.

The U.S. routinely and effectively deals with technological advances, emerging problems, and food safety incidents. It is enhancing early warning systems about pathogens in food. The legislation granting authorities to agencies generally enables them to revise regulations and guidance consistent with advances in technology, knowledge, and need to protect consumers.

U.S. food agencies are accountable to the President, to the Congress which has oversight authority, to the courts which review regulations and enforcement actions, and to the public, which regularly exercises its right to participate in the development of statutes and regulations by communicating with legislators, commenting on proposed regulations, and speaking out publicly on food safety issues.

II. United States Food Safety System

Introduction

The U.S. food safety system is based on strong, flexible, science-based laws and industry's legal responsibility to produce safe foods. Coordinated interactions among federal authorities having complementary and interdependent food safety missions, in partnership with their state and local government counterparts, provide a comprehensive and effective system. The implementation of the statutes and the food safety system over many years has resulted in very high levels of public confidence in the safety of food in the U.S.

Principal federal regulatory organizations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on guidance provided. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities, including DHHS's Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA's Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office; and the Department of Commerce's National Marine Fisheries Service (NMFS).

The FDA is charged with protecting consumers against impure, unsafe, and fraudulently labeled food other than in areas regulated by FSIS. FSIS has the responsibility for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. EPA's mission includes protecting public health and the environment from risks

posed by pesticides and promoting safer means of pest management. No food or feed item may be marketed legally in the U.S. if it contains a food additive or drug residue not permitted by FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance. APHIS' primary role in the U.S. food safety network of agencies is to protect against plant and animal pests and diseases. FDA, APHIS, FSIS, and EPA also use existing food safety and environmental laws to regulate plants, animals, and foods that are the results of biotechnology.

A. Laws And Implementing Regulations

The three branches of U.S. government -- legislative, executive, and judicial -- all have roles to ensure the safety of the U.S. food supply. Congress enacts statutes designed to ensure the safety of the food supply and that establish the nation's level of protection. The executive branch departments and agencies are responsible for implementation, and may do so by promulgating regulations, which the U.S. publishes in the *Federal Register* and which are also electronically available. Characteristics of the U.S. food safety system are the separation of powers and science-based decision-making. Agency decisions under U.S. food safety laws can be appealed to the courts which are empowered to settle such disputes.

Food safety statutes enacted by Congress provide regulatory agencies with broad authority but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. Food safety agencies then develop regulations that give specific direction and establish specific measures. When new technologies, products, or health risks must be addressed, agencies have the flexibility to revise or amend regulations generally without need for new legislation. Agencies are able to maintain their state-of-the-art scientific methods and analyses because changes of this type can be made at the administrative/technical level.

Major U.S. food safety authorizing statutes include the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), Food Quality Protection Act (FQPA), and Public Health Service Act.

Procedural statutes, which regulatory agencies must follow, include the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA), and the Freedom Of Information Act (FOIA). The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee. The FOIA provides the public with a statutory right to access federal agency information.

U.S. food safety programs are risk-based to ensure the public is protected from health risks of unsafe foods. Decisions within these programs are inherently science-based and involve risk analyses. Risk assessment is useful in understanding the magnitude of the problem faced, and it assists the agency in determining an appropriate risk management response.

The regulatory development process is conducted in an open and transparent manner. Regulations are developed and revised in a public process that not only allows, but encourages, participation by the regulated industry, consumers, and other stakeholders throughout the development and promulgation of a regulation. In developing new regulations and revising existing regulations, the agencies often provide the public a preliminary discussion and opportunity for comment by publishing an Advance Notice of Proposed Rulemaking (ANPR). It lays out the issues, presents the agency's suggested resolution, and solicits alternative solutions. The information received from the public is used by the agency to decide whether and how to pursue rulemaking further. All significant public comments must be addressed in the final regulation. The next steps are publication of a proposed regulation and publication of a final regulation, which is enforceable, with opportunities for public comment. The APA requires that the final regulation be justified by policy rationale, scientific bases, and legal authority.

When confronted by a particularly complex issue where advice is needed from experts who are not part of the agency, the regulatory agency may choose to hold a public meeting or convene an advisory committee meeting. Open, public meetings, structured according to the agency's needs, bring together experts and stakeholders via an informal process. These meetings are used to receive the public's input on a specific subject area or on the agency's future programs. An advisory committee meeting is structured more formally. Public meetings and advisory committee meetings are announced in the *Federal Register* and the meetings are held in public unless an exempt issue, such as trade secrets, confidential commercial information, or personal medical information, is being discussed.

If a person or organization wishes to challenge an agency decision, the complainant may take the agency to court. Thus, even after an agency issues a final regulation which responds to all comments received, an individual or organization may still challenge the agency decision. This legal action involves the third branch of the federal government, the judicial branch. The judiciary (the federal court system) plays a critical role in the regulatory process in that it reviews an agency's action in light of the substantive law and procedural requirements. An independent judge or panel examines the whole agency record of activity detailing what the agency did and why. If the court finds that the agency did not follow its statutory mandates, fulfil the procedural requirements, or have a rational basis for its action, the judicial system can overturn the agency's action. The judicial system also serves as a forum for agency-initiated enforcement actions.

Just as it is the responsibility of the food industry to sell only safe food, it is likewise its responsibility to obey applicable laws and regulations.

B. Risk Analysis And the U.S.'s Precautionary Approach

1. Risk Analysis

Science and risk analysis are fundamental to U.S. food safety policymaking. In recent years, the federal government has focused more intently on risks associated with microbial pathogens and on reducing those risks through a comprehensive, farm-to-table approach to food safety. This policy emphasis was based on the conclusion that the risks associated with microbial pathogens are unacceptable and, to a large extent, avoidable; and that multiple interventions would be required throughout the farm-to-table chain to make real progress in reducing foodborne pathogens and the incidence of

foodborne disease. This effort followed many years of concentration on managing chemical hazards from the food supply by regulation of additives, drugs, pesticides, and other chemical and physical hazards considered potentially dangerous to human health. It reflects the recognition that the approaches to analyses and review of biological hazards and safety concerns differ from those presented by chemicals.

The President's Food Safety Initiative, announced in 1997, recognized the importance of risk assessment in achieving food safety goals. The Initiative called for all federal agencies with risk management responsibilities for food safety to establish the Interagency Risk Assessment Consortium. The Consortium is charged with advancing the science of microbial risk assessment by encouraging research to develop predictive models and other tools.

The U.S. government has completed a risk analysis on *Salmonella enteritidis* in eggs and egg products which included the first farm-to-table quantitative microbial risk assessment. It is also conducting a risk analysis for *E. coli* 0157:H7 in ground beef and has entered into a cooperative agreement with Harvard University for a risk assessment of the transmission of Bovine Spongiform Encephalopathy by foods. The U.S. is also carrying out a risk analysis for *Listeria monocytogenes* in a variety of ready-to-eat foods.

Regulatory agencies also have made progress in implementing various risk management strategies. An example can be found in Hazard Analysis Critical Control Point (HACCP) regulations. Instead of including in the text of the regulation those specific steps industry must take under a HACCP system, food safety agencies provide general requirements and direct those being regulated to apply the guidelines and develop specific steps to achieve an effective HACCP program. HACCP systems are a risk management tool because they enable the user to identify hazards reasonably likely to occur and to develop a comprehensive and effective plan to prevent or control those hazards.

Performance standards for pathogen reduction and control represent another risk management tool. For example, the U.S. has in place pathogen reduction performance standards for *Salmonella* that slaughter plants and raw ground product must meet, and it also tests product to ensure that these standards are met. In the future, the government may establish performance standards for other pathogens of public health concern and define what food establishments that produce, process, or handle food must achieve.

Fair and objective regulatory decisions regarding food safety standards and requirements rely on risk analysis performed by competent authorities, qualified to make scientifically sound decisions. Risk analysis consists of risk assessment, risk management, and risk communication, which are interdependent.

Risk Assessment – Risk assessments are conducted in an objective manner. However, since data and scientific knowledge on any issue are never totally complete, an assessment of absolute risk is impossible. By explicitly considering uncertainties in the data and analyses, decisions can be made regarding the amount of uncertainty that is acceptable. U.S. policy decisions on procedures used for risk assessment can also ensure that risks are unlikely to be underestimated.

The first component of risk assessment, hazard identification, requires decisions on the effort expended to identify hazards. In the U.S., these are established by law and experience. Laws regarding the use of new food ingredients or pesticides require a

prescribed effort to uncover any hazards before introduction into the food supply. For products already on the market, hazards may be identified by experience (e.g., emerging pathogens) that require efforts to control risk.

The second component, hazard characterization, considers data regarding the potential hazard at different exposure levels and modes, including which data are most relevant for characterizing the hazard. While human data are always most relevant, animal data are usually used to characterize a hazard. The U.S. generally relies on data from the most sensitive species to characterize the risk. Where a safety threshold cannot be assumed, the U.S. may rely on linear mathematical models that are not likely to underestimate a risk. It is important to use the most realistic data and models consistent with current scientifically sound knowledge. When information is not available that can identify which is most realistic, data or models that can be shown not to underestimate hazards are used.

The third component, exposure assessment, must differentiate between short term exposure for acute hazards and long term exposure for chronic hazards. For acute hazards, such as pathogens, data on levels of pathogens causing illness in vulnerable population groups are important. For chronic hazards, such as chemicals that may cause cumulative damage, a lifetime averaged exposure is relevant.

Risk Management – Risk management is exercised by highly qualified regulatory authorities with the sole objective to provide high levels of protection to the U.S. consumer. Management of risk is necessary when much, some, little, or no data are available thus requiring knowledgeable experienced experts capable of making scientifically defensible decisions in the interest of public health. Risk management principles are set by law or by the risk manager's expert judgement to reduce risk to the lowest practical, or achievable, level.

U.S. laws require that the safe use of a food additive, an animal drug, and a pesticide be established before marketing; therefore risk management decisions are based on very substantial scientific evidence. For hazardous substances that are inherent components of foods (e.g., low levels of natural toxicants produced in potatoes) or unavoidable contaminants of food (e.g., mercury in fish, aflatoxin in grains), government intervention occurs when presence of a substance reaches a level known to present significant risk. The quantity and quality of scientific evidence may vary with the type of risk management decision.

As an example of risk management, every year the U.S. federal food agencies work together to develop a comprehensive, risk-based, annual sampling plan to detect drug and chemical residues in U.S. food. Violative residue information is used as the basis for standard-setting and for enforcement and other follow-up activities.

Risk Communication – Routine risk communication is inherent in the transparent regulatory process which is more fully described in Part D entitled, "Transparency." Transparent standards are employed to ensure fairness to all members of the food industry while protecting public health. U.S. law requires the government to allow and consider comment on the factual basis for a decision when it establishes regulations. Anyone can comment, including persons outside the U.S. There must be a substantial basis in law and fact for every rule. Information relied on by the government is made available for anyone to review. Government scientists use public communication media to explain to the public the science behind regulations.

When there is a need for emergency risk communication, alerts are conveyed through a nationwide telecommunication system linking all levels of the food safety system with the nationwide media so all citizens are made aware of the risk, and through global information sharing mechanisms by which international organizations (WHO, FAO, Office of International Epizootics and the World Trade Organization, if appropriate), regions such as EU, and individual countries are informed immediately.

Risk communication is critical during the risk assessment and management stages. The U.S. is committed to openness and transparency of its work to protect the public from food-related health risks. For example, regulatory agencies provide public notification of recalls of food products. Information about recalls is also provided on the agency's website, as are frequent reports of regulatory and enforcement actions taken against regulated food establishments. EPA's pesticides website contains the full risk analysis for specific pesticides, and risk analyses procedures have been made available to the public for comment. Where appropriate, risk analyses processes have been modified in response to these comments.

Another example of risk management are U.S. federal agency activities on the emerging issue of resistance from the use of antimicrobials in animals. Antimicrobial risk management includes establishment of monitoring and resistance thresholds before a drug can be approved; continuous monitoring of resistance in enteric bacteria from humans and food animals; obtaining information on factors responsible for promoting resistance; and taking regulatory actions as needed, including restrictions on a drug or removing it from the market.

2. Precautionary Approach

(This approach is described in detail in the annex on Precaution In U.S. Food Safety Decision Making.)

The genesis of many health, safety, and environmental laws is associated with the prevention of undesirable events and the protection of public health and the environment. Specific prevention and protection measures reflect differing provisions of law, regulation, and circumstances. However, they all are risk-based. The precautionary approach is exercised in a variety of ways.

An example of the U.S. precautionary approach to risk is the control system for ingredients in food and feed, such as the feeding prohibition of certain animal proteins to ruminants to prevent the introduction of BSE in this country. In implementing this prohibition through a regulation, the government followed existing APA procedures to explain in the *Federal Register* why it is proposed to take the action, including a description of the risk, and to evaluate the comments received from industry, academia, private citizens, and government agencies before publishing its final regulation.

Another illustrative example of the precautionary approach is the pre-market approval requirements established by law for food additives, animal drugs, and pesticides. The products are not allowed on the market unless, and until, they are shown by producers to be safe to the satisfaction of the regulatory authorities. When the petition is reviewed, data are evaluated to determine exposure to the additive, including exposure to all likely impurities in the additive. The degree of testing considered necessary depends on the class of chemical and exposure. The data or the lack of data drive a decision for

approval. The evaluation of all is documented. The final decision explaining the basis for all significant conclusions is published in the *Federal Register*. Persons disagreeing with the decision may file an objection with the reasons for disagreeing and request a hearing. After administrative remedies for appeal are exhausted, the government may be challenged in court on its approval or denial of a petition.

C. Dealing With New Technologies, Products, and Responding to Problems

In achieving the nation's farm-to-table food safety objective, the federal government is only one part of the equation. Federal agencies collaborate with state and local agencies and other stakeholders to encourage food safety practices and to offer assistance to industry and consumers on practices that promote food safety.

The U.S. recognizes the regulated industry as a stakeholder and as the party principally responsible for food safety. Establishments are responsible for producing food products that meet regulatory requirements for safety. The government's role is to set appropriate standards and do what is necessary to verify that the industry is meeting those standards and other food safety requirements. Consistent with modernization of inspection systems and the farm-to-table initiatives, federal agencies use their resources as efficiently and effectively as possible to protect the public from foodborne illness. As an extension of HACCP, the U.S. is testing new meat and poultry inspection models to determine whether or not additional protections can be provided consumers through redeployment of some in-plant resources to the distribution segment of the farm-to-table chain, which includes transportation, storage, and retail sale of products.

Federal food safety agencies regularly enter into partnerships with states and others such as grower organizations and public interest groups to encourage improved production practices, to develop and foster food safety measures that can be taken on the farm and in marketing channels to decrease public health hazards in food, to develop and implement safer pest management practices, and to develop good agricultural practices to minimize pesticide residues and microbial risks.

The country's emergency response capability is sound and being enhanced continually. For example, U.S. food safety regulatory agencies participate in FoodNet, a network whose objectives are to determine the frequency and severity of foodborne diseases and the proportion of common foodborne diseases that result from eating specific foods and describe the epidemiology of new and emerging bacterial, parasitic, and viral foodborne pathogens.

Information on possible foodborne disease outbreaks from FoodNet and reports to state and local health departments are followed up by those health departments in cooperation with federal food agency authorities to determine the course and nature of the outbreak. Appropriate public advisories are issued and enforcement actions taken about the products involved as soon as possible.

In addition, a new technique has been developed using pulsed-field gel electrophoresis (PGE), which permits CDC to match distinctive patterns of pathogenic materials that cause foodborne illness. Using these "fingerprinting" techniques, the single casual factor of a foodborne illness outbreak can be traced using epidemiological investigation and PGE. This has led to intervention and, in at least one recent case, cessation of a serious foodborne illness outbreak. Both FoodNet and PulseNet are basic building blocks for the U.S. system of foodborne illness prevention.

D. Transparency

Various U.S. statutes and executive orders establish procedures to ensure that regulations are developed in an open, transparent, and interactive manner and that, as appropriate, the regulatory process is similarly open to the public. Regulations and their implementation must lead to fulfillment of objectives for the public good such as protecting health, safety, and environment.

The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. Under the APA, a notice of proposed rulemaking must be published in the *Federal Register*, an official daily publication which is available through subscription and through the Internet at no cost. All regulations and legal notices issued by federal agencies and the President are published in the *Federal Register*. In addition, though the Internet is not an official publication, U.S. government agencies make extensive use of it to provide information on regulatory activities and enhance the transparency of their processes.

The President issued an Executive Order to strengthen agencies' processes for promulgating regulations. Also, several states require analysis of the impacts of regulations: there are requirements to analyze the impact of the regulation on small business (the Regulatory Flexibility Act); the impact of the regulation on the environment (the National Environmental Policy Act); and the impact of any information collection requirements contained in the regulation (the Paperwork Reduction Act).

FACA requires that certain kinds of groups whose advice is relied upon by the government for establishing regulations be chartered as an advisory committee, be constituted to provide balance and to avoid conflicts of interest, and to hold its advisory meetings in public with an opportunity for comment from those outside the committee.

FOIA's purpose is to expand the areas of public access to information beyond those originally set forth in the APA. Any person residing in the United States has a right of access to a wealth of government information and records, subject only to certain limited exemptions.

To ensure the broadest possible participation by the public, agencies publish their proposals on Internet sites and call attention to the proposed or final rule through press releases. The U.S. news media and interest groups follow the *Federal Register* and agency Internet sites closely and publish information about proposed and final regulations. In addition, U.S. agencies may hold public meetings to solicit input from interested persons. Meetings often include media coverage. For example, numerous public meetings were held to solicit input on the Food Safety Strategic Plan being developed by the President's Council on Food Safety; on the draft Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; as part of the process to develop the Food Safety Initiative; and on bioengineered foods, among other topics.

Regulatory agencies often offer guidance on ways to achieve compliance with regulatory requirements. Such guidance may describe situations where a food could become adulterated or misbranded or may describe data that would be needed to establish safety. Although such guidance does not have the effect of law (one need not follow it to

demonstrate that a food is safe and lawful, provided that all statutory and regulatory requirements are met), such advice is helpful to the food industry and to the consumer.

The Codex Alimentarius Commission (Codex) is the major international body for promoting the health and economic interests of consumers while encouraging fair international trade in food. Within the United States, Codex activities are coordinated by officials from USDA, HHS, and EPA. The U.S. Codex Office provides information via the *Federal Register* and the Internet concerning the Codex and its activities internationally and in the U.S.

E. System Accountability

U.S. food agencies are highly accountable to government's three branches and to the people:

- U.S. food agencies are accountable to the President – the chief executive – who has constitutional responsibility to assure that laws are faithfully executed; who appoints senior officials, and whose Office of Management and Budget clears significant regulations.
- U.S. food agencies are accountable to the Congress, the legislative branch of the U.S. government, which provides the food agencies their authority and budget; whole committees hold frequent oversight hearings; and the Senate must confirm the nomination of cabinet officers and senior officials.
- U.S. food agencies are accountable to the courts, the judicial branch of the U.S. government, which review food agency regulations and enforcement actions.
- Most importantly, U.S. food agencies are accountable directly to members of the public, who regularly exercise their right to participate in the development of laws and regulations, such as commenting on proposed regulations; whose guidance is sought in frequent public meetings; and who provide strong support for food safety regulation, the nutrition label, and other regulatory initiatives.

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
FDA Backgrounder
September 24, 1998

(This document also available in other languages.)

Food Safety: A Team Approach

Food and Drug Administration | Centers for Disease Control and Prevention
Food Safety and Inspection Service | Cooperative State Research, Education, and Extension Service
National Agricultural Libary, USDA/FDA Foodborne Illness Education Information Center
Environmental Protection Agency | National Oceanic and Atmostpheric Administration
Bureau of Alcohol, Tobacco and Firearms | U.S. Customs Service
U.S. Department of Justice | Federal Trade Commission
State and Local Governments

September 24, 1998

The United States maintains one of the world's safest food supplies, thanks in large part to an interlocking monitoring system that watches over food production and distribution at every level-locally, statewide and nationally.

Continual monitoring is provided by food inspectors, microbiologists, epidemiologists, and other food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies. Their precise duties are dictated by local, state and national laws, guidelines and other directives. Some monitor only one kind of food, such as milk or seafood. Others work strictly within a specified geographic area. Others are responsible for only one type of food establishment, such as restaurants or meat-packing plants. Together they make up the U.S. food safety team.

The Clinton administration's Food Safety Initiative, begun in 1997, strengthens the efforts of all the members of the nation's food safety team in the fight against food-borne illness, which afflicts between 6.5 million and 33 million Americans every year. One of the initiative's major programs got under way in May 1998 when the Department of Health and Human Services (which includes FDA), the U.S. Department of Agriculture, and the Environmental Protection Agency signed a memorandum of understanding to create a Food Outbreak Response Coordinating Group, or FORC-G. The new group will:

- increase coordination and communication among federal, state and local food safety agencies
- guide efficient use of resources and expertise during an outbreak
- prepare for new and emerging threats to the U.S. food supply.

Besides federal officials, members of FORC-G include the Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and National Association of State Departments of Agriculture.

The following table offers a closer look at the nation's food safety lineup. The agencies listed in the table also work with other government agencies, such as the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act, the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

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*U.S. Department of Health and Human Services **

Food and Drug Administration

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry
- Bottled water
- Wine beverages with less than 7 percent alcohol

Food Safety Role

Enforces food safety laws governing domestic and imported food, except meat and poultry, by:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical and microbial contamination
- Reviewing safety of food and color additives before marketing
- Reviewing animal drugs for safety to animals that receive them and humans who eat food produced from the animals
- Monitoring safety of animal feeds used in food-producing animals
- Developing model codes and ordinances, guidelines and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores. An example is the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent food-borne illness.
- Establishing good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs
- Working with foreign governments to ensure safety of certain imported food products
- Requesting manufacturers to recall unsafe food products and monitoring those recalls
- Taking appropriate enforcement actions

- Conducting research on food safety
- Educating industry and consumers on safe food handling practices

For More Information

Consumers: Call toll-free 1-888-INFO-FDA (1-888-463-6332).

Regional FDA offices, listed in the blue pages of the phone book under U.S. Government

Media inquiries: 202-205-4144

Consumers:
FDA's Outreach and Information Center
1-888-SAFEFOOD (1-888-723-3366)

www.cfsan.fda.gov/list.html

www.fda.gov/cvm/

Centers for Disease Control and Prevention

Oversees

- All foods

Food Safety Role

- Investigates with local, state and other federal officials sources of food-borne disease outbreaks
- Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels.
- Develops and advocates public health policies to prevent food-borne diseases
- Conducts research to help prevent food-borne illness
- Trains local and state food safety personnel

For More Information

Centers for Disease Control and Prevention
1600 Clifton Rd., N.E.
Atlanta, GA 30333

Media inquiries: 404-639-3286

General public: 404-639-3311

www.cdc.gov

* Also, HHS's National Institutes of Health conduct food safety research.

U.S. Department of Agriculture **

Food Safety and Inspection Service

Oversees

- Domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas and frozen foods
- Processed egg products (generally liquid, frozen and dried pasteurized egg products)

Food Safety Role

Enforces food safety laws governing domestic and imported meat and poultry products by:

- Inspecting food animals for diseases before and after slaughter
- Inspecting meat and poultry slaughter and processing plants
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards
- Seeking voluntary recalls by meat and poultry processors of unsafe products
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

For More Information

FSIS Food Safety Education and Communications Staff
Room 1175, South Building,

1400 Independence Ave., S.W.
Washington, DC 20250

Media inquiries: 202-720-9113

Consumers:
The Meat and Poultry Hotline, 1-800-535-4555
(In Washington, D.C., area, call 202-720-3333.)
TDD/TTY: 1-800-256-7072

www.fsis.usda.gov

Cooperative State Research, Education, and Extension Service

Oversees

- All domestic foods, some imported

Food Safety Role

- With U.S. colleges and universities, develops research and education programs on food safety for farmers and consumers

For More Information

Local cooperative extension services, listed in the blue pages of the phone book under county government

Cooperative State Research, Education and Extension Service
U.S. Department of Agriculture
Washington, DC 20250-0900
202-720-3029

www.reeusda.gov

National Agricultural Library
USDA/FDA Foodborne Illness Education Information Center

Oversees

- All foods

Food Safety Role

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness

- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness

For More Information

USDA/FDA Foodborne Illness Education Information Center
Food and Nutrition Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351

301-504-5719

www.nal.usda.gov/fnic/

** Also, a number of other USDA agencies conduct food safety activities.

U.S. Environmental Protection Agency

Oversees

- Drinking water

Food Safety Role

Foods made from plants, seafood, meat and poultry

- Establishes safe drinking water standards
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain
- Assists states in monitoring quality of drinking water and finding ways to prevent contamination of drinking water
- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides

For More Information

Environmental Protection Agency
401 M St., S.W.
Washington, DC 20460

202-260-2090

Regional EPA offices, listed in the blue pages of the phone book under U.S. Government

www.epa.gov

U.S. Department of Commerce

National Oceanic and Atmospheric Administration

Oversees

- Fish and seafood products

Food Safety Role

- Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards

For More Information

Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910

1-800-422-2750

seafood.nmfs.gov

U.S. Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Oversees

- Alcoholic beverages except wine beverages containing less than 7 percent alcohol

Food Safety Role

- Enforces food safety laws governing production and distribution of alcoholic beverages
- Investigates cases of adulterated alcoholic products, sometimes with help from FDA

For More Information

Bureau of Alcohol, Tobacco and Firearms
Market Compliance Branch
650 Massachusetts Ave., N.W.
Room 5200
Washington, DC 20226

202-927-8130

www.atf.treas.gov/alcohol/index.htm

U.S. Customs Service

Oversees

- Imported foods

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations

For More Information

U.S. Customs Service
P.O. Box 7407
Washington, DC 20044

Media inquiries: 202-927-1770

General public: Contact local ports of entry, listed in the blue pages of the phone book under U.S. Government, Customs Services

www.customs.ustreas.gov

U.S. Department of Justice

Oversees

- All foods

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts

For More Information

U.S. attorneys' offices in blue pages of phone book under U.S. Government

www.usdoj.gov

Federal Trade Commission

Oversees

- All foods

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising.

For More Information

FTC (Federal Trade Commission)
Consumer Response Center, CRC-240
Washington, DC 20580

Media inquiries: 202-326-2180
TDD: 202-326-2502

Consumers: 202-FTC-HELP
(202-382-4357)

www.ftc.gov

State and Local Governments

Oversees

- All foods within their jurisdictions

Food Safety Role

- Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders
- Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
- Embargo (stop the sale of) unsafe food products made or distributed within state borders

For More Information

City, county and state health, agriculture and environmental protection agencies, listed in the blue pages of the phone book under city, county and state government

This is a mirror of the page formerly at
<http://www.fda.gov/opacom/backgrounders/foodteam.html>

www.FoodSafety.gov - Gateway to Government Food Safety Information

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FDA Backgrounder
May 3, 1999
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Milestones in U.S. Food and Drug Law History

From the beginnings of civilization people have been concerned about the quality and safety of foods and medicines. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with such ingredients as ground peas or beans. Regulation of food in the United States dates from early colonial times. Federal controls over the drug supply began with inspection of imported drugs in 1848. The following chronology describes some of the milestones in the history of food and drug regulation in the United States.

1820

Eleven physicians meet in Washington, D.C., to establish the **U.S. PHARMACOPEIA**, the first compendium of standard drugs for the United States.

1848

DRUG IMPORTATION ACT passed by Congress requires U.S. Customs Service inspection to stop entry of adulterated drugs from overseas.

1862

PRESIDENT LINCOLN appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.

1880

PETER COLLIER, chief chemist, U.S. Department of Agriculture, recommends passage of a national food and drug law, following his own food adulteration investigations. The bill was defeated, but during the next 25 years more than 100 food and drug bills were introduced in Congress.

1883

DR. HARVEY W. WILEY becomes chief chemist, expanding the Bureau of Chemistry's food adulteration studies. Campaigning for a federal law, Dr. Wiley is called the "Crusading Chemist" and "Father of the Pure Food and Drugs Act." He retired from government service in 1912 and died in 1930.

1897

TEA IMPORTATION ACT passed, providing for Customs inspection of all tea entering U.S. ports, at the expense of the importers.

1898

Association of Official Agricultural Chemists (now AOAC International) establishes a **COMMITTEE ON FOOD STANDARDS** headed by Dr. Wiley. States begin incorporating these standards into their food statutes.

1902

The **BIOLOGICS CONTROL ACT** is passed to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans.

Congress appropriates $5,000 to the Bureau of Chemistry to study **CHEMICAL PRESERVATIVES AND COLORS** and their effects on digestion and health. Dr. Wiley's studies draw widespread attention to the problem of food adulteration. Public support for passage of a federal food and drug law grows.

1906

The original **FOOD AND DRUGS ACT** is passed by Congress on June 30 and signed by President Theodore Roosevelt. It prohibits interstate commerce in misbranded and adulterated foods, drinks and drugs.

The **MEAT INSPECTION ACT** is passed the same day.

Shocking disclosures of insanitary conditions in meat-packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines were the major problems leading to the enactment of these laws.

1907

First **CERTIFIED COLOR REGULATIONS**, requested by manufacturers and users, list seven colors found suitable for use in foods.

1911

In **U.S. v. JOHNSON**, the Supreme Court rules that the 1906 Food and Drugs Act does not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug.

1912

Congress enacts the **SHERLEY AMENDMENT** to over come the ruling in U.S. v. Johnson. It prohibits labeling medicines with false therapeutic claims intended to defraud the purchaser, a standard difficult to prove.

1913

GOULD AMENDMENT requires that food package contents be "plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count."

1914

In **U.S. v. LEXINGTON MILL AND ELEVATOR COMPANY**, the Supreme Court issues its first ruling on food additives. It ruled that in order for bleached flour with nitrite residues to be banned from foods, the government must show a relationship between the chemical additive and the harm it allegedly caused in humans. The court also noted that the mere presence of such an ingredient was not sufficient to render the food illegal.

THE HARRISON NARCOTIC ACT requires prescriptions for products exceeding the allowable limit of narcotics and mandates increased record-keeping for physicians and pharmacists who dispense narcotics.

1924

In **U.S. v. 95 BARRELS ALLEGED APPLE CIDER VINEGAR**, the Supreme Court rules that the Food and Drugs Act condemns every statement, design, or device on a product's label that may mislead or deceive, even if technically true.

1927

The Bureau of Chemistry is reorganized into two separate entities. Regulatory functions are located in the **FOOD, DRUG, AND INSECTICIDE ADMINISTRATION**, and nonregulatory research is located in the **BUREAU OF CHEMISTRY AND SOILS**.

1930

McNARY-MAPES AMENDMENT authorizes FDA standards of quality and fill-of-container for canned food, excluding meat and milk products.

The name of the Food, Drug, and Insecticide Administration is shortened to **FOOD AND DRUG ADMINISTRATION (FDA)** under an agricultural appropriations act.

1933

FDA recommends a complete revision of the obsolete **1906 FOOD AND DRUGS ACT**. The first bill is introduced into the Senate, launching a five-year legislative battle.

1937

ELIXIR OF SULFANILAMIDE, containing the poisonous solvent diethylene glycol, kills 107 persons, many of whom are children, dramatizing the need to establish drug safety before marketing and to enact the pending food and drug law.

1938

THE FEDERAL FOOD, DRUG, AND COSMETIC (FDC) ACT of 1938 is passed by Congress, containing new provisions:

- Extending control to cosmetics and therapeutic devices.
- Requiring new drugs to be shown safe before marketing-starting a new system of drug regulation.
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Providing that safe tolerances be set for unavoidable poisonous substances.
- Authorizing standards of identity, quality, and fill-of-container for foods.
- Authorizing factory inspections.
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.

Under the **WHEELER-LEA ACT**, the Federal Trade Commission is charged with overseeing advertising associated with products otherwise regulated by FDA, with the exception of prescription drugs.

1939

FIRST FOOD STANDARDS issued (canned tomatoes, tomato purée, and tomato paste).

1940

FDA TRANSFERRED from the Department of Agriculture to the Federal Security Agency, with Walter G. Campbell appointed as the first Commissioner of Food and Drugs.

1941

INSULIN AMENDMENT requires FDA to test and certify purity and potency of this lifesaving drug for diabetes.

1943

In **U.S. v. DOTTERWEICH**, the Supreme Court rules that the responsible officials of a corporation, as well as the corporation itself, may be prosecuted for violations. It need not be proven that the officials intended, or even knew of, the violations.

1944

PUBLIC HEALTH SERVICE ACT is passed, covering a broad spectrum of health concerns, including regulation of biological products and control of communicable diseases.

1945

PENICILLIN AMENDMENT requires FDA testing and certification of safety and effectiveness of all penicillin products. Later amendments extended this requirement to all antibiotics. In 1983 such control was found no longer needed and was abolished.

1948

MILLER AMENDMENT affirms that the Federal Food, Drug, and Cosmetic Act applies to goods regulated by the Agency that have been transported from one state to another and have reached the consumer.

1949

FDA publishes **GUIDANCE TO INDUSTRY** for the first time. This guidance, "Procedures for the Appraisal of the Toxicity of Chemicals in Food," came to be known as the "black book."

1950

In **ALBERTY FOOD PRODUCTS CO. v. U.S.** , a court of appeals rules that the directions for use on a drug label must include the purpose for which the drug is offered. Therefore, a worthless remedy cannot escape the law by not stating the condition it is supposed to treat.

OLEOMARGARINE ACT requires prominent labeling of colored oleomargarine, to distinguish it from butter.

DELANEY COMMITTEE starts congressional investigation of the safety of chemicals in foods and cosmetics, laying the foundation for the 1954 Miller Pesticide Amendment, the 1958 Food Additives Amendment, and the 1960 Color Additive Amendment.

1951

DURHAM-HUMPHREY AMENDMENT defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner.

1952

In **U.S. v. CARDIFF**, the Supreme Court rules that the factory inspection provision of the 1938 FDC Act is too vague to be enforced as criminal law.

FDA CONSUMER CONSULTANTS are appointed in each field district to maintain communications with consumers and ensure that FDA considers their needs and problems.

1953

FEDERAL SECURITY AGENCY becomes the Department of Health, Education, and Welfare (HEW).

FACTORY INSPECTION AMENDMENT clarifies previous law and requires FDA to give manufacturers written reports of conditions observed during inspections and analyses of factory samples.

1954

MILLER PESTICIDE AMENDMENT spells out procedures for setting safety limits for pesticide residues on raw agricultural commodities.

First large-scale **RADIOLOGICAL EXAMINATION OF FOOD** carried out by FDA when it received reports that tuna suspected of being radioactive was being imported from Japan following atomic blasts in the Pacific. FDA begins monitoring around the clock to meet the emergency.

1955

HEW SECRETARY OVETA CULP HOBBY appoints a committee of 14 citizens to study the adequacy of FDA's facilities and programs. The committee recommends a substantial expansion of FDA staff and facilities, a new headquarters building, and more use of educational and informational programs.

The **DIVISION OF BIOLOGICS CONTROL** became an independent entity within the National Institutes of Health, after polio vaccine thought to have been inactivated is associated with about 260 cases of polio.

1958

FOOD ADDITIVES AMENDMENT enacted, requiring manufacturers of new food additives to establish safety. The Delaney proviso prohibits the approval of any food additive shown to induce cancer in humans or animals.

FDA publishes in the Federal Register the first list of **SUBSTANCES GENERALLY RECOGNIZED AS SAFE (GRAS).** The list contains nearly 200 substances.

1959

U.S. CRANBERRY CROP recalled three weeks before Thanksgiving for FDA tests to check for aminotriazole, a weedkiller found to cause cancer in laboratory animals.

Cleared berries were allowed a label stating that they had been tested and had passed FDA inspection, the only such endorsement ever allowed by FDA on a food product.

1960

COLOR ADDITIVE AMENDMENT enacted, requiring manufacturers to establish the safety of color additives in foods, drugs and cosmetics. The Delaney proviso prohibits the approval of any color additive shown to induce cancer in humans or animals.

FEDERAL HAZARDOUS SUBSTANCES LABELING ACT, enforced by FDA, requires prominent label warnings on hazardous household chemical products.

1962

THALIDOMIDE, a new sleeping pill, is found to have caused birth defects in thousands of babies born in western Europe. News reports on the role of Dr. Frances Kelsey, FDA medical officer, in keeping the drug off the U.S. market, arouse public support for stronger drug regulation.

KEFAUVER-HARRIS DRUG AMENDMENTS passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them. The new law also exempts from the Delaney proviso animal drugs and animal feed additives shown to induce cancer but which leave no detectable levels of residue in the human food supply.

CONSUMER BILL OF RIGHTS is proclaimed by President John F. Kennedy in a message to Congress. Included are the right to safety, the right to be informed, the right to choose, and the right to be heard.

1965

DRUG ABUSE CONTROL AMENDMENTS are enacted to deal with problems caused by abuse of depressants, stimulants and hallucinogens.

1966

FDA contracts with the National Academy of Sciences/National Research Council to evaluate the **EFFECTIVENESS OF 4,000 DRUGS** approved on the basis of safety alone between 1938 and 1962.

CHILD PROTECTION ACT enlarges the scope of the Federal Hazardous Substances Labeling Act to ban hazardous toys and other articles so hazardous that adequate label warnings could not be written.

FAIR PACKAGING AND LABELING ACT requires all consumer products in interstate commerce to be honestly and informatively labeled, with FDA enforcing provisions on foods, drugs, cosmetics, and medical devices.

1968

FDA BUREAU OF DRUG ABUSE CONTROL and Treasury Department Bureau of Narcotics are transferred to the Department of Justice to form the Bureau of Narcotics and Dangerous Drugs (BNDD), consolidating efforts to police traffic in abused drugs.

REORGANIZATION of federal health programs places FDA in the Public Health Service.

FDA forms the **DRUG EFFICACY STUDY IMPLEMENTATION (DESI)** to implement recommendations of the National Academy of Sciences investigation of effectiveness of drugs first marketed between 1938 and 1962.

ANIMAL DRUG AMENDMENTS place all regulation of new animal drugs under one section of the Food, Drug, and Cosmetic Act-Section 512-making approval of animal drugs and medicated feeds more efficient.

1969

FDA begins administering **SANITATION PROGRAMS** for milk, shellfish, food service, and interstate travel facilities, and for preventing poisoning and accidents. These responsibilities were transferred from other units of the Public Health Service.

The **WHITE HOUSE CONFERENCE ON FOOD, NUTRITION, AND HEALTH** recommends systematic review of GRAS substances in light of FDA's ban of the artificial sweetener cyclamate. President Nixon orders FDA to review its GRAS list.

1970

In **UPJOHN v. FINCH** the Court of Appeals upholds enforcement of the 1962 drug effectiveness amendments by ruling that commercial success alone does not constitute substantial evidence of drug safety and efficacy.

FDA requires the first **PATIENT PACKAGE INSERT:** oral contraceptives must contain information for the patient about specific risks and benefits.

The **COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT** replaces previous laws and categorizes drugs based on abuse and addiction potential compared to their therapeutic value.

ENVIRONMENTAL PROTECTION AGENCY established; takes over FDA program for setting pesticide tolerances.

1971

PHS BUREAU OF RADIOLOGICAL HEALTH transferred to FDA. Its mission: protection against unnecessary human exposure to radiation from electronic products in the home, industry, and the healing arts.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH is established in the biological facilities of the Pine Bluff Arsenal in Arkansas. Its mission is to examine biological effects of chemicals in the environment, extrapolating data from experimental animals to human health.

Artificial sweetener **SACCHARIN**, included in FDA's original GRAS list, is removed from the list pending new scientific study.

1972

OVER-THE-COUNTER DRUG REVIEW begun to enhance the safety, effectiveness and appropriate labeling of drugs sold without prescription.

REGULATION OF BIOLOGICS-including serums, vaccines, and blood products-is transferred from NIH to FDA.

1973

THE U.S. SUPREME COURT upholds the 1962 drug effectiveness law and endorses FDA action to control entire classes of products by regulations rather than to rely only on time-consuming litigation.

LOW-ACID FOOD PROCESSING regulations issued, after botulism outbreaks from canned foods, to ensure that low-acid packaged foods have adequate heat treatment and are not hazardous.

CONSUMER PRODUCT SAFETY COMMISSION created by Congress; takes over programs pioneered by FDA under 1927 Caustic Poison Act, 1960 Federal Hazardous Substances Labeling Act, 1966 Child Protection Act, and PHS accident prevention activities for safety of toys, home appliances, etc.

1976

MEDICAL DEVICE AMENDMENTS passed to ensure safety and effectiveness of medical devices, including diagnostic products. The amendments require manufacturers to register with FDA and follow quality control procedures. Some products must have pre-market approval by FDA; others must meet performance standards before marketing.

VITAMINS AND MINERALS AMENDMENTS ("Proxmire Amendments") stop FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency.

1977

SACCHARIN STUDY AND LABELING ACT passed by Congress to stop FDA from banning the chemical sweetener but requiring a label warning that it has been found to cause cancer in laboratory animals.

1980

INFANT FORMULA ACT establishes special FDA controls to ensure necessary nutritional content and safety.

1982

TAMPER-RESISTANT PACKAGING REGULATIONS issued by FDA to prevent poisonings such as deaths from cyanide placed in Tylenol capsules. The Federal Anti-Tampering Act passed in 1983 makes it a crime to tamper with packaged consumer products.

FDA publishes first **RED BOOK** (successor to 1949 "black book"), officially known as Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food.

1983

ORPHAN DRUG ACT passed, enabling FDA to promote research and marketing of drugs needed for treating rare diseases.

1984

FINES ENHANCEMENT LAWS of 1984 and 1987 amend the U.S. Code to greatly increase penalties for all federal offenses. The maximum fine for individuals is now $100,000 for each offense and $250,000 if the violation is a felony or causes death. For corporations, the amounts are doubled.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective. At the same time, the brand-name companies can apply for up to five years additional patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process.

1985

AIDS TEST FOR BLOOD approved by FDA in its first major action to protect patients from infected donors.

1986

CHILDHOOD VACCINE ACT requires patient information on vaccines, gives FDA authority to recall biologics, and authorizes civil penalties.

1987

INVESTIGATIONAL DRUG REGULATIONS REVISED to expand access to experimental drugs for patients with serious diseases with no alternative therapies.

1988

FOOD AND DRUG ADMINISTRATION ACT of 1988 officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner of Food and Drugs appointed by the President with the advice and consent of the Senate, and broadly spells out the responsibilities of the Secretary and the Commissioner for research, enforcement, education, and information.

THE PRESCRIPTION DRUG MARKETING ACT bans the diversion of prescription drugs from legitimate commercial channels. Congress finds that the resale of such drugs leads to the distribution of mislabeled, adulterated, subpotent, and counterfeit drugs to the public. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.

GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT extends to veterinary products benefits given to human drugs under the 1984 Drug Price Competition and Patent Term Restoration Act. Companies can produce and sell generic versions of animal drugs approved after October 1962 without duplicating research done to prove them safe and effective. The act also authorizes extension of animal drug patents.

1989

FDA issued a nationwide recall of all over-the-counter dietary supplements providing 100 milligrams or more of **L-TRYPTOPHAN.** The recall was instituted because of a clear link between the consumption of L-tryptophan tablets and its association with a U.S. outbreak of Eosinophilia-Myalgia Syndrome (EMS) in 1989. Symptoms of EMS include fatigue, shortness of breath, rash, swelling of the extremities, and in some cases congestive heart failure. By 1990, The Centers for Disease Control and Prevention confirmed over 1,500 cases of EMS with 38 deaths. Officials estimate that there may have been 3,000-10,000 unreported cases. Numerous trace levels of impurities were identified in the L-tryptophan implicated in many of the EMS case,s and the links between L-tryptophan and EMS are still being investigated in the laboratory. **In 1990** FDA put an import alert in place prohibiting its importation.

1990

NUTRITION LABELING AND EDUCATION ACT requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services. The law preempts state requirements about food standards, nutrition labeling, and health claims and, for the first time, authorizes some health claims for foods. The food ingredient panel, serving sizes, and terms such as "low fat" and "light" are standardized.

SAFE MEDICAL DEVICES ACT is passed, requiring nursing homes, hospitals, and other facilities that use medical devices to report to FDA incidents that suggest that a medical device probably caused or contributed to the death, serious illness, or serious injury of a patient. Manufacturers are required to conduct post-market surveillance on permanently implanted devices whose failure might cause serious harm or death, and to establish methods for tracing and locating patients depending on such devices. The act authorizes FDA to order device product recalls and other actions.

1991

Regulations published to **ACCELERATE THE REVIEW OF DRUGS** for life-threatening diseases.

1992

GENERIC DRUG ENFORCEMENT ACT imposes debarment and other penalties for illegal acts involving abbreviated drug applications.

PRESCRIPTION DRUG USER FEE ACT requires drug and biologics manufacturers to pay fees for product applications and supplements, and other services. The act also requires FDA to use these funds to hire more reviewers to assess applications.

MAMMOGRAPHY QUALITY STANDARDS ACT requires all mammography facilities in the United States to be accredited and federally certified as meeting quality standards effective Oct. 1, 1994. After initial certification, facilities must pass annual inspections by federal or state inspectors.

1994

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT establishes specific labeling requirements, provides a regulatory framework, and authorizes FDA to promulgate good manufacturing practice regulations for dietary supplements. This act defines "dietary supplements" and "dietary ingredients" and classifies them as food. The act also establishes a commission to recommend how to regulate claims.

FDA announces it could consider **REGULATING NICOTINE** in cigarettes as a drug, in response to a Citizen's Petition by the Coalition on Smoking OR Health.

URUGUAY ROUND AGREEMENTS ACT extends the patent terms of U.S. drugs from 17 to 20 years.

ANIMAL MEDICINAL DRUG USE CLARIFICATION ACT allows veterinarians to prescribe extra-label use of veterinary drugs for animals under specific circumstances. In addition, the legislation allows licensed veterinarians to prescribe human drugs for use in animals under certain conditions.

1995

FDA declares **CIGARETTES** to be "drug delivery devices." Restrictions are proposed on marketing and sales to reduce smoking by young people.

1996

FEDERAL TEA TASTERS REPEAL ACT repeals the Tea Importation Act of 1897 to eliminate the Board of Tea Experts and user fees for FDA's testing of all imported tea. Tea itself is still regulated by FDA.

SACCHARIN NOTICE REPEAL ACT repeals the saccharin notice requirements.

ANIMAL DRUG AVAILABILITY ACT adds flexibility to animal drug approval process, providing for flexible labeling and more direct communication between drug sponsors and FDA.

FOOD QUALITY PROTECTION ACT amends the Food, Drug, and Cosmetic Act, eliminating application of the Delaney proviso to pesticides.

1997

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods.

1998

MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT continues 1992 Act until 2002.

First phase to **CONSOLIDATE FDA LABORATORIES** nationwide from 19 facilities to 9 by 2014 includes dedication of the first of five new regional laboratories.

Regulatory Framework

INTRODUCTION

This module covers an overview of the regulatory framework that is used by the Food Safety and Inspection Service (FSIS). This module provides you with information about the context in which you work. It is an overview of the regulatory framework for the Food Safety and Inspection Service (FSIS). As an agent of the federal government, you need to understand your legal responsibilities and the consequences that result when establishments do not comply with the laws and regulations governing meat, poultry, and egg products.

OBJECTIVES

The objectives of this training are as follows.

1. Understand where FSIS derives its authority.
2. Identify what is covered by the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).
3. Understand what regulations are and where they come from.
4. Understand what Directives are and where they come from.
5. Understand what Notices are and where they come from.
6. Understand the relationship among statutes, regulations, directives, and notices.

Most of your daily work will be guided by the directives and notices. But these are based on regulations and the statues.

Statutes

Let's go back to the first objective – to understand where FSIS gets the legal authority to regulate meat, poultry, and egg products. This legal authority can be traced all the way back to the United States Constitution. The Constitution grants the authority to regulate commerce among the states. The FMIA, PPIA, and EPIA were all adopted by Congress under that authority. Each of these Acts is intended to protect the health and welfare of the consuming public by preventing the introduction of adulterated or misbranded meat, poultry, or egg products into commerce. To illustrate, here's an example of a Congressional statement of findings from the FMIA (Section 602).

> ***"Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. 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. Unwholesome, adulterated, or misbranded meat or meat products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally."

The PPIA and EPIA contain similar statements of findings.

Here are a few other things that you need to know to understand where FSIS derives its legal authority for regulating meat, poultry, and egg products. One is that FSIS is an Agency within the U.S. Department of Agriculture. Another is that FSIS is the agency in the office of the USDA's Undersecretary for Food Safety. FSIS is a statutory agency in that the legal authority you carry out in your daily activities comes from the statue or the acts that we just mentioned. FSIS is charged by the Secretary of Agriculture with exercising her authority under the MIA, PPIA, and EPIA. The acts granted the legal authority for regulating meat, poultry, and egg products to the Secretary of Agriculture, who in turn has delegated it to FSIS. So, now you should understand that the authority for the actions that you take can be traced up through the Secretary of Agriculture and back to the statutes that were promulgated by Congress. As you go about your daily activities as a Public Health Veterinarian, you should be conscious of the fact that everything that you do is based on these statues. We must be able to trace the legal authority for enforcement actions back to a statutory basis. You do not need to be a legal expert to perform your job duties effectively. But you do need to have an awareness of where these authorities come from. You can find the statues on the web at http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking.

Regulations

Let's talk about how FSIS implements the statues. Inspection personnel are charged with carrying out the Acts. However, you will not use the Acts to guide your day to day work. FSIS issues documents that define for inspection personnel, the regulated industry, and the public how these Acts will be carried out. These documents are the ones that will guide you in your daily activities. But, their basis is in the Acts.

These documents that clarify the statutes are called regulations. As mentioned earlier, most of your work will be guided by the regulations. You will use citations from regulations when you complete a Noncompliance Record. Regulations are adopted by a public process that involves notice, comment, and rule making.

Let's talk about the steps involved in the rule making process. First, the Agency publishes a proposed rule. In this proposed rule, FSIS sets out its initial thinking on a topic. The proposed rule may result from legislation that requires the development of a rule, from a request by the Administrator or other federal management official, or some other reason (e.g., external event). A great deal of background work, including collecting and analyzing data, often goes into the development of a proposed rule. A proposed rule is developed by

a docket team. FSIS Directive 1232.4 describes how a docket team is established and the process used to develop a proposed rule. The proposed rule is published for public review in the Federal Register. You can see a current list of proposed rules on the FSIS web site under the section for Federal Register Publications at http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking. Once the proposed rule has been posted, the public, including members of the regulated industry, academia, consumer groups, and private individuals have the opportunity to comment on the proposal. The comment period usually lasts sixty days.

After reviewing and considering all of the comments on the proposed rule, the Agency then publishes a final rule. Examples of some significant rules recently published include the Pathogen Reduction and HACCP rule (in 9 CFR section 417) and the Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-eat Products (in 9 CFR 430.4).

Each regulation has an effective date. Sometimes the effective date follows very closely with the publication of the regulation. At other times, there is a period of several months between the publication of the final regulation and the effective date to allow the regulated industry time to make changes to implement the provisions of the regulation. In some cases, the effective date for large establishments differs from the effective date for small and very small establishments. Upon the effective date of the regulation, the regulated industry must take steps to comply with the rule, and FSIS is responsible for ensuring that the rule is implemented appropriately by establishments.

Sometimes, even after being given the opportunity for comment, there is disagreement with the legal basis for the regulation. Even after the regulation has been implemented, interested parties have the opportunity to challenge the regulations in court. For example, a group challenged through court action the Agency's enforcement of the pathogen reduction regulation related to *Salmonella* testing. As a result of the court's ruling, FSIS changed the way it addressed sample set failures.

If you review the FMIA, PPIA, and EPIA, you will see that they are very general in nature. The regulations, on the other hand, are rules that take the general principles of the statues and apply them to specific situations.

Let's walk through an example that shows how the Acts and the regulations are linked. Section 603(b) of the FMIA covers humane methods of slaughter for livestock. It states,

> ***"For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspected at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method."***

Note that this section of the Acts references the Humane Methods of Slaughter Act that is found in 7 U.S.C. 1901-1906. The regulation that provides more specific information for inspection personnel about how to carry out the Act is found in 9 CFR 313, "Humane Slaughter of Livestock." A review of the information contained in this regulation will show that it covers specifics such as how livestock should be handled (e.g., driven at a walk with minimum excitement, no sharp objects used, dealing with disabled animals, access to water and feed) and permitted methods of stunning. It also outlines what inspection personnel must do if the establishment fails to comply with the regulation (e.g., notify the establishment, when to issue an NR, conditions under which inspection may be suspended).

Directives

When FSIS issues a regulation, we also issue at least one Directive. Directives contain instructions to inspection personnel about how to implement and enforce the rules. Directives provide information about inspection methods, regulatory decision making, documentation of noncompliance, and appropriate enforcement actions. You can find electronic copies of current FSIS Directives on the FSIS web site (search under key word "Directives" or go to the section for Regulations and Policies) – OR you can find the FSIS Directives on the web at Regulations, Directives & Notices. Directives have no expiration date. Inspection personnel are to follow the information contained in the Directives until they are rescinded or replaced.

Remember that when a Directive is issued, it provides the specific instructions for how you and other inspection program personnel carry out a provision of the statute and the regulation. It's the basis for conducting inspection. It may contain some attachments, such as Q&A's, Compliance Guidelines for the industry, or specific instructions (e.g., for collecting samples) that clarify for inspection personnel and/or industry how the regulation is to be carried out. Please note that when the attachments to a Directive include Compliance Guidelines, these are not representative of regulatory requirements. Instead, they are exactly what their title suggests – guidelines to help industry understand how they can go about complying with the regulations.

Recently published Directives reflect the thought process you should use in carrying out inspection procedures – not black and white, yes/no answers. This is because the regulations now focus on providing performance standards that give industry room for innovation, rather than a command and control approach that requires all of industry to do the same thing to meet the requirements of a regulation. Let's look back at FSIS Directive 6900.2 to see how it lays out the thought process you are to use in verifying regulatory requirements. The Directive discusses how inspection personnel are to verify compliance with regulation 313.2. This part of the regulation addresses driving livestock, dealing with disabled livestock, and stunning methods. The following questions are posed for inspection personnel to use in a thought process that will lead them to make a determination about whether the establishment is complying with the regulation.

Are animals driven from the unloading ramp to the holding pens with a minimum of excitement and not at a running pace?

Are electronic prods and other implements used as little as possible to move animals within the establishment?

Are animals driven by using an object that would not cause unnecessary pain?

Are disabled animals separated from ambulatory animals and placed in a covered pen?

Do animals have access to water?

Is there sufficient room in holding pens for animals held over night?

Notice that these questions allow the establishment latitude on how they comply with the regulations. If they were written in a command and control format, they would list specifics, such as how often (hours, minutes) animals must have access to water, or detail the amount of water that must be available in relation to the number of cattle in a pen (e.g., so many gallons of water provided per so many head of cattle). However, the black and white, or command and control approach takes away industry's ability to innovate and make improvements in the manner in which they comply with the regulations. Using the thought process often means that you have to work a little harder to make a determination about regulatory compliance. But, it is better overall in terms of the results that are obtained for public health.

In following through with our example of humane slaughter, to show the link between the Acts, regulations, and Directives, FSIS Directive 6900.2 covers humane slaughter. It's titled "Humane Handling and Slaughter of Livestock." If you look at the references section on the first page of the Directive, you'll see that the Act 7 U.S.C.1901, 1902, 1906, and the regulation 9 CFR 313 are cited. The background section also covers the Humane Methods of Slaughter Act of 1978, and the regulation 9 CFR 313. Then, the directive provides specific instructions on the verification methods inspection program personnel should perform associated with each part of 9 CFR 313. It outlines questions that inspection program personnel should use to verify that establishments are complying with the regulations, and thus with the Acts. It discusses specific situations, such as ritual slaughter (e.g., Kosher, Halal). Then, it discusses exactly what inspection program personnel are to do if the establishment fails to comply with the regulations. For example, it indicates the type of information to be included on the NR, such as the Humane Activities Tracking System (HATS) category. It outlines the specific circumstances under which inspection should be suspended.

Remember, the Acts provide FSIS with the legal authority to ensure humane handling and slaughtering of animals. Regulation 313 provides more detail about what is required of the industry. FSIS Directive 6900.2 provides specific instructions for inspection program personnel on verifying that industry complies with the regulations. When you determine that there is noncompliance in relation to humane handling, it must relate to a provision in the regulations. You will document this regulation citation on the NR that you write describing the noncompliance. You must be guided by the regulations when determining noncompliance. It is unacceptable and inappropriate to make a determination that there is noncompliance if it cannot be linked to a regulation.

Notices

Now that you have a good understanding about FSIS Directives, let's talk about FSIS Notices. Notices are instructions to FSIS inspection personnel to address a particular

problem that has arisen. The need for Notices is often identified by the Policy Development Division as a result of a number of questions about a specific topic from the field. You can find FSIS Notices on the web at Regulations, Directives & Notices. Notice 12-05, *"Documentation of Humane Handling Activities"* was issued on February 18, 2005. Among the reasons for its issuance was to provide inspection program personnel with clarification regarding what information they are to record in the HATS tab under the Livestock Humane Handling task in the Public Health Information System (PHIS), and what information they are to include on noncompliance records (NRs) issued for humane handling noncompliance. Notices are numbered based on the fiscal year in which they are issued, and the number of other Notices issued. For example, Notice 12-05 was issued in fiscal year 05 (February 2005), and it was the 12th technical notice issued for 2005. Notices specify an expiration date. For Notice 12-05, the expiration date (shown at the bottom of page 1) was 03/01/05. They are often used as temporary measures until a more comprehensive policy is developed, which may include the issuance of a new regulation and a Directive or Directives. Notices are the shortest and most focused type of direction provided to inspection program personnel. Note that Notice 12-05 references 9 CFR 313 and 500 (Humane Slaughter of Livestock and Rules of Practice regulations, respectively) and FSIS Directive 6900.2. The Notice is only seven pages long, and it has one attachment.

Correspondence between acts, regulations, directives, and notices

You should understand that there is not a one-to-one correspondence between statutory provisions, regulations, Directives, and Notices. For example, a small (or short) statutory provision may result in a very detailed regulation, with multiple Directives, and perhaps Notices as well. Let's look at the statutory provision covering ante mortem inspection – Section 603(a) of the FMIA. This provision reads,

> ***"Examination of animals before slaughtering: diseased animals slaughtered separately and carcasses examined. 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 cattle, sheep, swine, goats, horses, mules, and other equines 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; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter."***

This short statutory provision is the basis for an extensive regulation, 9 CFR 309. This regulation includes subparts 1 through 18. It covers a range of topics including ante mortem inspection of livestock in pens, identifying disease conditions, dealing with dead and dying animals, disposal of condemned animals, specific diseases, residues, livestock used for research purposes, and official marks of inspection.

Acts → Regulations → Directives → Notices

Summary

To summarize what we've covered, the statute is the legal foundation for our activities. More details about regulatory requirements are set forth in regulations. FSIS Directives and Notices provide specific instructions for your daily work to verify that establishments are complying with the regulations.

When you determine that there is noncompliance, you link it to a regulation and you list the citation of that regulation on the NR. The regulations are based on the statues. The statutes are used when there are legal challenges to actions taken by FSIS. If the action taken is challenged in court, an FSIS Program Investigator will add statutory citations to the ones you have provided based on the regulations.

REFERENCES

1. Federal Meat Inspection Act
2. Poultry Products Inspection Act
3. Human Methods of Slaughter Act
4. Regulation 313
5. Regulation 500
6. Directive 6900.2
7. Notice 12-05

WORKSHOP

Statute – 603(b) included in the student handout
Regulation – 313.1
Directive – 6900.2
Notice 12-05

What does statute 603(b) cover?

What is the relationship between statute 603(b) and regulation 313.1?

What is the relationship between regulation 313.1 and Directive 6900.2?

What is the relationship between Directive 6900.2 and Notice 12-05?

Supplement for Workshop

REGULATION

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

Sec.
313.1 Livestock pens, driveways and ramps.
313.2 Handling of livestock.
313.5 Chemical; carbon dioxide
313.15 Mechanical; captive bolt.
313.16 Mechanical; gunshot.
313.30 Electrical; stunning or slaughtering with electric current.
313.50 Tagging of equipment, alleyways, pens or compartments to prevent inhumane slaughter or handling in connection with slaughter.
313.90 [Reserved]

AUTHORITY: 7 U.S.C. 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 44 FR 68813, Nov. 30, 1979, unless otherwise noted.

§ 313.1 Livestock pens, driveways and ramps.

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable conctruction and maintenance.

(c) U.S. Suspects (as defined in § 301.2(xxx)) and dying, diseased, and disabled livestock (as defined in § 301.2(y)) shall be provided with a covered pen sufficient, in the opinion of the inspector, to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.

(d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

[44 FR 68813, Nov. 30, 1979, as amended at 53 FR 49848, Dec. 12, 1988]

§ 313.2 Handling of livestock.

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement

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

FSIS DIRECTIVE

6900.2
Revision 1

11/25/03

Humane Handling and Slaughter of Livestock

PART I –- GENERAL

I. PURPOSE

This directive informs inspection program personnel of the requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including the slaughter of livestock by religious ritual methods, is humane. This directive explains how inspection program personnel should approach these activities.

II. CANCELLATION

FSIS Directive 6900.2, dated 10/7/03

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to provide additional clarification to the instructions in Part V, Ritual Slaughter of Livestock.

IV. REFERENCES

9 CFR parts 313 and 500, the Humane Methods of Slaughter Act - 7 U.S.C. 1901, 1902, and 1906, and FSIS Directive 6900.1 – Humane Handling of Disabled Livestock.

V. BACKGROUND

A. The Humane Methods of Slaughter Act of 1978 (HMSA) (Section 1901, 1902 and 1906, Attachment 1) states that the slaughtering and handling of livestock are to be carried out only by humane methods. In that Act, Congress determined (among other things) that the use of humane methods of handling and slaughtering livestock prevents needless suffering of animals and results in safer and better working conditions for employees in slaughter establishments.

B. Once a vehicle carrying livestock enters an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 313.2.

PART II -- VERIFICATION OF THE LIVESTOCK PENS, DRIVEWAYS, and RAMPS

A. What are the regulations related to livestock pens, driveways and ramps?

Section 313.1 states:

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(*b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.*

(*d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.*

NOTE: Verification of compliance with 9 CFR 313.1(c) is addressed in FSIS Directive 6900.1, Humane Handling of Disabled Livestock.

B. How do inspection program personnel verify compliance with this regulation?

When verifying compliance with 9 CFR 313.1(a), (b), and (d), inspection program personnel should determine whether the pens, driveways, and ramps are designed and maintained to prevent injury or pain to the animals. To do this, inspection program personnel need to seek answers to questions such as:

1. Are pens free of loose boards or openings, so that the head, feet or legs of an animal will not be injured?

2. Are the floors of pens, ramps, and driveways constructed so that an animal is not likely to fall (e.g., cleated, waffled, use of sand)?

3. Are driveways arranged so that sharp turns or sudden reversals of direction are minimized, so that they are not likely to cause injury to the animals?

These questions are examples and are not an all-inclusive list.

THIS DIRECTIVE TRUNCATED FOR TRAINING PURPOSES ONLY

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

FSIS NOTICE

12-05 | 2-18-05

DOCUMENTATION OF HUMANE HANDLING ACTIVITIES

I. PURPOSE

This notice reissues the information in FSIS Notice 35-04 to include additional information for verification activities under Category VIII - Stunning Effectiveness and Category IX - Check for Conscious Animals. This notice also provides information regarding inspection program personnel's response to egregious humane handling noncompliances. In the last paragraph of paragraph III, this notice provides Public Health Veterinarians in multiple In-Plant Performance System (IPPS) assignments instructions related to HATs. All other information from FSIS Notice 35-04 remains unchanged, and this notice continues to provide inspection program personnel with clarification regarding what information they are to record in Humane-handling Activities Tracking (HAT) under the Electronic Animal Disposition Report System (eADRS), and what information they are to include on noncompliance records (NRs) issued for humane handling noncompliances.

II. BACKGROUND

On November 25, 2003, FSIS issued FSIS Directive 6900.2, Revision 1, which provided inspection program personnel with instructions on regulatory requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including the slaughter of livestock by religious methods, is humane. All inspection program personnel are responsible for ensuring that animals are humanely handled and treated at all times.

III. HAT AND HAT CATEGORIES

The eADRS system replaced the use of FSIS paper forms to report information about animals presented for slaughter. The eADRS data provides valuable information concerning animal diseases and welfare in the U.S. HAT is one component of the eADRS. The HAT component provides FSIS with data on the time FSIS personnel spend verifying, as set out in FSIS Directive 6900.2, Revision 1, that humane handling and slaughter requirements are met. So that FSIS will have accurate and complete data, the HAT component is designed to record the time spent on humane handling

related activities and to separate that time into nine specific categories (see attachment).

PHV's that conduct antemortem and postmortem inspection disposition activities as part of a multi-IPPS assignment are to conduct one or more HATs procedures whenever they have cause to visit an establishment. Any non-compliance finding will be immediately addressed. These PHV's may enter the results of compliant HAT's procedures while at the establishment or the next time they log onto Performance Based Inspection System (PBIS).

Category I - Adequate Measures for Inclement Weather: Under this category, inspection program personnel record their verification of how the establishment adapts its facilities and handling practices to inclement weather to ensure the humane handling of animals. When the weather conditions warrant concern (e.g., extreme cold, heat, humidity, heavy rains, or high winds), inspection program personnel are to assess what effect these conditions have on the establishment's humane handling of animals (9 CFR 313).

Specific examples of the effects inclement weather can have on humane handling are:

- animal could fall or injure themselves because of snow, ice, mud, etc. [9 CFR 313.1(b)]

- water that is frozen and, therefore, inaccessible. [9 CFR 313.2(e)]

Category II - Truck Unloading: Under this category, inspection program personnel record their verification of the establishment's humane handling procedures while unloading livestock.

Specific examples of verification procedures include observing that:

- the state of repair of vehicles, ramps, and driveways permit the unloading of animals without injury [9 CFR 313.1(a)]

- the proper positioning of vehicles and unloading ramps permits the unloading of animals without injury [9 CFR 313.1(b)]

- animals are unloaded and driven to pens with a minimum of excitement and prod use [9 CFR 313.2(a) and (b)]

- disabled animals are handled in accordance with 9 CFR 313.2 (d).

THIS NOTICE TRUNCATED FOR TRAINING PURPOSES ONLY

FSIS Safety and Health Training for Public Health Veterinarians

Contents

Module 1: Introduction

The objective of this training course is to provide FSIS Public Health Veterinarians (PHVs) training in their responsibility for safety and health compliance in the workplace, and to provide an understanding and awareness of the causes of FSIS injuries and illnesses, and preventive measures that can be taken.

OSHA's Training Philosophy

The Occupational Safety and Health Administration's (OSHA) philosophy on training is reflected in the requirements of the standards they promulgate and enforce. OSHA's requirements reflect their philosophy that training is a necessary component of every employer's safety and health program for protecting workers from injuries and illnesses. Training employees in the safety and health aspects of their jobs is a responsibility of the employer that is explicitly stated in, and a requirement of many OSHA standards. OSHA believes that training will help provide a solution when ignorance of specific job hazards and of proper work practices contributes to a higher injury and illness rate.

Training Requirements

OSHA has promulgated many standards affecting FSIS employees in plants and laboratories. Older standards usually require "Training" as a general statement. Newer standards prescribe the type, frequency, and effectiveness of training for employees and supervisors. OSHA requires documentation of individual training.

OSHA Standards with Training Requirements

OSHA Standard	***Training Frequency***		
	At Initial Assignment	Workplace Change	Annual
Supervisor/Employees Training	X	X	
Hazard Communication	X	X	
Personal Protective Equipment	X	X	
Occupational Noise	X	X	X
Lockout-Tagout	X	X	
Permit Required Confined Spaces	X		
Emergency Action Plans	X	X	
Accident Prevention Signs and Tags	X		

Module 2: Program Overview

Regulations and Directives

The following topics are covered in this module:

- Federal Laws and Regulations
- FSIS Safety and Health Program
- Environmental, Safety and Health Group
- Material Management Service Center

Federal Laws and Regulations

Occupational Safety and Health Act

The declared Congressional purpose of the Occupational Safety and Health Act of 1970 is to "assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources." Under the Act, the federal government is authorized to develop and set mandatory occupational safety and health standards applicable to any business affecting inter-state commerce. The responsibility for promulgating and enforcing occupational safety and health standards rests with the Department of Labor's OSHA. OSHA is required to develop standards for recognized hazards. Under the Act, Federal departments are required to establish safety and health programs.

Executive Order 12196

Executives Orders (EO) on Federal Employee Safety and Health Preceded the 1970 Act. One of the more recent, EO 12196, Occupational Safety and Health Programs for Federal Employees, signed 2-26-80 provides for:

Appointment of a Designated Safety and Health Official (DASHO)
Prompt Abatement
No Reprisals
Workplace Inspections
Training
Safety and Health Committees

OSHA Regulations

OSHA is responsible for promulgating legally enforceable standards. OSHA may require the use of practices, means, methods, or processes that are reasonably necessary and appropriate to protect employees on the job. Employers are held responsible for being familiar with the standards applicable to their activities and ensuring that employees are provided with and use the required personal protective equipment. The following is a list of the OSHA regulations.

General Industry Standards – 29 CRF 1910
Agriculture – 29 CFR 1928
Federal Employee Program – 29 CFR 1960

Only General Industry and Federal Employee Programs affect meat, poultry and egg product inspection activities.

General Industry Standards

The General Industry Standards that primarily affect FSIS operations include:

- Walking-Working Surfaces – Subpart D
- Exit Routes, Emergency Action Plan, and Fire Prevention Plan – Subpart E
- Occupational Health and Environmental Control – Subpart G
  - Occupational Noise Exposure – 1910.95
- Personnel Protective Equipment – Subpart I
- General Environmental Controls – Subpart J
  - Accident Prevention Signs and Tags – 1910.145
  - Permit-required Confined Space – 1910.146
  - Control of Hazardous Energy (Lockout/Tagout) – 1910.147
- Medical and First Aid – Subpart K
- Toxic and Hazardous Substance – Subpart Z
  - Formaldehyde – 1910.1048
  - Hazard Communication – 1910.1200

Federal Employee Programs

29 CFR 1960, Element for Federal Employee Occupational Safety and Health Programs, is an OSHA Standard that applies only to Federal agencies and their employees. The parts of this Standard that apply to FSIS employees include:

- Responsibilities and Rights
- Inspection and Abatement
- Safety and Health Committees
- Training
- Injury and Illness Reporting

FSIS Safety and Health Program

Responsibilities

Assistant Administrator, Office of Management (OM), is the DASHO and has overall responsibility for management of the FSIS Safety and Health Program. The Environmental, Health and Safety Group (ESHG), is responsible for the planning, policy development and management of the program.

The Inspector-In-Charge (IIC) is responsible for front-line management of the program at the plant level.

FSIS Directives

Several FSIS safety and health directives have been issued which provide guidance for compliance with OSHA standards. The directives will be revised and updated to reflect changes in OSHA standards and FSIS policy. Below is a list of the directives relating to safety and health.

4791.1 Basic Occupational Safety and Health Program
4791.5 Hazard Communication Program
4791.6 Procedures for Workplace and Travel Emergencies
4791.11 Lockout/Tagout Safety Procedures
4791.12 Reporting and Correcting Occupational Hazards
- Part 1- Basic Provisions
- Part 2 - Reporting and Correcting Hazards

4791.13 Workplace Inspections, and Injury, Illness and Motor Vehicle Incident Reporting
- Part 1- Basic Provisions
- Part 2 - Safety and Health Workplace Inspections
- Part 3 - Injury, Illness and Motor Vehicle Incident Reporting and Recordkeeping Guidelines

4792.1 First Aid

Environmental, Safety and Health Group

The Environmental, Safety & Health Group (ESHG) prevents accidents, injuries, and illnesses by providing assistance and training, assessing trends and performing inspections to evaluate safety programs.

Occupational Safety: Prevent accidents and injuries by providing assistance and training, assessing trends and performing inspections to evaluate safety programs.

Occupational Health: Prevent illness by assessing workplace exposures to chemicals for ongoing operations and new technologies. Also provides industrial hygiene support on chemical, physical and biological health hazards.

Environmental Management: Reduce impacts to the environment by assisting laboratory operations and ensuring compliance with EPA regulations and Presidential Executive Orders.

The ESHG maintains an FSIS safety website at: Environmental, Safety and Health Topics. The public website contains information such as forms and directives related to the safety program, information about OSHA injury forms, and contact information for Occupational Safety and Health Specialists.

The ESHG also maintains an internal safety website on the FSIS intranet at: Inside FSIS Environmental, Safety and Health Topics (Level 2 eAuthentication is needed to access this site). The intranet site contains occupational health and safety information for FSIS employees and safety committees such as injury and illness reports.

Environmental, Safety and Health Group Team Lead

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The Occupational Safety and Health Specialists (OSHS) are the primary contacts for the FSIS employees. The specialists are assigned to one or more districts. The map above specifies these assignments.

Contact information (and OSHA posters) can be found at: https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/audience-employees/employee-safety

OSHA Poster

OSHA Safety Poster must be posted in all USDA offices. The poster is required by OSHA and has contact information for the OSHS and the DASHO.

The poster also lists the outlines of a Federal Safety program including the responsibilities for FSIS and FSIS employees.

FSIS Directive 4791.1 States:

> A. OSHA requires that every FSIS workplace display the "Federal Agency Occupational Safety and Health Protection for Employees" poster (Safety Poster) in a prominent location within the workplace. The Safety Poster is available on the FSIS safety intranet site and the public safety site.
>
> B. The Safety Poster lists the rights of employees and their representatives. These include the right to:
>
> 1. Participate in Department and Agency OSH Programs;
>
> 2. Access OSHA standards, monthly injury and illness reports (via Inside FSIS Environmental, Safety and Health Topics), and Agency OSH procedures;
>
> 3. Report and require correction of unsafe and unhealthy working conditions; and
>
> 4. Report unsafe or unhealthy working conditions without reprisal.
>
> C. Although not listed on the safety poster, the Agency recognizes the rights of employees and their representatives to:
>
> 1. Participate in the development of safety and health standards; and

2. Decline to perform an assigned task because of reasonable belief that it poses an imminent danger of serious bodily harm or death and there is not sufficient time to seek effective corrective action through normal hazard reporting and abatement procedures.

D. The DASHO contact information is listed on the FSIS Safety Poster.

Module 3: Hazard Communication Standard

FSIS Hazard Communication Program

The following topics are covered under Hazard Communication:

- Introduction
- OSHA Hazard Communication
- FSIS Hazard Communication Program
- Methods of Hazard Communication
- Health Hazards of Chemicals

Introduction

There are many chemicals used in meat, poultry and egg product facilities. Some of the more common ones include chlorine, ammonia and carbon dioxide. You have the right-to-know how to work safely with and around these chemicals.

OSHA requires employers to evaluate the potential hazards of chemicals in the workplace and to provide information, training and appropriate protective measures on these hazards. This is known as Hazard Communication.

OSHA Hazard Communication Standard

The Hazard Communication Standard is found in 29 CFR 1910.1200. The purpose of this standard is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. The standard applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency. It does not apply to ionizing radiation, non-ionizing radiation, biological hazards, or hazardous waste.

Under the standard, chemical manufactures or importers are required to determine the hazards of the chemicals which they produce or import. Typically this information is provided to employers on a document known as a safety data sheet (SDS), and on container labels. Employers are required to transmit this information to their employees by means of a comprehensive hazard communication program.

A Hazard Communication Program must include the following elements:

- A written program
- A current list of all hazardous chemicals present in the workplace
- Chemical container hazard labeling
- Safety Data Sheets (SDS's) for chemicals present in the workplace
- Employee training regarding chemical hazards and protective measures
- Other forms of warning as needed

<u>Training Requirements</u>

An employee is required to be provided with information and training on hazardous chemicals in their workplace at the time of their initial assignment. Retraining is required when a new physical or health hazard that the employee was not previously trained about is introduced into their workplace, there is a close call event involving chemicals, a failure in hazard communication procedures occurs, and/or when there is reason to doubt employee proficiency.

FSIS Hazard Communication Program

The FSIS Hazard Communication Program is found in FSIS directive 4791.5. It applies to FSIS employees working in meat, poultry, and import establishments. The program assigns the inspector-in-charge (IIC) as the overall coordinator of the program for FSIS employees in each plant or facility.

As part of the FSIS Hazard Communication Program, the ESHG is responsible for:

— Reviewing the Hazard Communication Program annually and updating as needed; developing training for FSIS employees; providing information on the hazards of chemicals used by FSIS; assisting with interpreting chemical hazard information provided by facilities, conducting hazard assessments to determine appropriate engineering controls and PPE; and conducting air monitoring to evaluate employee exposures.

As part of the FSIS Hazard Communication Program, the IIC is responsible for:

— Maintaining a copy of the Hazard Communication Program at the worksite and making it available to employees; reviewing the plant level FSIS program on an annual basis; making the written program available to employees; providing an SDS when requested by an employee; and providing chemical hazard information to inspectors by means of chemical inventories, hazard warning labels, SDS's and employee training programs.

As part of the FSIS Hazard Communication Program, FSIS employees are responsible for:

— Reading and understanding the written FSIS Hazard Communication Program; recognizing situations where hazardous chemicals are present in your workplace; notifying your supervisor of hazardous conditions; understanding how the information on the SDS applies to the specific use of the chemical in your workplace; and properly using and wearing the FSIS-supplied personal protective equipment.

Methods of Hazard Communication

Safety Data Sheets (SDS), container labeling, and chemical inventories are used to transmit information concerning the hazards of chemicals to employers and employees.

<u>Safety Data Sheets (SDS)</u>
An SDS is a document which provides specific information about a hazardous chemical

in accordance with OSHA guidelines. The SDS is prepared by the manufacturer of the chemical, and includes physical and health information, recommended control measures, and precautions for the safe handling and use of a chemical.

Format

OSHA has developed guidelines for what information should be included on an SDS. A typical format is shown below:

Section	Contents
1.	Identification
2.	Hazard(s) identification
3.	Composition/information on ingredients
4.	First-aid measures
5.	Fire-fighting measures
6.	Accidental release measures
7.	Handling and storage
8.	Exposure control/personal protection
9.	Physical and chemical properties
10.	Stability and reactivity
11.	Toxicological information
12.	Ecological information
13.	Disposal considerations
14.	Transport information
15.	Regulatory information
16.	Other information

Manufactures are permitted to withhold some information from a SDS which is considered a “trade secret.” Trade Secret Information must be provided immediately upon request during an emergency, or at the request of a physician. The user of the information must agree to keep the information confidential.

Location

An SDS for every chemical found in the workplace must be kept in a location that is easily accessible to employees. The IIC should ensure that the location where the SDS are stored is known and that inspectors have access to them always.

Interpretation

SDS are generally written by the chemical manufacturer for the “pure product” (e.g. 100% concentration) and not for the diluted form of the chemical as it is used in most applications at poultry and red meat establishments. This must be taken into consideration when reviewing the information found on the SDS. This is especially true for the health hazard information as the health effects for the concentrated solution are generally more severe than for the diluted solution.

Container Labeling

Specific information for the chemicals used in the workplace can also be found on container labels. All chemical containers must be labeled, unless the container is a portable container in the control of a specific person for their immediate use. All labels must use the same name as it appears on the SDS.

Chemical Inventories - Plant Chemicals

Most of the chemicals present in meat, poultry and egg product plants are part of the processes and cleaning aides used by the plant. Plant management is responsible for maintaining a list of all hazardous chemicals. The plant should update the list as necessary, and include when new chemicals are introduced into the establishment.

Chemical Inventories - FSIS Chemicals

FSIS only purchases and uses small quantities of chemicals at select plants. These chemicals are primarily used for field tests and pathology samples. FSIS is required to provide the SDS and container labeling for these chemicals. FSIS is also required to obtain and share information regarding the chemicals used in the plant with plant management.

Health Hazards of Chemicals

Introduction

The effect a chemical substance has on the body depends on the dose. The dose the body absorbs is dependant upon three factors:

- How much of the chemical you are exposed to (concentration)
- How long you are exposed (duration)
- How often you are exposed (frequency)

Type of Health Effects

Acute effects occur rapidly over a short time period and usually involve exposures to high concentrations of chemicals. Chronic effects occur over a long time period (months, years, or a lifetime) and usually involve exposures to lower concentrations of chemicals.

Exposure Routes

Chemicals can enter the body by:

- Inhalation - the chemical is absorbed through the lungs into the bloodstream
- Absorption - the chemical is absorbed through the skin or mucous membranes
- Ingestion - the chemical is absorbed through the gastrointestinal tract (from eating and drinking contaminated items, or smoking after hands have touched contaminated items)
- Injection - the chemical is absorbed via needles, compression air, knives, broken glass, etc.

Categories of Health Effects

- Irritant - in sufficient concentration will produce an inflammatory response or reaction of the eye, skin, or respiratory system
- Corrosive - causes visible destruction of, or permanent changes, in living tissue at the site of contact
- Sensitizer - causes an allergic reaction of the skin or respiratory system over time. Once the sensitivity is developed, exposure to even a small amount of the material may cause a severe reaction
- Carcinogens - cause malignant tumors (cancer)
- Teratogens - cause birth defects in a developing fetus
- Mutagens - cause a mutation in the genetic code (chromosomal changes)

Specific Chemical Hazards in FSIS Workplaces

Many chemicals are used in meat, poultry, egg products, and import facilities such as disinfectants, sanitizers, cleaning agents and processing aides. Some common chemicals are listed below:

- Chlorine is used in water sprays in numerous locations on the evisceration line, on the reprocessing line, and in the pre-chiller and chillers
- Ozone is used to disinfect recycled water for use in the chillers and the on-line reprocessing carcass washes
- Acids, bases, quaternary ammonia and sodium hypochlorite are chemicals commonly used for sanitation
- Peroxyacetic Acid (PAA) is a common antimicrobial in poultry establishments. It is stored as a mix of solution with acetic acid, hydrogen peroxide and peroxyacetic acid.

In addition, new chemical antimicrobial treatments are continuously being tested in plant trials in an attempt to find more effective ways to ensure food products are safe from harmful bacteria. Some examples are listed below:

- Acidified sodium chlorite solution (Sanova System)
- Ammonium hydroxide
- Acetic acid
- Acidic calcium sulfate (Mionix)
- Carbon Dioxide (TomCo)
- Sodium Acid Sulfate
- Chlorine Dioxide (Zep ® Antimicrobial Treatment System)
- Lactoferrin Antimicrobial Spray

Other hazards covered by the Hazard Communication Program are present in FSIS workplaces.

- Exhaust gases, such as carbon monoxide and sulfur compounds, may be present from forklift trucks, singers, cooking operations, and rendering stacks.
- Ammonia and Freon are used in refrigeration systems and exposures may occur from leaks.
- Carbon dioxide (in the form of dry ice) is used in food packaging, and (as a gas) in some chiller systems to lower the pH of the water.

All of these chemicals have similar health effects, including: eye, nose, throat and respiratory irritation, nasal discharge, cough, wheezing, bronchitis, and skin irritation with prolonged, direct contact. However, it is very important to refer to the SDS's at your duty station for specific health hazard information.

Evaluation of Chemical Hazards

The ESHG conducts hazard assessments and monitoring to evaluate occupational exposures and determine appropriate control measures. The ESHG conducts air sampling and wipe testing to determine if inspectors may be overexposed to chemicals, biological agents, and physical hazards. Industrial hygiene surveys are arranged

through the ESHG Occupational Safety and Health Specialist assigned to the district in which the plant is located. In certain instances, the ESHG may provide an IIC with real-time sampling equipment to conduct on-site monitoring.

Resources

Health Hazard Information Sheets (HHIS) are available at:

https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=HealthHazard6410

Module 4: Personal Protective Equipment (PPE)

Introduction

The term PPE refers to a variety of devices and clothing which are designed to protect the eyes, face, head, hands, arms, body, and feet by creating a barrier against workplace hazards. PPE should not be used as a substitute for engineering, work practice, or administrative controls. Instead, it should be used in conjunction with these controls to provide for employee safety and health in the workplace.

Hazard Assessment

A hazard is the potential for harm and is often associated with a condition or activity that, if left uncontrolled, can result in an injury, illness, or death. Hazards found in FSIS plant workplaces include:

- Chemical (Toxic and Corrosive)
- Electrical (Shock and Short Circuits)
- Ergonomics (Strains and Sprains)
- Falls (Slips and Trips)
- Noise (Above 85 dB)
- Temperature Extreme (Heat and Cold)

In order to determine which PPE will provide the best protection, the ESHG has completed many workplace hazard assessments. It has been determined that certain types of PPE are required to be worn based on the workplace hazards that have been identified during workplace hazard assessments. Workplace hazards, and therefore required PPE, can be specific to your duty station.

Training

Inspectors must be able to demonstrate their ability to properly use PPE before being allowed to perform work requiring the use of that PPE. OSHA standard 1910.132 requires that a PPE program be established to ensure that the appropriate PPE has been selected and that employees are trained in its proper use. FSIS directive 4791.1 provides additional guidance on PPE in relation to FSIS workplaces.

FSIS employees who are required to use PPE will be trained in the following areas:

- When PPE is necessary
- What PPE is necessary
- How to properly adjust and wear PPE
- Limitations of the PPE
- The proper care, maintenance, useful life, and disposal of the PPE
- After training is conducted, it should be recorded on PPE Training Sheets. Use FSIS Form 3530-12, Meeting Attendance/Training Completion Signature Form

Supply Source – Materials Management Service Center (MMSC)

Most required and other optional PPE is available through the Materials Management Service Center (MMSC). Available PPE includes such items as hardhats, ear muffs, earplugs, impervious gloves, cut-resistant gloves, freezer vests, freezer jackets and face shields after approval.

Per FSIS directive 3410.3, permanent, full-time FSIS inspectors and veterinarians are reimbursed for the direct purchase of the following types of PPE and safety equipment: skid-resistant footwear, hand tools, knives, sharpening steels, node hooks, scabbards, chains with break away link, and flashlights.

Head Protection

Prevention of head injuries is an important factor in every safety program. Accidents and injuries data indicate that most workers who suffered impact injuries to the head were not wearing head protection. Head injuries are caused by falling or flying objects, or by bumping the head against a fixed object. Head protection, in the form of protective hats, must do two things – resist penetration and absorb the shock of a blow.

Requirements and Fit

The OSHA standard for head protection is 29 CFR 1910.135. FSIS directive 4791.1, Revision 2, requires that hardhats be worn at all inspected plant facilities. Hardhat headbands are adjustable in 1/8-size increments. When the headband is adjusted to the right size, it provides sufficient clearance between the shell and the head. The removable or replaceable type sweatband should cover at least the forehead portion of the headband and the shell should be of one-piece seam.

Eye and Face Protection

Studies indicate that about 60 percent of workers who suffered eye injuries were not wearing protective eye equipment. Protective eye and face equipment is required by OSHA where there is a reasonable probability of preventing injury when such equipment is used. The OSHA standard for eye and face protection is 29 CFR 1910.133. The Material Management Service Center provides 2 types of safety glasses which may provide protection from small flying objects and bodily fluids from animals. Face shields are available after approval for Brucellosis.

Ear Protection

Exposure to high noise levels can cause hearing loss or impairment. The OSHA standard for hearing protection is 29 CFR 1910.95, Occupational Noise Exposure. Ear protection is presented in detail in the next training module, Occupational Noise.

Hand Protection

Examples of injuries to hands are cuts, burns, electrical shock, and absorption of chemicals. There is a wide assortment of gloves for protection against various hazardous situations. It is important to know the performance characteristics of gloves relative to the specific hazard anticipated: e.g., exposure to cuts or protection from biological material.

Requirements

The OSHA standard for hand protection is 29 CFR 1910.138. FSIS Directive 4791.1, Revision 3, contains the following requirement for hand protection:
Red meat slaughter inspectors must wear a cut-resistant glove on the non-knife hand when performing inspection tasks that require a knife and the assignment of two or more inspectors.

Hand Protection

The Material Management Service Center provides cut resistant gloves, latex gloves, and nitrile examination gloves. Nitrile and latex gloves are offered to reduce the risk of exposure to zoonotic diseases. Use of latex gloves is voluntary.

Foot Protection

Slips, trips and falls are the major cause of accidents. They cause 15 percent of all accidental deaths and are second only to motor vehicles as a cause of fatalities. Meat, poultry and egg product plants have wet and slippery walking and working surfaces.

The OSHA standard for foot protection is 29 CFR 1910.136. This standard does not require foot protection for wet slippery surfaces. However, FSIS provides reimbursement for footwear that has skid-resistant soles, water-resistant uppers, and a closed heel and toe. Soles made from leather, wood, hard plastic, or metal materials are excluded.

FSIS directive 3410.3, Revision 4, provides for reimbursement of protective footwear that meet the conditions described above. Reimbursement is limited to actual expenses, and the total allowance during the fiscal year shall not exceed $70. However, supervisors may authorize reimbursement for additional replacement of skid-resistant footwear (up to an additional $70 per pair) on an “as needed” basis.

Respiratory Protection

Respirators (dust masks) are available through the Material Management Service Center. Approval is required before they can be ordered.

Material Management Service Center

The Material Management Service Center (MMSC), located in Beltsville, Maryland, is part of the Administrative Services Division. It is a vital part of the FSIS Safety and Health Program. The MMSC distributes and supplies over 30 types of personal protective equipment (PPE) and other safety and health related items to FSIS field employees.

The following is a list of the safety and health items stocked at the MMSC:

- Eye Protection: Safety Glasses (2 types)
  Anti-Fog Eyeglass Wipes
- Face Protection: Face Shields (Available after approval)
- Head Protection: Hardhats

- Hand Protection: Cut-Resistant Gloves (3 sizes)
  Nitrile Protective Gloves (5 sizes)
  Disposable Latex Gloves (4 sizes)
- Body Protection: Freezer Coats
  Freezer Vests
  Freezer Jackets
  Aprons
- Heat Stress Management: Neck Cooling Scarves
  Sqwinchers (3 flavors)
- Leg Protection: Pant Gaiters
- Respiratory Protection: Dust Masks (3 types) [RESTRICTED, Approved Use Only]
- Hearing Protection: Ear Muffs (2 types)
  Foam Plugs (4 types)
  Reusable Plugs (3 types)
  Canal Caps
- Locks: Lockout/Tagout
- First Aid: First Aid Kits (2 types)
  First Aid Kit Refill
  Instant Cold Packs

Safety and Health Items Reimbursed by FSIS

Not all safety and health items are issued by the (MMSC) Material Management Service Center. Directive 4310.3, Revision 4, provides for reimbursement to permanent full-time inspection personnel for the following inspection expenditures:

- Work clothing
- Skid-resistant footwear
- Personal inspection equipment
- Flashlights and replacement batteries
- Hand, wrist, and arm support devices

Resources

Personal Protective Equipment
Directive 4791.1 Section XI

Training material is available at:
https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=PPE1681

Module 5: Occupational Noise

The following sections are included in this module:

- Introduction
- FSIS Hearing Conservation Program
- Hearing Protection

Introduction

The purpose of this module is to provide you with information regarding the FSIS Hearing Conservation Program and the necessary training to help safeguard your hearing.

The following objective will be covered:

- The effects of noise

The FSIS Hearing Conservation Program includes the following:

- purpose and procedures of audiometric testing
- monitoring noise levels
- purpose, advantages, and disadvantages of various types of hearing protectors
- selection, fit, use, and care of the different types of hearing protectors

Noise is defined as “unwanted sound.” Exposures to high levels of noise cause hearing loss and may cause other harmful health effects such as stress and fatigue. Work-related hearing loss is one of the most common occupational diseases in the United States. The amount of hearing loss caused by noise depends on how loud the noise is and how long you are exposed. The loudness of a noise is measured in decibels (dB). Noise greater than 85 dB can damage hearing if the exposure is long enough. FSIS employees working in meat, poultry and egg product plants may be exposed daily to noise in this decibel range.

Noise-induced hearing loss can be temporary or permanent. Temporary hearing loss results from short-term exposures to noise, with normal hearing returning after a period of rest. Generally, prolonged exposure to high noise levels over a period of time gradually causes permanent damage. There is no cure for noise-induced hearing loss. Prevention of excessive noise exposure is the only way to avoid hearing damage!

The OSHA Occupational Noise Standard (29 CFR 1910.95) requires that a Hearing Conservation Program be implemented to protect workers from suffering hearing impairment as a result of being exposed to significant levels of occupational noise. A Hearing Conservation Program must be implemented when employees are exposed to noise at or above 85 dB at any time during the workday.

FSIS Hearing Conservation Program

FSIS Directive 4791.1 includes the elements included in the FSIS Hearing Conservation Program:

- Audiometric testing
- Monitoring of noise levels
- Provision of hearing protectors
- Training

Audiometric Testing

An audiogram or hearing test is essential for early detection of hearing loss. These tests must be administered by trained professionals who follow the specifications for conducting these tests as outlined in the OSHA Standard.

There are two types of audiograms required in a hearing conservation program: baseline and annual audiograms. The baseline audiogram is the reference audiogram against which all future audiograms are compared. Baseline audiograms must be provided within 6 months of an employee's first exposure at or above an 8-hour TWA of 85 dB. Annual audiograms must be conducted within one year of the baseline. It is important to test hearing on an annual basis to identify any changes in hearing ability. If a hearing loss has occurred, protective follow-up measures can be initiated before hearing loss progresses. Annual audiograms can also help identify whether your hearing protection properly fits and whether you are using it correctly.

Audiograms will be provided to all FSIS employees at no cost, including reimbursement of travel expenses where necessary. Arrangements for you to have an audiogram will be made through your supervisor. One thing to remember about your audiogram: For an accurate test do not expose yourself to high noise levels (at work or at home) for 14 hours prior to your test. If necessary, use hearing protection during this time. The FLS is responsible for setting up audiograms. Federal Occupational Health (FOH) may also be used as a source for audiograms. Their contact information is (415) 436-7916.

For Hearing Conservation Program questions concerning testing locations, billing and copies of the audiometric testing please contact Lynn McGourty 612-659-8574 or via email at lynn.mcgourty@fsis.usda.gov.

Monitoring Noise Levels

In accordance with FSIS Directive 4791.1, Basic Occupational Safety and Health Program, noise monitoring results must be recorded on FSIS Form 4791-20 and posted in the Government office of each establishment. New measurements must be made and the form updated any time noise levels may have increased, such as with a change in equipment, process, or layout of the establishment. Front Line Supervisors have been provided with a sound level meter to periodically check the noise levels in the work area. Monitoring has shown that noise levels within a meat, poultry, or egg products plant are typically between 85 to 105 dB. FSIS requires employees to wear hearing protection if they are exposed to noise levels of 85 dBA TWA or greater. A good rule of thumb: If you have to shout to talk to someone 2-3 feet away, the noise level is probably greater than 85 dB.

A significant change in hearing ability is called a Standard Threshold Shift (STS). If comparison of the annual audiogram to the baseline audiogram indicates a standard threshold shift has occurred, then you will be notified in writing within 21 days and may be referred for further testing. If an STS is identified and you do not already wear hearing protection, you will be fitted with hearing protection and given instruction on how to use it. If you were already wearing hearing protection, you will be refitted and retrained.

Provision of Hearing Protectors

The selection of proper hearing protection is essential to preventing noise-induced hearing loss. Hearing protection must be chosen based on its ability to block enough noise to reduce your exposure to at least 85 dB. This can be determined by using the Noise Reduction Rating (NRR) listed on the package the hearing protection comes in. To determine whether your hearing protection provides enough protection, use the following formula:

1) Subtract seven from the NRR number, which is given in decibels (e.g., 26dB - 7 = 19).
2) Divide the result by two (e.g., 19 ÷ 2 = 9.5).
3) Subtract the result from the original workplace noise exposure level in decibels (e.g., 94dB - 9.5 = 84.5).

The actual sound level your ear is exposed to should be 85 dB or below.

Training

FSIS employees who are included in the FSIS Hearing Conservation Program will receive training on the effects of noise, the selection, use, fit and care of hearing protectors. Supervisors are responsible for providing training to their employees. Training slides are available on the FSIS Intranet safety site at:

https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=HearingConservation8037

Hearing Protection

There are two basic types of hearing protectors: earplugs, which fit inside the ear canal, and ear muffs, which fit over the ear. The type of hearing protection you select will depend on the noise level to which you are exposed, the fit of the hearing protector and your personal choice for comfort. In some cases with very high exposure, it may be necessary to wear both earplugs and ear muffs. FSIS stocks many different types of hearing protectors. These include foam earplugs, pre-molded earplugs, canal caps, and ear muffs.

Advantages and Limitations of the Various Types

- Foam earplugs are comfortable for all day use. They will also adjust to many different sizes of ear canal, so sizing is usually not a problem.
- Pre-molded earplugs are reusable and come in many different sizes.
- Canal caps are a good choice if you have to insert and remove your hearing protection many times throughout the day. However, they do not offer as much noise reduction as earplugs or muffs.

- Ear muffs are also a good choice if hearing protection is inserted and removed many times throughout the day.

Tips for Choosing the Best Type of Hearing Protection

- Choose hearing protection that works well at your job site.
- Be sure your hearing protection is the right size for you. There are many different types and sizes of ear plugs available.
- Practice inserting and removing your hearing protectors so you become comfortable using them.
- Frequently check the fit to be sure you are using your hearing protection correctly.
- Always wear your hearing protection when in areas of noise levels greater than 85 dB.
- Learn the right way to care for your hearing protectors and know when to replace them.

Directions for Fitting Hearing Protection

Inserting Foam Earplugs

- Make sure both your hands and the earplugs are clean and dry
- Roll the plug between your fingers and thumb until it forms a long, thin cylinder (about this wide "O") so that about half the length of the plug will fit into your ear canal
- Reach over your head with your opposite hand and pull upward and outward on the top portion of your ear. This will extend the opening to the ear canal
- With the other hand, insert the plug as far as it will go into the ear canal
- Hold your finger against the plug until the plug has fully expanded in the ear canal

Test for fit using the hum test: After inserting one plug, talk out loud or hum. Your voice should seem louder and more resonant in the plugged ear.

Inserting Pre-Molded Earplugs

- Reach over your head using your opposite hand and pull the top portion of your ear upward and outward
- Insert the plug with a gentle rocking motion until you have sealed the ear canal. You should feel a vacuum-like seal when this occurs

Test for fit using the tug test. Tug gently back and forth on the stem of the plug. The plug has been inserted correctly if you feel resistance and a gentle sense of suction on the eardrum.

Inserting Canal Caps

- Place the neckband in the under-the-chin position
- Grasp the base of the caps to spread the neckband and fit the caps in the ears
- With the caps in place, pull the top of one ear upward and outward while firmly pushing and wiggling the neckband so the cap seals the ear canal. Repeat with the other ear

Test for fit using the loudness test. Once the canal caps are inserted, cup your hand over your ears. You should not notice any less noise with your hands over your ears than with the hearing protectors alone.

Fitting Ear Muffs

- Place the headband over your head
- Pull the ear cups down to fully cover your ears. Ear muffs should completely cover the outer ear to provide a good seal. Make sure hair, glasses, caps, and jewelry don't prevent the muffs from sealing your ears
- Adjust the headband for a snug, comfortable fit that gives you the best noise reduction

Test for fit by doing the loudness test in reverse. Lift one side of the ear muff off your ear. You should notice a sharp increase in noise as you break the seal of the ear muff around your ear.

Proper Care of Hearing Protection

- Foam earplugs are meant to be used once then thrown away. However, you can wash them in warm, soapy water, rinse them well, and let them air dry if need be. They should be discarded if they become hard or are no longer springy.

- Pre-molded earplugs are reusable. They should be washed with warm, soapy water when they become dirty, dried thoroughly, and stored in a plastic case between uses. If they harden or become discolored, they need to be replaced.

- Canal caps are reusable and can be washed with warm, soapy water when they become dirty. They need to be discarded when the caps become hard or discolored.

- Ear muffs are reusable and can be used as long as the pads of the muffs are soft and flexible, with no tears or cracks.

Importance of Consistent Use

If hearing protectors are not worn correctly or worn consistently throughout workshift (when in areas of noise that exceed 85 dB), their actual attenuation (their ability to reduce the amount of noise) will decrease rapidly as compared with the NRR (Noise Reduction Rating) listed on the package.

Effect of Inconsistent use on the Amount of Noise Reduction

When hearing protection is NOT WORN for 30 minutes in a work-day (where the noise Levels exceed 85 dB) the ability of the hearing protector to reduce the amount of noise by 30 dB, drops to almost 10 dB. For example, if you were exposed to a noise level of 100 dB and a hearing protector with a NRR of 30 dB was properly worn for the entire work shift, your ear would actually be exposed to 77 dB [100 dB – (30dB-7)]. However, if you did not wear the hearing protector for 30 minutes out of the day, your ear would actually be exposed to about 97 dB (a level that is hazardous to your hearing)

Module 6: Lockout/Tagout

Introduction

Employees can be seriously or fatally injured if the machinery/equipment they service or maintain unexpectedly energizes, starts up, or releases energy. Inspection of machines and equipment is a servicing/maintenance activity. To help protect employees from hazardous energy, OSHA issued the Control of Hazardous Energy (Lockout/Tagout) Standard. OSHA has estimated that nearly 2% of all workplace deaths can be eliminated by adhering to the requirements of this Standard. It was estimated that compliance with the Standard will prevent about 122 fatalities, 28,400 lost workday injuries, and 31,900 non-lost workday injuries each year.

Application

This standard applies to all sources of energy, including, but not limited to: mechanical, electrical, hydraulic, pneumatic, chemical, and thermal energy. This standard applies to inspection personnel performing pre-operational process verification inspection or verification of pre-operational or operational corrective action when such tasks expose them to hazardous energy. It does not apply if employees are performing service or maintenance tasks that do not expose them to the unexpected release of hazardous energy. The standard does not apply while servicing a cord and plug connected piece of electrical equipment or machinery.

OSHA Standard

The employer must establish an energy control (lockout/tagout) program to ensure employees isolate machines/equipment from their energy source. The employer must also establish procedures for putting appropriate lockout or tagout devices on the energy isolating devices, and when appropriate, procedures must address stored energy. These procedures must be inspected at least annually. If tagout devices are used on machinery or equipment that can be locked out, then additional procedures must be implemented to protect employees. Procedures can be developed to meet the needs of the workplace and the types of machines/equipment being maintained or serviced.

Employers are required to develop, document, and use procedures to control potentially hazardous energy. Procedures must outline the scope, purpose, authorization, rules, and techniques that employees will use to control hazardous energy. Procedures must provide at least the following information:

- A statement on how to use the procedure
- Specific procedural steps to shut down, isolate, block and secure machines or equipment
- Specific steps designating the safe placement, removal, and transfer of lockout/tagout devices and who is responsible for them
- Specific requirements for testing machines and equipment to determine and verify the effectiveness of locks, tags, and other energy control devices

The energy control procedure must be implemented in the following sequence:

— Prepare for shutdown
— Shut down the machine/equipment

— Disconnect or isolate the machine from the energy source
— Apply lockout or tagout device
— Release, restrain or otherwise render safe all stored or residual energy
— Verify energization and deenergization of the machine/equipment

The machine must be reenergized as follows:

— Inspect machines/equipment to determine if they are intact
— Check to assure that everyone is positioned at a safe distance from the machine/equipment
— Remove locks and tags
— Notify affected employees that locks and tags have been removed

FSIS Lockout/Tagout Program

Details of the FSIS Lockout/Tagout Program, which was developed in accordance with OSHA Standard 29 CFR 1910.147, are found in FSIS Directive 4791.11. Authorized FSIS employees are required to lock and tag out machines or equipment to perform pre-op process verification inspections in coordination with the establishment's lockout/tagout program. The process proceeds as follows: The plant develops lockout/tagout procedures in accordance with the OSHA Standard. During lockout/tagout procedures, a plant authorized employee places a lock on the energy isolating device. Then, the FSIS authorized employee also places a lock on the energy isolating device. An alternative lockout/tagout procedure is to use a lock box. First, the plant employee places a lock on the energy isolating device and puts its key in a lock box. Then the FSIS authorized employee places a lock on the lock box.

Cooperative Agreement (Attachment #1 in FSIS Directive 4791.11)

A cooperative agreement is an agreement developed by Inspector-In-Charge and plant management. It establishes lockout/tagout procedures at an inspected establishment. Plant and FSIS authorized employees verify that stored or residual energy has dissipated or is restrained. This is accomplished by the authorized FSIS employee observing the plant authorized employee verifying isolation. The authorized FSIS employee then notifies the plant authorized employee when inspection tasks requiring lockout are completed.

Inspection and Training

Front-line supervisors or another designee conduct the annual inspection of FSIS energy control procedures. FSIS employees must receive initial lockout/tagout training prior to performing inspection tasks that require application of lockout/tagout procedures. Retraining is required for authorized FSIS employees if there is a change in job assignment, a change in machines, equipment or processes, or a change in the energy control procedures. Retraining is also required if periodic inspection reveals deficiencies in the employee's knowledge, or use, of an energy control procedure.

Module 7: Confined Spaces

Definition

A confined space is a location which:

- Is large enough to enter and work in
- Has limited or restricted means of entry and exit, and
- Is not designed for continuous human occupancy

Examples of confined spaces include: pits, silos, tanks, hoppers, storage bins, railroad or truck tank cars, reactor vessels, and machinery enclosures. Confined spaces are dangerous!! There are many health and safety hazards associated with them and entering them may exposure you to risk of death, serious injury, or acute illness.

Hazards Include:

- Lack of oxygen
- Being trapped by the internal configuration of the space
- Being engulfed by materials in the space
- Presence of flammable or toxic gases or vapors
- Injury by mechanical equipment in the space
- Injury by release of pressure, heat, steam, or reentry of tank contents

The number one cause of death in confined spaces is asphyxiation due to hazardous atmospheres. Untrained rescuers (e.g. employees entering spaces to aid or save co-workers) account for 60% of deaths annually.

<u>Summary of OSHA Requirements</u>

According to OSHA Standard 29 CFR 1910.146, confined spaces which contain a hazard are regulated by OSHA as “permit-required” confined spaces. “Permit-required” means that an actual written permit is required to be completed before a person can enter the confined space.

The entry permit specifies the entry conditions, provides results of testing for oxygen content and toxic/flammable vapors, specifies initial and periodic air monitoring requirements, specifies the steps needed to prepare the space for entry, purging, flushing, ventilation and isolation (lockout/tagout, blanking pipes/lines), designates key personnel (attendants and entry supervisors), specifies entry time frames, specifies what external hazard controls must be in place, and details rescue and retrieval means.

If a workplace contains permit-required spaces, the employer must post danger signs to warn exposed employees stating:

“DANGER – PERMIT REQUIRED CONFINED SPACE – DO NOT ENTER”

<u>Applicability to Food Inspection Activities</u>
It is FSIS policy that employees DO NOT enter or work in confined spaces. Therefore, in accordance with the OSHA Standard, FSIS is required to:

- Evaluate the workplace to determine if any spaces which FSIS may need to enter are permit-required confined spaces
- Take measures to prevent employees from entering the spaces
- Evaluate any changes to non-permitted confined spaces that increase the hazards (requiring them to be permitted)

The establishment's responsibilities are to identify permit-required confined spaces, ensure those which impact FSIS operations are clearly marked with warning signs, and inform FSIS employees of the location of these spaces and FSIS policy prohibiting entry into them.

FSIS employees are responsible for being familiar with the location of permit-required confined spaces at their duty station/s. For permit-required confined spaces which require inspection, FSIS employees will arrange to have the interior of permit-required confined spaces inspected by other means that do not require the FSIS employee to enter the space.

Module 8: Walking and Working Surfaces

Introduction

Slips, trips and falls are the major cause of accidents. They cause 15 percent of all accidental deaths and are second only to motor vehicles as a cause of fatalities. The walking and working surfaces within meat, poultry and egg product plants may be hazardous. OSHA Standard 29 CFR Part 1910, Subpart D, contains the requirements for walking and working surfaces and applies to all FSIS workplaces.

Slips, trips and falls are the number one cause of FSIS employee accidents.

The following is a summary of the OSHA Standards for walking and working surfaces. The IIC should notify subordinates or plant management if you observe or are informed of violations of the standards. FSIS does not have the authority to require the abatement of hazards in private sector workplaces. In lieu of abatement, FSIS institutes administrative controls, work practice controls, or requires the use of personal protective equipment.

General Housekeeping Guidance
Work areas shall be kept clean and orderly and in a sanitary condition. The floor of every workroom shall be maintained in a clean and dry condition so far as possible. Where wet processes are used, drainage shall be maintained and gratings, mats, or raised platforms shall be provided. Working areas shall be kept free from protruding nails, splinters, holes, and loose boards.

Aisles and Passageways
Aisles and passageways shall be kept clear and in good repair with no obstruction across, or in aisles. Permanent aisles and passageways shall be appropriately marked. Aisles should be sufficiently wide for use of mechanical handling equipment such as motor trucks. Improper aisle widths and poor housekeeping may result in injuries to employees and limit exit during emergencies.

Protection of Open-Sided Runways
Every runway shall be guarded by a standard railing on all sides 4 or more feet from the floor level. A toe board must be provided whenever tools, machine parts, or materials are likely to be used. Regardless of height, open-sided floors, walkways, platforms and runways above or adjacent to a hazardous operation must be guarded with a standard railing and toe guard.

Guarding Floor and Wall Openings
Holes and openings can present extremely dangerous hazards. FSIS employees may fall through the openings or over the sides to the level below. Objects such as tools or parts may fall through the holes and strike FSIS personnel. FSIS personnel must be protected from floor openings/holes and open-sided platforms. They also must use stairway railings and guards.

Guarding Floor and Wall Openings and Holes
Floor openings may be covered or guarded with rails. Open-sided floors or platforms, 4 or more feet above the adjacent floor, must be guarded, with the exception of the

“working” side of an inspection platform. Toe boards must be provided on platforms. Every flight of stairs with 4 or more risers must have railings.

Fixed Industrial Stairs
Provide access to and from places of work, and should be inspected for hand rails, stair rails, and treads.

Portable Ladders
Portable ladders include step, single and extension ladders. Step ladders shall be equipped with a secure locking device to hold the front and back of the ladder in the open position. Ladders shall be maintained in good condition at all times. Ladders should always be placed with a secure footing. Short ladders shall not be spliced together to make long ladders. FSIS employees shall always face the ladder going up or down, and both hands shall be used when climbing or descending ladders.

Fixed Industrial Ladders
Fixed ladders are permanently attached to a structure, building, or equipment. Fixed ladders shall be maintained in a safe condition and inspected periodically.

Manually Propelled Ladders and Stands
These devices are commonly used by FSIS employees to conduct final inspections. All exposed surfaces of mobile ladders and stands shall be free of sharp edges, burrs, or other safety devices. Guardrails and toe boards are required for work levels that are equal to or greater than 10 feet high.

Safety Considerations
Wear skid-resistant footwear with adequate tread on the soles. Use the “packing house shuffle” when walking in slippery areas. Walk, do not run in establishments.

Module 9: Electrical Safety

(Excerpt from OSHA electrical safety website)

Overview

Working with electricity can be dangerous. Engineers, electricians, and other professionals work with electricity directly, including working on overhead lines, cable harnesses, and circuit assemblies. Others, such as office workers and sales people, work with electricity indirectly and may also be exposed to electrical hazards. Electricity has long been recognized as a serious workplace hazard. OSHA's electrical standards are designed to protect employees exposed to dangers such as electric shock, electrocution, fires, and explosions.

Resources

More information is available at this OSHA website:

https://www.osha.gov/SLTC/electrical/

Module 10: Machine Guarding

(Excerpts from OSHA Machine Guarding site)

Overview

Moving machine parts have the potential to cause severe workplace injuries, such as crushed fingers or hands, amputations, burns, or blindness. Safeguards are essential for protecting workers from these preventable injuries. Any machine part, function, or process that may cause injury must be safeguarded. When the operation of a machine or accidental contact injure the operator or others in the vicinity, the hazards must be eliminated or controlled.

Guards and Devices

The best way to prevent amputations caused by stationary or portable machinery is with machine safeguarding:

Guards provide physical barriers to hazardous areas. They should be secure and strong, and workers should not be able to bypass, remove, or tamper with them. Guards should not obstruct the operator's view or prevent others from working.

Devices help prevent contact with points of operation and may replace or supplement guards. Devices can interrupt the normal cycle of the machine when the operator's hands are at the point of operation.

Resources

More information is available at this OSHA website:

https://www.osha.gov/SLTC/machineguarding/index.html

Module 11: Burns

Overview
FSIS IPP primarily experience burns from sanitizing stations. The water is extremely hot and can cause 3rd degree burns.

Burns can occur when IPP use hot sanitizer water to clean gloves.

Do not put hands in sanitizer water!

Types of Burns
Excerpts from NIH (https://www.nigms.nih.gov/education/pages/Factsheet_Burns.aspx)

A burn is tissue damage caused by heat, chemicals, electricity, sunlight, or nuclear radiation. The most common burns are those caused by hot liquid or steam, building fires, and flammable liquids and gases.

Burns are defined by how deep they are and how large an area they cover. A large burn injury is likely to include burned areas of different depths.

Deep burns heal more slowly, are more difficult to treat, and are more prone to complications such as infections and scarring. Very deep burns are the most life-threatening of all and may require amputation. Types of burns include:

- First-degree burns damage the outer layer (epidermis) of the skin. These burns usually heal on their own within a week. A common example is a sunburn.

- Second-degree burns damage not only the outer layer but also the layer beneath it (dermis). These burns might need a skin graft—natural or artificial skin to cover and protect the body while it heals—and they may leave a scar.

- Third-degree burns damage or completely destroy both layers of skin including hair follicles and sweat glands and damage underlying tissues. These burns always require skin grafts.

Module 12: Emergency Procedures

Proper planning for emergencies is an essential part of occupational safety and health. The purpose of an Emergency Action Plan is to facilitate and organize employer and employee actions during workplace emergencies. All employees should be familiar with the emergency procedures and safe evacuation routes for each workplace to which you are detailed.

Requirements

According to OSHA Standard 29 CFR 1910.38, the development of a written plan of action and employee training regarding their actions and responsibilities under the plan is required. FSIS Directive 4791.6 provides procedures for the development of these plans. Each FSIS workplace (plant, laboratory or office) must have its own written plan. Types of emergencies include fires, explosions, chemical releases, bomb threats or bombings, weather related incidents, earthquakes, and power failures.

Use FSIS Form 4791-21 *FSIS Occupant Emergency Plan*.

The minimum required elements in an emergency action plan include, procedures for reporting a fire or other emergency; procedures for emergency evacuation, including type of evacuation and exit route assignments; procedures to be followed by employees who remain to operate critical plant operations before they evacuate; procedures to account for all employees after evacuation; and the job title of the employee who may be contacted for more information about the plan.

Training

The plan shall be reviewed with all employees when the plan is developed, an employee is initially assigned, the employee's responsibilities under the plan change, or the plan is changed. The written plan shall be kept at the workplace and made available for employee review. Diagrams illustrating evacuation routes and emergency exits should also include assembly points and equipment (fire extinguishers, first aid kits, spill kits) that may be needed in an emergency. These diagrams should be posted in a prominent place for all employees to see.

Medical Services and First Aid

Safety and health programs are intended to minimize the likelihood of injury and illness as a result of occupational hazards. However, it is unrealistic to expect that accidents will not occur from time to time. Thus, employers must plan for medical emergency response, which can vary from providing simple first aid to more serious injuries requiring medical attention or hospitalization.

Medical Services and First Aid, Standard 29 CFR 1910.151, is meant to ensure that employees receive medical attention when needed. FSIS Directive 4792.1 provides further direction on this activity.

Injuries in the Workplace
FSIS employees should seek immediate medical attention if an injury occurs in the workplace. FSIS employees should be familiar with their specific workplace procedures for notifying their supervisors and summoning emergency medical care.

The IIC/FLS should develop a plan for obtaining emergency first aid at either a plant health clinic managed by a health professional, a local community paramedical unit, or a hospital in close proximity to the workplace. FSIS employees should know the location or phone number of these medical services.

First Aid Supplies

The Materials Management Service Center (MMSC) provides two sizes of first aid kits for the plant and automobile. Band-aids and antibiotic ointment may be ordered separately from the MMSC.

Training

FSIS will not provide first aid training if any one of the following three conditions is met:

- There is a plant health unit managed by a health care professional
- There is a local community paramedical unit within a 15-minute response time (from the time of injury until first aid treatment)
- There is a health care facility within a 15-minute response time (from the time of injury until first aid treatment)

97 percent of inspected plants meet one or more of the above conditions. ESHG will coordinate first aid training on a case-by-case basis, where applicable.

Module 13: Heat Stress and Cold Stress

Heat Stress

Heat stress is a problem that affects up to an estimated 10 million workers in the United States each year. During the hot summer months, FSIS inspectors may be exposed to extreme conditions of hot temperatures and high relative humidity in meat and poultry slaughter plants. For additional information please visit the ESHG Site for Heat Stress:

FSIS Intranet
https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=HeatStress6553

FSIS Public Site
https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/audience-employees/employee-safety/heat-stress

The Body's Reaction

When exposed to severe heat the body tries to maintain a constant internal, or core, temperature by acclimating to the work environment. Blood flow is increased to the skin to release excess heat, and sweat is produced by the body. When sweat evaporates it cools the skin.

Types of Heat Injuries

- Heat cramps
- Heat exhaustion
- Heat stroke

The more common heat injuries are heat cramps and heat exhaustion. These disorders are not life-threatening; however, they may be intermediate steps on the way to heat stroke. Heat stroke, on the other hand, is a life-threatening emergency that requires immediate medical attention.

Heat Cramps and Heat Exhaustion

Workers experience symptoms such as undue fatigue or heat cramps while working in the heat. Heat exhaustion victims often experience headaches, dizziness or lightheadedness, weakness, mood changes such as irritability, nauseousness, pale skin (indicating very low oxygen delivery), and feeling faint. Treatment for heat cramps and heat exhaustion include moving the victim to a cool, shaded area to rest, loosening and removing heavy clothing, and keeping the victim hydrated (about a cup of cool water every 15 minutes) unless the victim is nauseous. If heat cramps persist, intravenous fluids, and therefore medical attention, will be required. Observe the victim closely and if sweating suddenly stops, or the worker loses consciousness or becomes disoriented, he or she should be treated as a heat stroke victim who needs immediate medical attention.

Heat Stroke

In the early stages, workers typically have hot, dry skin (they are not sweating). The skin is typically red (has a sunburn appearance), but may be blotchy or pale blue-gray, and internal body temperature is very high. The victim may experience mood changes such as irritability, mental confusion or the inability to think straight, seizures, or lose consciousness. Breathing may be faster and deeper than normal. Heat stroke is a life-threatening medical emergency that requires immediate attention from medically trained personnel. While waiting for medical help, first aid should be initiated. Remove the worker from the heat source to a cool, shaded area, loosen and remove any heavy clothing, have the victim drink a cool cup of water (about four ounces) every 15 minutes, if they are conscious and not sick to their stomach, and cool the worker as rapidly as possible by maximizing airflow across the body (by fanning).

FSIS Heat Stress Management Program

There is currently no specific OSHA standard or FSIS directive for heat stress. However, OSHA may cite Federal agencies for heat stress violations under 29 CFR 1960.8(a). FSIS is constrained by 29 CFR 1960.1(g) from requiring abatement of heat hazards in a private sector workplace, but IICs should work with plant management on high heat days to improve ventilation and cooling of work areas.

FSIS has only three realistic options for managing exposures and for protecting employees working in high temperature environments in plants:

- Administrative – employee awareness training on actions to reduce the effects of heat stress
- Administrative – increasing the effectiveness of fluid intake using electrolyte replacement supplements (Sqwinchers)
- Personal protective equipment – neck cooling scarves

Using all three of these approaches is the basis of the FSIS Heat Stress Management Program.

Sqwinchers are an electrolyte replacement drink, scientifically formulated to replace mineral salts and replenish fluids and sugars at optimal absorption rates (electrolytes are depleted as a result of dehydration or through physical exertion). Six ounces of water are added to a Sqwincher package. The package also serves as a cup. Sqwinchers are issued by the MMSC as a box of 50 under the following item numbers:

- Lemon Lime, FSIS-69-LL
- Fruit Punch FSIS-69-FP

Neck cooling scarves are small bandanas with cooling crystals that can be soaked in cool water for 30 minutes and then worn around the neck all day. They are washable and can be reused many times before replacing. They are available from the MMSC under the item number FSIS-68 (dozen per pack).

Prevention of Heat Stress Disorders

Educate and train workers on ways to prevent heat-related illness, to recognize the signs and symptoms of heat-related illnesses, and how to respond. Encourage workers to drink plenty of water (about a cup of cool water every 15 to 20 minutes), and to avoid coffee, tea, alcohol, and caffeinated soft drinks that dehydrate the body. Encourage workers to wear lightweight, light-colored, loose-fitting clothing. If clothes become completely saturated, workers should change into dry clothing. It is suggested the break area be cooler than the work environment.

Cold Stress

Workplace temperatures below 61° F may result in exposures to cold stress. The actual development of cold-stress related disorders will depend on conditions such as air temperature, air speed, the insulating value of clothing, the duration of the exposure, and the environment (e.g., exposure to wet conditions). Cold-related illness can slowly overcome a worker who has been chilled by low temperatures, brisk winds, or wet clothing.

Some FSIS inspectors may have processing assignments in areas which are maintained at or below 40°F. Also, FSIS inspectors may be required to enter walk-in freezers and coolers.

Cold Stress Disorders: Frostbite and Hypothermia

Frostbite and hypothermia are two cold stress disorders. Frostbite is more common, and is a result of freezing of the extracellular fluid in the skin. Hypothermia is the most dangerous cold stress disorder, and is a result of abnormally low core body temperature (at or below 95°F).

Frostbite:
Frostbite usually occurs on the extremities, such as the fingers, toes, ears and nose. Initially, pain occurs at the afflicted site. As nerves become damaged, the pain subsides, and skin becomes hard and numb. Affected tissue becomes pale and white or grayish in color. Although frostbite is not life-threatening, tissue damage can be severe and permanent. Prompt medical attention is required. Move the victim to a warm, dry area, remove any wet or tight clothing that may affect blood flow to the affected area, do not rub the affected area, and place the affected area in a warm (105°F) water bath to slowly warm the tissue. Do not pour warm water directly on the affected area. Warming the tissue too fast will cause tissue damage.

Hypothermia:
Symptoms of hypothermia include uncontrollable shivering, intense feelings of cold, fatigue or drowsiness, cool, bluish-color skin, falling blood pressure, and an irregular heartbeat. Victims become incoherent and clumsy in their movements. If you recognize someone experiencing these symptoms, call for emergency help immediately. Move the person to a warm, dry area, remove wet clothing, and replace with warm, dry clothing or blankets. Care should be taken to gently warm the victim to prevent cardiovascular problems. Do not rub the victim's body or place them in a warm water bath. Keep the feet elevated and the trunk warm to protect against shock. Circulatory and ventilatory function may be compromised. As a result, cardiopulmonary resuscitation may be needed. The victim's pulse and breathing should be checked periodically.

FSIS Cold Stress Management Program

Currently there is no specific OSHA standard or FSIS directive for cold stress. However, OSHA may cite Federal agencies for cold stress violations under 29 CFR 1960.8 (a). The FSIS Cold Stress Management Program consists of providing awareness training and freezer and cooler attire.

Freezer PPE is supplied by the MMSC. Six sizes of each of the following are available:

- Freezer Coat, Full-Length, Breast Pocket, Side Seam Openings for Access to Pants Pockets, Rated to -30° F
- Freezer Jacket, Cold Room Jacket, Waste Length with Sleeves, Breast Pocket, 2 Insulated Hand-warmer Pockets
- Freezer Vest, Cold Room Sleeveless Vest, Waste Length, Breast Pocket, 2 Insulated Hand-warmer Pockets, Rated -0° F

Prevention of Cold Stress Disorders

Train workers to recognize the signs and symptoms of cold-related illness, and how to respond. Avoid exposure to extreme cold (-13°F or below) or moderate cold (5°F or below) with high wind (25 mph or greater) i.e., wind-chill effective temperatures of 60°F and below increase the risk of frostbite and hypothermia. Avoid contact with cold metal (metallic surfaces below 32°F) or liquids of low vapor pressure, such as alcohol or cleaning fluids. These can increase the possibility of frostbite. Also it is important to select the proper insulating clothing specific to the working conditions (cold, wet, windy), layer clothing to adjust to changing environmental temperatures, and wear a hat and gloves, in addition to underwear that will keep water away from the skin. Dry or replace wet clothing.

Module 14: Safety Signs and Tags

Specifications for Accident Prevention Signs and Tags, OSHA Standard 29 CFR 1910.145, require employee instruction on danger, caution and safety signs. There is no FSIS directive on this subject. This section provides an overview on safety colors, symbols and labels.

Colors used for Safety Symbols:

Red – Fire, danger, and stop
Orange – Warning
Yellow – Caution
Green – Safety
Blue – Notice

Safety Symbols

Triangle or diamond-shaped signs
- Hazard alerts
- Orange or yellow in color

Mandatory action symbols
- Inform of some type of necessary action
- Circular shape, blue in color

Square or rectangular signs
- Provide general safety information
- Green in color

Symbol within a circle with a slash going from upper left to lower right
- Denotes prohibited action

Safety Labels

Hazard communication labels
- Denote flammability, health effects, reactivity, special hazards
- Provided in a variety of formats
- OSHA Hazard Communication GHS Pictograms:

HCS Pictograms and Hazards

Health Hazard  • Carcinogen • Mutagenicity • Reproductive Toxicity • Respiratory Sensitizer • Target Organ Toxicity • Aspiration Toxicity	**Flame**  • Flammables • Pyrophorics • Self-Heating • Emits Flammable Gas • Self-Reactives • Organic Peroxides	**Exclamation Mark**  • Irritant (skin and eye) • Skin Sensitizer • Acute Toxicity (harmful) • Narcotic Effects • Respiratory Tract Irritant • Hazardous to Ozone Layer (Non-Mandatory)
Gas Cylinder  • Gases Under Pressure	**Corrosion**  • Skin Corrosion/ Burns • Eye Damage • Corrosive to Metals	**Exploding Bomb**  • Explosives • Self-Reactives • Organic Peroxides
Flame Over Circle  • Oxidizers	**Environment** (Non-Mandatory)  • Aquatic Toxicity	**Skull and Crossbones**  • Acute Toxicity (fatal or toxic)

National Fire Protection Association

Legend

Number Code:
- 4 - Extreme
- 3 - High
- 2 - Moderate
- 1 - Slight
- 0 - Insignificant

Color Code:
- Red - Fire hazard
- Yellow - Reactivity
- White - Specific hazard
- Blue - Health hazard

Hazardous Materials Identification System:

Piping labels

- Flammable, chemically reactive, radioactive, hot, cold – yellow in color
- Liquid, non-flammable mixtures – green in color
- Gaseous mixtures – blue in color
- Fire-quenching materials – red in color

Module 15: Zoonotic Diseases

Zoonotic diseases are diseases and infections that are naturally transmitted between vertebrate animals (including their carcasses and by-products) and man. Currently there is no OSHA standard or FSIS directive for zoonotic diseases. Although a review of CA-1 and CA-2s over a 5-year period have demonstrated a very low potential for exposure to zoonotic diseases among the FSIS workforce (based on only a few documented cases), information regarding zoonotic diseases in the workplace is provided to FSIS employees. This includes precautions to be taken and the awareness needed to reduce the potential of a FSIS employee contracting a zoonotic disease in the workplace.

In 2017, FSIS issued a Notice that addresses the hazards of brucellosis in the workplace. See FSIS Notice 34-17.

Diseases of concern to FSIS employees working in red meat and/or poultry plants include Anthrax, Avian Influenza, Brucellosis, Bovine Spongiform Encephalitis (BSE), Q-Fever, Tuberculosis, Tularemia, and West Nile Virus, Brucellosis, Zika, Rabies and Psittacosis.

Typical Symptoms

Many zoonotic diseases cause symptoms that are non-specific and influenza-like. General symptoms can include fever, chills, malaise, headache, muscle and joint pain, and fatigue. Early diagnoses and treatment are important to keep many zoonoses from progressing into a more severe stage. Therefore, it is important that the examining physician be made aware of your occupation and type of workplace, as well as any potential contact with animals or animal products that might be infected with a zoonotic disease.

Protective Measures

The main mode of transmission for many zoonoses and greatest potential risk of exposure to zoonoses for FSIS employees is from contact with tissue, blood, and bodily fluids of infected animals. Therefore, FSIS inspectors and veterinarians should protect their eyes, nose, mouth and any open cuts against exposures to potentially infected tissues or fluids. Face Shields at the MMSC are available upon approval. For example, open cuts should be covered with a waterproof bandage. Gloves should be worn to reduce direct contact, and safety glasses or a face shield should be worn when the potential for a significant exposure to splashes or tissue spatter exists. In addition, practice good personal hygiene; wash hands after contact and do not touch face, eyes, nose or mouth with contaminated hands or gloves.

Module 16: Egress

Introduction
Emergency egress is extremely important. In 1991, twenty-five plant workers were killed in a fire at a poultry plant in Hamlet, North Carolina due to locked/blocked emergency exits. The Wikipedia page for the incident is found at this URL:
https://en.wikipedia.org/wiki/Hamlet_chicken_processing_plant_fire

FSIS addresses the requirements for emergency egress in Directive 4791.16 Section XI.

Exit Doors.

a. Workplace exits are identified with readily visible, internally or externally illuminated "Exit" signs. Any door, passage, or stairway that is not an exit will have a "Not an Exit" sign.

b. Exit doors are **always unlocked** when the building **is occupied**.

c. Locks or latches are used on exit doors in occupied buildings **only** under one of the following conditions:

1) Building is protected by an operable automatic fire detection system or an operable automatic sprinkler system either of which unlocks the doors automatically when the system is actuated.

2) Doors are secured by panic and fire exit hardware.

3) Doors are secured by a latch that is operable with a single releasing motion. The force to release the latch may not exceed 15 lbf. Seals to secure a latch that meet the 15 lbf., or less requirement are available from commercial sources.

NOTE: Numbered company seals, which plant management uses to secure unborn animal handling areas when visual supervision by inspection personnel does not meet the 15 lbf. or less requirement.

Regulatory Reference

Information can also be found on the OSHA website at:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10620

Further information is also available on the Inside FSIS Safety website at:
https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=ExitSigns3439

Module 17: Workplace Inspections

Workplace inspections are required by 29 CFR 1960 and FSIS Directive 4791.1.

Inspections are completed annually by the IIC using FSIS Form 4791-23 and 4791-24.

The Quick Guide is not required but could be used as a helpful tool for the FSIS Safety Program elements if needed (see Appendix 1).

Module 18: OSHA Record Keeping
(excerpts from OSHA training module)

What Forms are Completed?

- OSHA Form 300 – Log of Work-Related Injuries and Illnesses
- OSHA Form 301 – Injury and Illness Incident Report
- OSHA Form 300A – Summary of Work-Related Injuries and Illnesses

What is Work Related?

- *Cases caused by events or exposures in the work environment*
- *Cases contributed to by events or exposures in the work environment*
- *Cases significantly aggravated by events or exposures in the work environment*

What are the severity criteria for recording a work-related injury or illness?

- *Death*
- *Loss of consciousness*
- *Days away from work*
- *Restricted work activity or job transfer*
- *Medical treatment beyond first aid*

Other Reporting Criteria

- Significant diagnosed injury or illness
- Needlestick and sharps injuries – section 1904.8 (PDF)
- Medical removal – section 1904.9 (PDF)
- Hearing loss – section 1904.10 (PDF)
- Tuberculosis – section 1904.11 (PDF)

Resources

- *Recordkeeping web page (https://www.osha.gov/recordkeeping)*
- *Q&A Search web page (https://www.osha.gov/recordkeeping/faq_search/index.html)*
- *Local OSHA Offices https://www.osha.gov/html/RAmap.html)*
- *E-correspondence/Contact us (https://www.osha.gov/html/Feed_Back.html)*

Module 19: Safety and Health Committees

FSIS Policy

Safety and health committees are allowed at Federal agencies in accordance with Executive Order 12196 and 29 CFR 1960.36 to 1960.41. Certified safety and health committees have special benefits and requirements. USDA does not have recognized certified safety and health committees. In October 2002, FSIS Labor Management Agreement superceded the current FSIS Directive 4791.1, Part 2. FSIS policy regarding safety and health committees is found in article 9, section 5 of the Agreement, and provides for non-certified Circuit level safety and health committees. The Agreement also specifies committee composition, meetings and expenses. A committee should consist of two union members and at least one agency representative. Meetings are to be held semi-annually, and travel and per diem expenses will be paid for by safety committee union representatives within the circuit.

Training

According to 29 CFR 1960.58, supervisors should receive training regarding the FSIS Safety and Health Program, general industry standards applicable to the assigned workplaces, agency procedures for reporting hazards, agency procedures for reporting and investigating allegations of reprisal, agency procedures for the abatement of hazards, and other appropriate rules and regulations.

According to 29 CFR 1960.59, employees should be given specialized job safety and health training appropriate to the work they perform, the FSIS Safety and Health Program, and FSIS employee rights and responsibilities.

Injury and Illness Reports

Requirements for the injury illness log and summary of occupational injuries and illnesses are found in 29 CFR 1960.67 and 1960.69, respectively. FSIS Directive 4791.13 provides guidance. Each FSIS workplace should maintain a log of all occupational injuries and illnesses that occur at that establishment. Log entries should be made within six days of the injury and/or illness.

The ESHG also maintains monthly Injury and Illness reports. They are available from the FSIS intranet at this URL:

https://inside.fsis.usda.gov/fsis/emp/static/centerContent/fsisPage.jsp?keyword=SafetyReport7611

Module 20: OSHA Inspections

If OSHA is at the establishment for any reason, the supervisor should:

- Notify the Occupational Safety and Health Specialist
- Notify the Frontline Supervisor (or DM)

OSHA must conduct an opening conference

The ESHG must be included in the opening conference meeting either in person or by phone.

OSHA Phone #: 800-321-OSHA (6742)

Employees may contact OSHA for any reason however, the ESHG should be consulted to resolve safety related issues.

Appendix 1: Quick Guide Checklist for FSIS Safety Program

Hazard Communication

- ☐ Signed Attachment I
  - Directive 4791.5, Attachment 1 (include FSIS and Establishment)
    - Note: typo on the document has two entries for FSIS
  - Write in location of Safety Data Sheet library
- ☐ List of chemicals in the USDA office
  - Antimicrobials, refrigerants (including dry ice/CO_2), and sanitizers
- ☐ Chemicals labeled correctly
- ☐ Include chemical monitoring system (if applicable) on FSIS form 4791-21
- ☐ Include chemical release alarm systems (if applicable) on FSIS from 4791-21
- ☐ Documented Training for IPP
  - One time - Read Safety Data Sheets (SDS) for chemicals IPP may be exposed to
  - Use Health Hazard Information Sheets (HHIS) when possible (see link below)
    - For example, use HHIS for peroxyacetic acid instead of SDS when training

Occupant Emergency Plan

- ☐ FSIS Form 4791-21 completed
- ☐ Documented training
  - One-time training for all IPP (including relief)

Hearing Conservation Plan

- ☐ Annual hearing test
- ☐ One-time FSIS Form 4791-20 noise level form complete
  - Update only as needed when changes warrant a new survey
- ☐ Documented training
  - Annual Hearing Conservation training (link below)

LOTO

- ☐ Annual review (IPS)
  - Record name, date, equipment viewed
  - Use equipment specific procedure from establishment during review
- ☐ Cooperative agreement signed (current FSIS and establishment management)

- ☐ Location of equipment specific procedures (page 3 H.3.)
- ☐ Floorplan/Schematic (identifies each piece of equipment and energy isolation point)
- ☐ Documented Training
    - o One time general - AgLearn lockout/tagout course
    - o One time site specific – Read cooperative agreement, review floorplan/schematic.

Personal Protective Equipment

- ☐ PPE available for IPP
- ☐ Documented training
    - o Proper use of PPE (New employees or when new PPE is introduced – link below)

Annual Inspection

- ☐ FSIS Form 4791-23 (office inspection)
- ☐ FSIS Form 4791-24 (establishment inspection)

Safety Committee

- ☐ Safety committee meeting held twice annually (Calendar Year)
- ☐ Safety committee meeting notes posted (FSIS Form 4791-2)
- ☐ Safety committee inspections completed (FSIS Forms 4791-23 and 4791-24)

OSHA Record Keeping

- ☐ OSHA form 300A posted February 1 – April 30 (Previous Calendar Year)
- ☐ OSHA recordable injuries captured on OSHA forms 300 and 301

OSHA Poster - Occupational Safety and Health Specialist

- ☐ OSHA poster available with Occupational Safety and Health Specialist (OSHS) contact information

Training Records

- ☐ Training recorded and maintained for 5 years

Appendix 2: Quick Guide Resources

Hazard Communication
Directive 4791.5
Health Hazard Information Sheets (e.g.; PAA, carbon dioxide, ammonia refrigerant)

Occupant Emergency Plan
FSIS Form 4791-21

Hearing Conservation Plan
Annual training material
Hearing test resources/required payment form
FSIS Form 4791-20

Lockout/Tagout
Directive 4791.11
Word version of Cooperative Agreement

Personal Protective Equipment
Directive 4791.1 Section XI
Training material

Annual Inspection
FSIS Forms 4791-23 and 4791-24

Safety Committee
Training Information 4791.1 Section VIII.F. and Section IX.
FSIS Form 4791-Safety Committee Minutes

OSHA Record Keeping
OSHA Forms 300, 300A, 301 and resource page

OSHA Poster
OSHS contact information posters

Training Records
Directive 4791.1 Section IX.E
FSIS Form 3530-12

Appendix 3: FSIS Directives

Directive 3410.6, Reimbursement Provisions for Inspection Expenditures

Directive 4791.1, Rev. 3 Basic Occupational Safety and Health Program

Directive 4791.3, Use of Formaldehyde in Laboratory Samples

Directive 4791.5, Hazard Communication Program

Directive 4791.6, Emergency Procedures in the Workplace

Directive 4791.7, Monitoring Employee Exposure to Occupational Radiation

Directive 4791.8, Air Contaminants Safety Awareness Program

Directive 4791.11, Lockout/Tagout Safety Procedures

Directive 4791.12, Reporting and Correcting Occupational Hazards

Directive 4791.13, Workplace Inspections and Injury, Illness and Motor Vehicle Incident Reporting

Directive 4791.15, Radiation Safety Program

Directive 4792.1, First Aid

Appendix 4: Annual Safety Requirements

LOCKOUT / TAGOUT

TRAINING – Refer to FSIS Directive 4791.11, Rev.1, Part IX. Training must be provided prior to performing pre-operational process verification inspection or verification of pre-operational or operational corrective action.

INSPECTION – Refer to FSIS Directive 4791.11, Rev. 1, Part XII. An inspection of the energy control procedures must be conducted annually

RETRAINING – Refer to FSIS Directive 4791.11, Rev. 1, Part XII.
Retraining must be provided whenever a change occurs in the employee's job assignment, machines, equipment or processes or energy procedures. Additional training is also required if the annual inspection reveals a deviation or inadequacy in the employee's knowledge or use of the approved procedure.

HEARING CONSERVATION

NOISE MONITORING—Refer to FSIS Directive 4791.1, Rev. 3, Part Three and OSHA Standard 29 CFR 1910.95. Monitoring must be repeated whenever a change in production processes, equipment, or controls increases noise exposures.

AUDIOMETRIC TESTING—Refer to OSHA Standard 29 CFR 1910.95. Annual audiometric testing must be offered to inspection personnel who work in environments that are at or exceed 85 decibels at any point during the work shift.

ANNUAL TRAINING—Refer to OSHA Standard 29 CFR 1910.95. Annual training must be provided to inspection personnel who work in environments that are at or exceed 85 decibels at any point during the work shift.

WORKPLACE SAFETY AND HEALTH INSPECTIONS

OFFICES—Refer to FSIS Directive 4791.13, Part one. Conduct annual office safety and health inspection using Form 4791.23, Safety and Health Inspection Checklist for Office Facilities and post on bulletin board.

PLANT FACILITIES—Refer to FSIS Directive 4791.13, Part one. Conduct annual plant facility safety and health inspection using Form 4791.24, Safety and Health Inspection Checklist for Plant Facilities and post on bulletin board.

OSHA Log 300A

OSHA 300A Posted from February 1 to April 30.

HAZARD COMMUNICATION PROGRAM TRAINING

Refer to FSIS Directive 4791.5, Part V. Training must be provided to each employee who is exposed to or is potentially exposed to hazardous chemicals. Additional training must be provided whenever a new hazardous chemical is introduced to the work area.

OCCUPANT EMERGENCY PLAN TRAINING

Refer to FSIS Directive 4791.6, Rev. 2, Part XVI. Training must be provided when the plan is first developed; when new employees, relief employees and visitors come to the workplace; when new equipment, materials, or processes are introduced; and when emergency procedures are updated or changed.

Appendix 5: OSHA Safety Poster

Occupational Safety and Health Protection for Employees of the United States Department of Agriculture Food Safety and Inspection Service (FSIS)

The Occupational Safety and Health Act of 1970, Executive Order 12196 and 29 CFR 1960 require the heads of Federal agencies to furnish to employees places and conditions of employment that are free from job safety and health hazards.

FSIS Responsibilities

1. General Requirements
The FSIS Administrator will furnish employees places and conditions of employment that are free from on-the-job safety and health hazards.

2. OSHA Regulations
FSIS will comply with applicable regulations of the Occupational Safety and Health Administration (OSHA).

3. Reporting Hazards
FSIS will respond to employee reports of hazards in the workplace.

4. Workplace Inspections
FSIS will insure that each workplace is inspected annually for hazardous conditions. FSIS will post Notices of Unsafe or Unhealthful Working Conditions found during the inspections for a minimum or three working days, or until the hazard is corrected, whichever is later.

5. Correction of Unsafe Conditions
FSIS will take prompt action to assure that hazardous conditions are eliminated. Imminent danger conditions will be corrected immediately.

6. Safety and Protective Equipment
FSIS will acquire, maintain, and require use of appropriate protective and safety equipment.

7. Safety and Health Training
FSIS will provide occupational safety and health training for employees.

8. Reporting Accidents, Injuries and Occupational Illnesses
Supervisors must submit a supervisor's report of accidental injury/illness for all work-related accidents, injuries or occupational illnesses experienced by employees under their supervision.

9. Safety and Health Committees
FSIS will support safety and health committees that are formed from management and employee representatives.

Employee Responsibilities

1. Compliance with Standards
Employees shall comply with all OSHA and approved FSIS occupational safety and health standards, policies, and directives.

2. Safety and Protective Equipment
Employees shall use appropriate protective and safety equipment provided by FSIS.

Rights of Employees and Their Representatives

1. Participation in Safety and Health Program
Employees and their representatives shall have the right to participate in the FSIS Safety and Health Program. Employees shall be authorized official time for these activities.

2. Access to Records and Documents
Employees and their representatives shall have access to copies of applicable OSHA and other recognized standards and regulations; FSIS safety and health policies and directives; accident, injury, and illness statistics of FSIS.

3. Reporting Hazards
Employees and their representatives shall have the right to report unsafe or unhealthful working conditions to appropriate officials and to request an inspection of the workplace. The name of the employee making the report will be kept confidential if requested.

4. Freedom from Fear of Reprisal
Employees and their representatives are protected from restraint, interference, coercion, discrimination, or reprisal for exercising any of their rights under the FSIS Safety and Health Program.

Responsible Officials

The Designated Agency Safety and Health Official (DASHO) for FSIS is:

Office of Management (OM),
Assistant Administrator
Office: (202) 720-4425
Washington, DC 20250

The Safety and Health Designee for this workplace is:

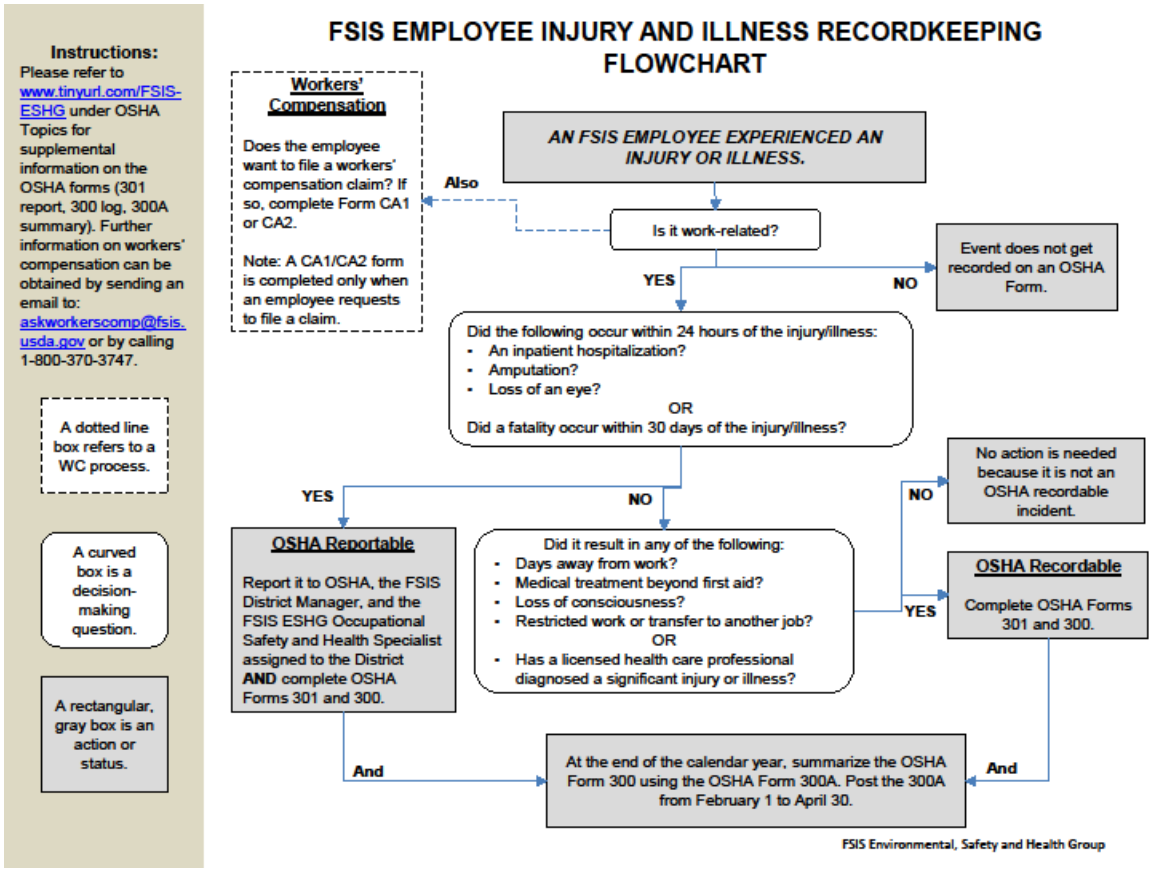
Curtis Wallis
Occupational Safety and Health Specialist (OSHS)
800 Buchanan St.
Albany, CA
Office: 510-769-5750
Cell: 240-472-5006
Fax: 510-982-4998
Email: curtis.wallis@fsis.usda.gov

Further Information

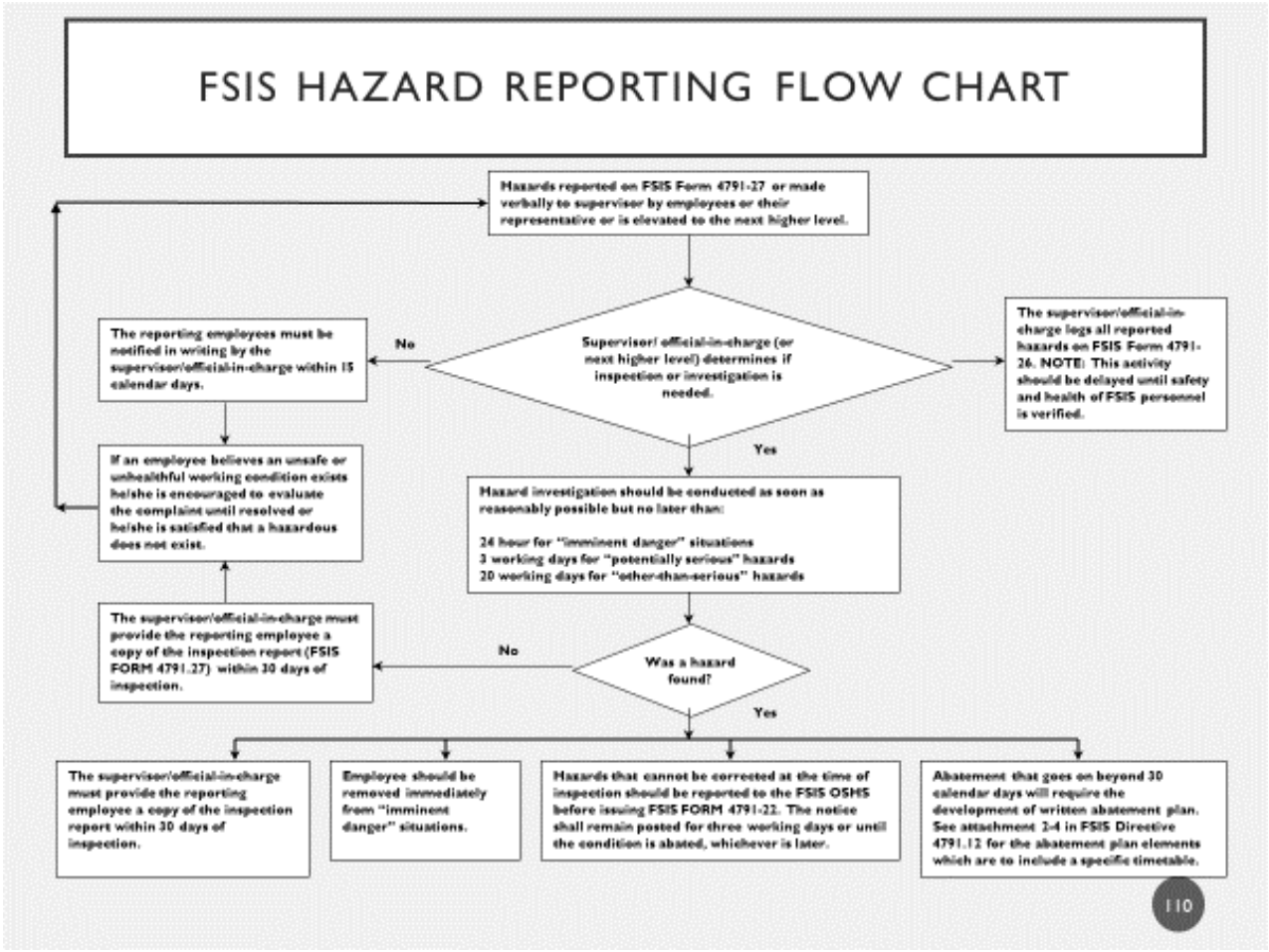
This notice highlights the FSIS employee job safety and health program. More information about the FSIS program or its standards and procedures may be obtained from the workplace Safety and Health Designee.

09/20/2011

Appendix 6: OSHA Recordkeeping Flowchart



Appendix 7: Hazard Reporting Flowchart



Human Resource Basics

PERFORMANCE MANAGEMENT

Performance standards are established for each position in FSIS. The supervisor must provide each employee with a performance plan "Performance Plan, Progress Review and Appraisal Worksheet" form AD435 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, and discusses the employee's performance with regard to each element in the performance plan at both the mid-year and annual reviews. The employees sign their performance plan at the beginning of the appraisal period, at the mid-year review and at the end of appraisal period. Ongoing communication is maintained with at least one progress review midway in the rating cycle.

Supervisors are obligated to advise an employee when his/her 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
- Placing the employee in a Performance Improvement Plan (usually for 60-90 days); at the end of which the employee improves, is removed, or is demoted.

Note: See directive 4040-430 for detailed information on performance management. https://www.ocio.usda.gov/sites/default/files/docs/2012/DR-4040-430_Performance_Mgmt_Final_2013_09_30.pdf).

PROBATIONARY EMPLOYEES

Newly hired federal employee 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 the Labor and Employee Relations Division 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 the Labor and Employee Relations Division.

OFFICIAL PERSONNEL FOLDER

OPF is the common acronym for *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 form, 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. In FSIS, the field employee OPF is physically located in the Human Resources Field Office, Minneapolis, MN. Your OPF follows you throughout your career with the Federal government. When you are not employed by a Federal Agency, your OPF is kept at the National Personnel Records Center. The OPF is subject to the Privacy Act. You and your supervisor can review it; however, others must have the written permission from you to review the file.

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) increases to the GS Pay Scale 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, would receive 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 (WGI) are regularly occurring pay increases given to General Schedule (GS) employees in Grades 1-15 (See OPM.GOV).

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 get the Labor and Employee relations Division involved 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 Performance Improvement Plan (PIP), usually 60-90 days.

WGI DIRECTIVE

If an employee's performance improves during the PIP, the WGI is granted retroactively to the initial due date. The employee will receive an initial "lump sum" reflecting the amount of the WGI withheld during the PIP; and then, the regular amount thereafter.

(See FSIS Directive 4531.1 for detailed information on WGI procedures.) Specific instructions for withholding WGI's for bargaining unit employees can be found in this Directive and in the Labor Management Agreement.

STAFFING METHODOLOGY

Staffing levels are determined by Office of Field Operations management personnel by assessing the workload in a plant. 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 a plant occurs, the District sends Form SF-52 to the Human Resources Field Office to initiate the re-staffing process.

USE OF INTERMITTENTS (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 and/or District Office 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 District Office, 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. Intermittents are only eligible to work 1280 hours per year and are hired on an on-call basis.

Intermittents 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. Intermittents are provided on-the-job training at the plant 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 he/she 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 following website: Veterinary Opportunities.
There are also regularly occurring articles in The Beacon (which is distributed to FSIS employees by e-mail) on career paths in FSIS.

Supervisors should seek advice from their manager on how to counsel subordinates. There is an FSIS Career Guide and an FSIS Leadership Career Guide available on the Intranet at https://inside.fsis.usda.gov/fsis/emp/static/employee/career/career.jsp that can help Agency employees plan and develop their careers. Supervisors can assist direct reports by reviewing job applications of inspectors, 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 (*www.usajobs.gov*) and submit an application. A "Vacancy Announcement" is prepared and distributed which advertises a vacant position, with a request for all qualified applicants. Supervisors in plants are required to post vacancy announcements received from the Human Resources Field Office on the bulletin board in the Government Office. 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 "FSIS Wide", only FSIS employees can apply; if it is "Government Wide", all federal employees can apply; if it is "All Sources", 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, D.C. Applicants submit a resume 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 within the area of consideration contained on the vacancy announcement.
- Be evaluated based on the vacancy requirements (e.g. degrees, knowledge, skills, and abilities) stated in the vacancy announcement.
- Rate high enough to be included among the "best qualified" group that is referred to the hiring manager on a certification of eligible applicants or "cert" for selection consideration.

The Human Resources Office will

- Screen each application for basic eligibility (to determine if the applicant's background meets the experience and education requirements described in the vacancy announcement).
- Identify which qualified applicants have to 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 (applicants' scores are not given to the manager).
- Refer "best qualified" applicants to the manager for selection consideration. There is no exact number of applicants referred to the manager; it depends on a variety of factors such as how close the applicants are in terms of their qualifications. (When more than 10 applications are received, a panel is convened to review each applicant's qualifications to determine which applicants are the "best qualified". Additionally, other factors such as special hiring authorities, applicants with veteran's preferences, etc., will factor into the number of candidates that appear on a promotion certificate.)

Managers can select from the “best qualified” list, or 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

Recommending Officials (RO) may interview all, some, or none of the applicants. If the RO conducts 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.

ETHICS

If you have any questions concerning an ethical matter, you can consult the FSIS Directive on Employee Responsibilities and Conduct, seek advice and guidance from your supervisor, and/or an Employee Relations Specialist in the Labor and Employee Relations Division to resolve conflicts of interest. You can also contact a U.S. Department of Agriculture Ethics Advisor at https://www.ethics.usda.gov/advisor.htm Some of the more common questions deal with the following concerns:

- Because of our regulatory role in official establishments, bribery situations can and do occur. FSIS employees should immediately contact the USDA Office of the Inspector General (OIG) immediately (without disclosing this information to the person offering the bribe). OIG will provide instructions on how to proceed.

- Conflicts of interest do occur and must be addressed. There can be financial conflicts of interest, family member conflicts, outside employment conflicts, etc.

- Misuse of office, a recurring example at the in-plant level, is the use of a Federal inspection badge for purposes not related to official duties. (For example, an employee displays a badge to a law enforcement official to avoid a speeding ticket.) FSIS strictly enforces the policy of disciplining employees for all types of misuse of office.

- Employees cannot use government property for any reason unrelated to official government business.

References:

- Standards of Ethical Conduct for Employees of the Executive Branch, 5 Code of Federal Regulations (CFR) Part 2635 and Executive Order 12674
- FSIS Directive 4735.3, Employee Responsibilities and Conduct

WORK UNIT MEETINGS

In-plant work unit meetings are an opportunity to discuss new policies, conduct training, correlate procedures and solicit the concerns of the group. They are usually conducted when plant is on down time. However, if overtime proves to be necessary, be sure to get pre-approval from your frontline supervisor, since expenditure of funds is involved. Some work unit meetings are initiated by the District Office or the Frontline Supervisor, 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. The types of training normally conducted during this time include ethics, sexual harassment, or workplace violence.

Workshop - Food Inspector Performance Standards (On-line)

Scenario 1 Food Inspector Performance Standards:

Break up into pairs. Role play setting standards. One person plays the supervisor, the other plays the inspector; then, switch.

Supervisor Role: (40 minutes total, 20/20)

1. Identify the type of plant (e.g. poultry slaughter, livestock slaughter, processing)
2. Identify the job of the inspector (e.g. head inspector, viscera inspector)
3. Role play-identify what is "meets" expectations for each element that applies. (not all may/will)-Note-it is shown in user's guide (meets). Then, let inspector ask questions. Sign and date the form.
4. Switch roles. (20 minutes)

Debrief:

Did you learn anything? _____

Tool: Food Inspector Performance Standards (On-line)

Scenario 2 Performance Elements

1. Individually (5 minutes) – Review the performance elements.
    a. List what you would do to meet expectations as stated.
    b. List what you would do to exceed the expectations.
2. Break up into groups of 4-5 (15 minutes) - Discuss what you came up with for exceeding expectations.
3. Remain in original groups (20 minutes) – Each group reports out.

Debrief: Large group

Are there any trends? _____

Tool: Food Inspector Performance Standards (Off-line)

OFFICE OF WORKERS' COMPENSATION PROGRAM (OWCP) IN FSIS

I. PURPOSE: The Federal Employee Compensation Act (FECA) provides medical and wage loss compensation benefits to civilian employees of FSIS for disability due to injury or disease sustained while in the performance of duty. The FECA is remedial in nature, and proceedings under it are non-adversarial.

II. OWCP STRUCTURE: The Division of Federal Employees' Compensation administers the FECA. This program is administered through the operations of twelve Department of Labor (DOL) District Offices. Each of these offices is headed by a District Director, Supervisory Claims Examiners and Claims Examiners.

BACKGROUND/OVERVIEW

III. FSIS STRUCTURE: All claims initiated by FSIS employees are sent to the Workers' Compensation Branch (WCB) of the Food Safety and Inspection Service. The WCB is located in Minneapolis, MN. The WCB consists of seven employees including the Branch Chief. The Claims Technicians are responsible for daily Case Administration. The Case Manager and Case Specialists are responsible for Case Management.

IV. ESTABLISHING A BEST PRACTICE OWCP PROGRAM IN FSIS: Research in the Workers' Compensation arena shows there are five major areas that need focus in order to have a successful, well run workers' compensation program.

A. Efficient Case Administration Program
B. Active Case Management Program
C. Strong Occupational Safety & Health Program
D. Effective Communication
E. Commitment from Top Management

V. CASE ADMINISTRATION PROGRAM: Responsible for the day-to-day receipt, review and submission of claim forms. In reviewing claim forms for Traumatic Injuries, CA-1, the WCB makes sure all pertinent information and material is provided, including date and time injury occurred, cause of injury, nature of injury, OSHA site code, FSIS Agency Code, Facility Code and other information. If the claim is for Occupational Injury/Illness, assures employee completes CA-2 and appropriate CA-35 Form, including all pertinent information, including date claimant first realized the disease or illness was caused by employment and how realized, nature of injury or illness, was injury/illness caused by third party. Reviews and monitors the use of Continuation of Pay, Code 67. Reviews and forwards CA-7, Claim for Compensation, CA-16, Authorization for Examination and/or Treatment, CA-17, Duty Status Report. As appropriate, initiates participation in the Work Hardening Program (WHP) and

Alternative Duty Program (ADP). Processes Leave Buybacks. Contacts appropriate OWCP offices to obtain information, and answers questions from claimants.

VI. CASE MANAGEMENT: Responsible for identifying and using return-to-work strategies, including job offers; tracking and improving FSIS activities under POWER, Protecting Our Workers and Ensuring Reemployment initiative; closely reviewing all chargeback costs; reviewing and tracking possible 3rd party recoveries; capturing cost avoidance data; promoting the use of ADP and WHP; monitoring claimants in Vocational Rehabilitation and improving fraud investigation activity.

VII. OCCUPATIONAL SAFETY & HEALTH PROGRAM: This is critical in the identification of workplace hazards and the prevention of workplace injuries and illnesses. Keep in mind that if you have a safety concern or one is brought to your attention and you need assistance in addressing it, you can contact through your supervisor the designated safety specialist that services your district.

VIII. EFFECTIVE COMMUNICATION: Our "Best Practice" OWCP Program puts emphasis on efficient and effective communication. This is done through attending various meetings in the field, publishing subject-matter Beacon Articles, and using the e-mailbox, "Ask Workers Comp."

IX. COMMITMENT FROM MANAGEMENT: A key for successful "Best Practice" OWCP Program is a commitment from Management. Their commitment is demonstrated by our Branch-level designation as well as our own budget and other dedicated resources.

X. PROTECTING OUR WORKERS & ENSURING REEMPLOYMENT (POWER) INITIATIVE: Signed by President Obama on July 19, 2010; will run from FY 11 – FY14 (Succeeds and expands the Safety, Health and Return to Employment (SHARE) initiative). Through the Department of Labor, Federal Agencies are directed to establish goals and track performance in seven areas:

1. *Reduce* injury/illness total case rates
2. *Reduce* injury/illness lost time case rates
3. *Analyze* lost time injury and illness data
4. *Increase* the timely filing of workers' comp claims
5. *Increase* the timely filing of wage loss claims
6. *Reduce* lost production day rates
7. *Increase* return to work rate for injured worker

XI. REVISED OWCP DIRECTIVE 4810.1 Revision 2, ON-THE-JOB INJURY AND ILLNESS COMPENSATION AND PREVENTION PROGRAM: Cancelled FSIS Directive 4610.8, Returning to Work after a Workplace Injury and FSIS Directive 4810.1, Injury Compensation (signed July 19, 2005). Covers a number of items including the responsibilities of Agency management, WCB, supervisors, employees, program offices, and others; the Presidential initiative, entitlements, claims management,

return-to-work and vocational rehabilitation, injury and illness prevention. Key points: Employee must give to supervisor within **48 hours of injury** the proper OWCP forms; and Supervisor needs to provide copies of these forms to the WCB within **24 hours** of receipt of the properly completed forms. (Fax or scan/email)

Any forms mentioned below are available on line at http://www.dol.gov/owcp/dfec **with the exception of the CA-16 (request CA-16 from the WCB). Also, copies are in Supervisor's Guide to Workers' Compensation (see CD). Check on line for CURRENT forms.**

XII. TRAUMATIC INJURY: A traumatic injury is defined as a wound or other condition of the body caused by external forces, including stress or strain. The injury must be identifiable by time and place of occurrence and member of the body affected; it must be caused by a specific event or incident or series of events or incidents within a single day or work shift.

A. Notice of Injury – Form CA-1. When an employee sustains a traumatic injury in the performance of duty, the employee should file a written report on Form CA-1. The form should be given to the supervisor within 48 hours of the date of injury. If the employee is incapacitated, someone acting on his or her behalf can file the form. The form must contain the original signature of the person giving notice. The supervisor should:

(1) Review the front of the form for completeness and accuracy, and obtain any missing information including a witness statement if available.

(2) If there is any factual evidence that the claim is questionable/not valid, it should be addressed in boxes 28-36. If the supervisor is challenging the validity of the claim, the supervisor should attach any written, factual, supporting documentation when submitting the forms to the WCB. (Provide a copy of the challenge with the CA-1 form to the employee).

(3) Complete and sign the reverse of Form CA-1, including the telephone number and forward it to the WCB within 24 hours.

(4) Advise the employee that Continuation of Pay (COP) must be supported by prima facie medical evidence and the employee has 10 days from the date of injury to get this medical information. Must also advise employee that FSIS has alternative duty/work hardening available. Give employee copy of Medical Provider letter to take to each physician advising physician of our return-to-work programs. The use of COP must be controverted if the claim is being challenged or the disability is a result of occupational disease or illness, the injury occurred off the employing premises and the employee was not engaged in official "off-premises" duties, the injury was caused by the employee's willful misconduct, the injury was not reported on the CA-1 within 30 days following the injury, and work stoppage first

occurred more than 45 calendar days following the injury. (Advise the employee if the use of COP is being controverted).

B. Continuation of Pay – Code 67. Used for traumatic injuries only. It runs for 45 calendar days and must be supported by medical evidence within 10 calendar days from the first visit and within 48 hours for any subsequent visits (medical, physical therapy). Weekends count toward the 45 calendar days. Any absence for a doctor's visit or physical therapy, even for 1 hour, counts as one calendar day and an employee should not use more than up to four hours for such a visit. Code 66, Administrative leave, is used for the remainder of the work shift during which the traumatic injury occurred. The 45 calendar days for COP would start the next day. The WCB will send an employee who is using COP a letter explaining pay options along with Form CA-7, approximately 14 days before the 45 calendar day period ends.

C. Authorization for Medical Treatment – Form CA-16. The supervisor completes the front of this form and gives it to the employee along with the medical provider letter (ADP/WHP) within four hours of the employee's request. When completing the front of this form, make sure a brief description of the injury is provided. Upon receiving medical care, the employee makes sure Part B Attending Physician's Report, is completed by the medical provider. This should be given to the supervisor who should forward it to the WCB in Minneapolis as soon as possible.

XIII. OCCUPATIONAL DISEASE: Is defined as a condition produced in the work environment over a period longer than one workday or shift. It may result from a systemic infection, repeated stress or strain, exposure to toxins, poisons, or fumes, or other continuing conditions of the work environment.

A. Notice of Occupational Disease – Form CA-2. When an employee sustains an occupational disease or illness, the employee should file a written report on Form CA-2. The form should be given to the supervisor within 48 hours of the employee realizing the illness or disease was caused by his/her employment. The supervisor should issue the employee two copies of the appropriate checklist, Form CA-35 A-H, for the disease claimed (To facilitate submittal of evidence, specific checklists have been devised for various conditions). The employee provides one copy to the physician to show what is needed on the medical report and one for the employee's use when writing up own statement to give to the supervisor. (See page 73 of the Supervisor's Guide to Workers' Compensation.) **The Agency should NOT issue Form CA-16, Authorization for Medical Treatment, for occupational diseases or illnesses.** If an employee misses work, the employee can use their own leave (subject to agency policy) or they may take LWOP. If the employee elects LWOP, the employee should complete Form CA-7 every pay period for which the employee is disabled due to the claimed work-related illness or injury. Employee should be made aware that there may be an interruption of pay if the claim is not yet accepted or there is missing medical evidence. This is why it is important that all supporting medical information should be sent to the WCB in Minneapolis. We

can then communicate to the DOL the key elements due to the illness or disease that would prevent the employee from performing their regular job duties. This will help insure the claim is processed as quickly as possible by DOL.

XIV. Form CA-7, Claim for Compensation. CA-7 is used to claim compensation for loss of wages, leave buy-backs, and schedule awards. If an employee stops work due to a work-related injury or illness/disease, employee may choose to have compensation paid to them by OWCP. OWCP will pay compensation at the rate of 66 2/3% (no dependents or spouse) or 75% (spouse living with them or dependents) federal tax free. The employee must be in non-pay status (LWOP) for the time the employee is claiming loss of wages. Any payment of OWCP compensation from a CA-7 must be supported by medical evidence. Any CA-7 initiated must be immediately submitted to Minneapolis to minimize the period when the employee is not receiving wages or compensation.

XV. Third Party Settlements. A third party refers to an injury or illness caused by a person or object which indicates there is legal liability on a party other than the U.S. Government to pay the damages. The U.S. Government has the right to recover any payments it made if the claimant collets money from another source. While a claim is pending against a third party, OWCP continues to provide the full range of medical and compensation benefits authorized by the law. In the event of recovery from the third party, the employee must first pay outstanding legal fees and then may retain 20% of the amount remaining. The government is then refunded the amount of medical and compensation payments made up to the time of settlement. Remaining monies belong to the claimant, but some of it may be used as credits against future possible expenses through OWCP.

XVI. Schedule Awards. OWCP will pay a claimant when there is permanent loss or loss of use of specified members, functions and organs of his/her body. Payment is made for a specified number of days or weeks according to the severity of the impairment. A scheduled award is paid when the medical evidence shows that the schedule part of the body has reached maximum medical improvement. A scheduled award is not allowed for impairment of the back, heart or brain. However, compensation is paid for wage loss associated with these body parts.

XVII. Contact Us. To contact the Workers' Compensation Branch our mailing address is:

USDA, Food Safety and Inspection Service
Office of Management
Human Resources Business Systems Division
Work Life Services Branch
920 2nd Avenue S., Suite 1300
Minneapolis, MN 55402
P. 1-800-370-3747 #
F. NEW 844-876-9473

Federal Employee's Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation

U.S. Department of Labor
Office of Workers' Compensation Programs

Employee: Please complete all boxes 1 - 15 below. Do not complete shaded areas.
Witness: Complete bottom section 16.
Employing Agency (Supervisor or Compensation Specialist): Complete shaded boxes a, b, and c.

Employee Data

1. Name of employee (Last, First, Middle)

2. Social Security Number: **111-11-1111**

3. Date of birth Mo. Day Yr.

4. Sex ☐ Male ☐ Female

5. Home telephone

6. Grade as of date of injury Level Step

7. Employee's home mailing address (include street address, city, state, and ZIP code)

XXXXXXXXXX

City: **XXXXXXXXXXXXXX** State: **DC** ZIP Code: **11111**

8. Dependents
☐ Wife, Husband
☐ Children under 18 years
☐ Other

Description of Injury

9. Place where injury occurred (e.g. 2nd floor, Main Post Office Bldg., 12th & Pine)

10. Date injury occurred Mo. Day Yr.

Time ☐ a.m. ☐ p.m.

11. Date of this notice Mo. Day Yr.

12. Employee's occupation

13. Cause of injury (Describe what happened and why)

14. Nature of injury (Identify both the injury and the part of body, e.g., fracture of left leg)

a. Occupation code

b. Type code

c. Source code

OWCP Use - NOI Code

Employee Signature

15. I certify, under penalty of law, that the injury described above was sustained in performance of duty as an employee of the United States Government and that it was not caused by my willful misconduct, intent to injure myself or another person, nor by my intoxication. I hereby claim medical treatment, if needed, and the following, as checked below, while disabled for work:

☑ a. Continuation of regular pay (COP) not to exceed 45 days and compensation for wage loss if disability for work continues beyond 45 days. If my claim is denied, I understand that the continuation of my regular pay shall be charged to sick or annual leave, or be deemed an overpayment within the meaning of 5 USC 5584.

☑ b. Sick and/or Annual Leave

I hereby authorize any physician or hospital (or any other person, institution, corporation, or government agency) to furnish any desired information to the U.S. Department of Labor, Office of Workers' Compensation Programs (or to its official representative). This authorization also permits any official representative of the Office to examine and to copy any records concerning me.

Signature of employee or person acting on his/her behalf _____ **Date** _____

Any person who knowingly makes any false statement, misrepresentation, concealment of fact or any other act of fraud to obtain compensation as provided by the FECA or who knowingly accepts compensation to which that person is not entitled is subject to civil or administrative remedies as well as felony criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment or both.

Have your supervisor complete the receipt attached to this form and return it to you for your records.

Witness Statement

16. Statement of witness (Describe what you saw, heard, or know about this injury)

Name of witness: **XXXXXXXXXXXX** Signature of witness Date signed

Address City State ZIP Code

Form CA-1
Rev. Apr. 1999

Official Supervisor's Report: Please complete information requested below:

Supervisor's Report

17. Agency name and address of reporting office (include street address, city, state, and ZIP code): XXXXXXXX

OWCP Agency Code: XXXXXX

XXXXXXXXX

OSHA Site Code:

City: XXXXXXXXX State: DC ZIP Code: 11111

18. Employee's duty station (include street address, city, state, and ZIP code): XXXXXXXXXXXXXX City: XXXXXXXXXX State: DC ZIP Code: 11111

19. Employee's retirement coverage ☐ CSRS ☐ FERS ☐ Other, (identify)

20. Regular work hours From: ☐ a.m. ☐ p.m. To: ☐ a.m. ☐ p.m.

21. Regular work schedule ☐ Sun. ☐ Mon. ☐ Tues. ☐ Wed. ☐ Thurs. ☐ Fri. ☐ Sat.

22. Date of Injury Mo. Day Yr.

23. Date notice received Mo. Day Yr.

24. Date stopped work Mo. Day Yr. Time: ☐ a.m. ☐ p.m.

25. Date pay stopped Mo. Day Yr.

26. Date 45 day period began Mo. Day Yr.

27. Date returned to work Mo. Day Yr. Time: ☐ a.m. ☐ p.m.

28. Was employee injured in performance of duty? ☐ Yes ☐ No (If "No," explain)

29. Was injury caused by employee's willful misconduct, intoxication, or intent to injure self or another? ☐ Yes (If "Yes," explain) ☐ No

30. Was injury caused by third party? ☑ Yes ☐ No (If "No," go to item 32.)

31. Name and address of third party (include street address, city, state, and ZIP code): XXXXXXX

City State ZIP Code

32. Name and address of physician first providing medical care (include street address, city, state, ZIP code)

City State ZIP Code

33. First date medical care received Mo. Day Yr.

34. Do medical reports show employee is disabled for work? ☐ Yes ☐ No

35. Does your knowledge of the facts about this injury agree with statements of the employee and/or witnesses? ☐ Yes ☐ No (If "No," explain)

36. If the employing agency controverts continuation of pay, state the reason in detail.

37. Pay rate when employee stopped work $ Per

Signature of Supervisor and Filing Instructions

38. A supervisor who knowingly certifies to any false statement, misrepresentation, concealment of fact, etc., in respect of this claim may also be subject to appropriate felony criminal prosecution.

I certify that the information given above and that furnished by the employee on the reverse of this form is true to the best of my knowledge with the following exception:

Name of supervisor (Type or print): XXXXXXXXXXXXX

Signature of supervisor Date: 11/11/1

Supervisor's Title: XXXXXXXXXXXXXX Office phone: (111) 111-1111

39. Filing instructions
- ☑ No lost time and no medical expense: Place this form in employee's medical folder (SF-66-D)
- ☐ No lost time, medical expense incurred or expected: forward this form to OWCP
- ☐ Lost time covered by leave, LWOP, or COP: forward this form to OWCP
- ☐ First Aid Injury

Instructions for Completing Form CA-1

Complete all items on your section of the form. If additional space is required to explain or clarify any point, attach a supplemental statement to the form. Some of the items on the form which may require further clarification are explained below.

Employee (Or person acting on the employees' behalf)

13) Cause of injury

Describe in detail how and why the injury occurred. Give appropriate details (e.g.: if you fell, how far did you fall and in what position did you land?)

14) Nature of Injury

Give a complete description of the condition(s) resulting from your injury. Specify the right or left side if applicable (e.g., fractured left leg: cut on right index finger).

15) Election of COP/Leave

If you are disabled for work as a result of this injury and filed CA-1 within thirty days of the injury, you may be entitled to receive continuation of pay (COP) from your employing agency. COP is paid for up to 45 calendar days of disability, and is not charged against sick or annual leave. If you elect sick or annual leave you may not claim compensation to repurchase leave used during the 45 days of COP entitlement.

Supervisor

At the time the form is received, complete the receipt of notice of injury and give it to the employee. In addition to completing items 17 through 39, the supervisor is responsible for obtaining the witness statement in Item 16 and for filling in the proper codes in shaded boxes a, b, and c on the front of the form. If medical expense or lost time is incurred or expected, the completed form should be sent to OWCP within 10 working days after it is received.

The supervisor should also submit any other information or evidence pertinent to the merits of this claim.

If the employing agency controverts COP, the employee should be notified and the reason for controversion explained to him or her.

17) Agency name and address of reporting office

The name and address of the office to which correspondence from OWCP should be sent (if applicable, the address of the personnel or compensation office).

18) Duty station street address and zip code

The address and zip code of the establishment where the employee actually works.

19) Employers Retirement Coverage.

Indicate which retirement system the employee is covered under.

30) Was injury caused by third party?

A third party is an individual or organization (other than the injured employee or the Federal government) who is liable for the injury. For instance, the driver of a vehicle causing an accident in which an employee is injured, the owner of a building where unsafe conditions cause an employee to fall, and a manufacturer whose defective product causes an employee's injury, could all be considered third parties to the injury.

32) Name and address of physician first providing medical care

The name and address of the physician who first provided medical care for this injury. If initial care was given by a nurse or other health professional (not a physician) in the employing agency's health unit or clinic, indicate this on a separate sheet of paper.

33) First date medical care received

The date of the first visit to the physician listed in item 31.

36) If the employing agency controverts continuation of pay, state the reason In detail.

COP may be controverted (disputed) for any reason; however, the employing agency may refuse to pay COP only if the controversion is based upon one of the nine reasons given below:

a) The disability was not caused by a traumatic injury.

b) The employee is a volunteer working without pay or for nominal pay, or a member of the office staff of a former President;

c) The employee is not a citizen or a resident of the United States or Canada;

d) The injury occurred off the employing agency's premises and the employee was not involved in official "off premise" duties;

e) The injury was proximately caused by the employee's willful misconduct, intent to bring about injury or death to self or another person, or intoxication;

f) The injury was not reported on Form CA-1 within 30 days following the injury;

g) Work stoppage first occurred 45 days or more following the injury;

h) The employee initially reported the injury after his or her employment was terminated; or

i) The employee Is enrolled in the Civil Air Patrol, Peace Corps, Youth Conservation Corps, Work Study Programs, or other similar groups.

Employing Agency - Required Codes

Box a (Occupation Code), Box b (Type Code), Box c (Source Code), OSHA Site Code

The Occupational Safety and Health Administration (OSHA) requires all employing agencies to complete these items when reporting an injury. The proper codes may be found in OSHA Booklet 2014, "Recordkeeping and Reporting Guidelines.

OWCP Agency Code

This is a four-digit (or four digit plus two letter) code used by OWCP to identify the employing agency. The proper code may be obtained from your personnel or compensation office, or by contacting OWCP.

Benefits for Employees under the Federal Employees' Compensation act (FECA)

The FECA, which is administered by the Office of Workers' Compensation Programs (OWCP), provides the following benefits for job-related traumatic injuries:

(1) Continuation of pay for disability resulting from traumatic, job-related injury, not to exceed 45 calendar days. (To be eligible for continuation of pay, the employee, or someone acting on his/her behalf, must file Form CA-1 within 30 days following the injury and provide medical evidence in support of disability within 10 days of submission of the CA-1. Where the employing agency continue's the employee's pay, the pay must not be interrupted unless one of the provision's outlined in 20 CFR 10.222 apply.

(2) Payment of compensation for wage loss after the expiration of COP, if disability extends beyond such point, or if COP is not payable. If disability continues after COP expires, Form CA-7, with supporting medical evidence, must be filed with OWCP. To avoid interruption of income, the form should be filed on the 40th day of the COP period.

(3) Payment of compensation for permanent impairment of certain organs, members, or functions of the body (such as loss or loss of use of an arm or kidney, loss of vision, etc.), or for serious defringement of the head, face, or neck.

(4) Vocational rehabilitation and related services where directed by OWCP.

(5) All necessary medical care from qualified medical providers. The injured employee may choose the physician who provides initial medical care. Generally, 25 miles from the place of injury, place of employment, or employee's home is a reasonable distance to travel for medical care.

An employee may use sick or annual leave rather than LWOP while disabled. The employee may repurchase leave used for approved periods. Form CA-7b, available from the personnel office, should be studied BEFORE a decision is made to use leave.

For additional information, review the regulations governing the administration of the FECA (Code of Federal Regulations, Chapter 20, Part 10) or pamphlet CA-810.

Privacy Act

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), you are hereby notified that: (1) The Federal Employees' Compensation Act, as amended and extended (5 U.S.C. 8101, et seq.) (FECA) is administered by the Office of Workers' Compensation Programs of the U.S. Department of Labor, which receives and maintains personal information on claimants and their immediate families. (2) Information which the Office has will be used to determine eligibility for and the amount of benefits payable under the FECA, and may be verified through computer matches or other appropriate means. (3) Information may be given to the Federal agency which employed the claimant at the time of injury in order to verify statements made, answer questions concerning the status of the claim, verify billing, and to consider issues relating to retention, rehire, or other relevant matters. (4) Information may also be given to other Federal agencies, other government entities, and to private-sector agencies and/or employers as part of rehabilitative and other return-to-work programs and services. (5) Information may be disclosed to physicians and other health care providers for use in providing treatment or medical/vocational rehabilitation, making evaluations for the Office, and for other purposes related to the medical management of the claim. (6) Information may be given to Federal, state and local agencies for law enforcement purposes, to obtain information relevant to a decision under the FECA, to determine whether benefits are being paid properly, including whether prohibited dual payments are being made, and, where appropriate, to pursue salary/administrative offset and debt collection actions required or permitted by the FECA and/or the Debt Collection Act. (7) Disclosure of the claimant's social security number (SSN) or tax identifying number (TIN) on this form is mandatory. The SSN and/or TIN), and other information maintained by the Office, may be used for identification, to support debt collection efforts carried on by the Federal government, and for other purposes required or authorized by law. (8) Failure to disclose all requested information may delay the processing of the claim or the payment of benefits, or may result in an unfavorable decision or reduced level of benefits.

Note: This notice applies to all forms requesting information that you might receive from the Office in connection with the processing and adjudication of the claim you filed under the FECA.

Receipt of Notice of Injury

This acknowledges receipt of Notice of Injury sustained by
(Name of injured employee)

Which occurred on (Mo., Day, Yr.)

At (Location)

Signature of Official Superior | Title XXXXXXXXXXXXXX | Date (Mo., Day, Yr.)

*U.S. GPO: 1999-454-845/12704

Form CA-1
Rev. Apr. 1999

Notice of Occupational Disease and Claim for Compensation

U. S. Department of Labor
Office of Workers' Compensation Programs

Employee: Please complete all boxes 1 - 18 below. Do not complete shaded areas.
Employing Agency (Supervisor or Compensation Specialist): Complete shaded boxes a, b, and c.

Employee Data

1. Name of Employee (Last, First, Middle)

2. Social Security Number: 111-11-1111

3. Date of birth Mo. Day Yr.

4. Sex

5. Home telephone: (111)111-1111

6. Grade as of date of last exposure Level Step

7. Employee's home mailing address (include street address, city, state, and ZIP code)
XXXXXXXXXX
City: XXXXXXX State: DC ZIP Code: 11111

8. Dependents
- ☐ Wife, Husband
- ☐ Children under 18 years
- ☐ Other

Claim Information

9. Employee's occupation
XXXXXXXXX

a. Occupation code

10. Location where you worked when disease or illness occurred (include street address, city, state, and ZIP code)
XXXXXXXXX
City: XXXXXXXX State: DC ZIP Code: 11111

11. Date you first became aware of disease or illness
Mo. Day Yr.: 11/11/1

12. Date you first realized the disease or illness was caused or aggravated by your employment
Mo. Day Yr.: 11/11/1

13. Explain the relationship to your employment, and why you came to this realization
XXXX

14. Nature of disease or illness
XXXX

OWCP Use - NOI Code
b. Type code
c. Source code

15. If this notice and claim was not filed with the employing agency within 30 days after date shown above in item #12, explain the reason for the delay.
XXXXX

16. If the statement requested in item I of the attached instructions is not submitted with this form, explain reason for delay.
XXXXXX

17. If the medical reports requested in item 2 of attached instructions are not submitted with this form, explain reason for delay.

Employee Signature

18. I certify, under penalty of law, that the disease or illness described above was the result of my employment with the United States Government, and that it was not caused by my willful misconduct, intent to injure myself or another person, nor by my intoxication. I hereby claim medical treatment, if needed, and other benefits provided by the Federal Employees' Compensation Act.

I hereby authorize any physician or hospital (or any other person, institution, corporation, or government, agency) to furnish any desired information to the U.S. Department of Labor, Office of Workers' Compensation Programs (or to its official representative). This authorization also permits any official representative of the Office to examine and to copy any records concerning me.

Signature of employee or person acting on his/her behalf _____ Date

Have your supervisor complete the receipt attached to this form and return it to you for your records.

Any person who knowingly makes any false statement, misrepresentation, concealment of fact or any other act of fraud to obtain compensation as provided by the FECA or who knowingly accepts compensation to which that person is not entitled is subject to civil or administrative remedies as well as felony criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment or both.

For sale by the Superintendent of Documents, U.S. Government Printing Office Washington, DC 20402

Official Supervisor's Report of Occupational Disease: Please complete information requested below

Supervisor's Report

19. Agency name and address of reporting office (include street address, city, state, and ZIP Code)

XXXX

OWCP Agency Code

OSHA Site Code

City | State | ZIP Code

20. Employee's duty station (include street address, city, state, and ZIP code) | City | State | ZIP Code

21. Regular work hours From: 11 ☐ a.m. ☐ p.m. To: ☐ a.m. ☐ p.m.

22. Regular work schedule ☐ Sun. ☐ Mon. ☐ Tues. ☐ Wed. ☐ Thurs. ☐ Fri. ☐ Sat.

23. Name and address of physician first providing medical care (include city, state, ZIP code)

City | State | ZIP Code

24. First date medical care received Mo. Day Yr

25. Do medical reports show employee is disabled for work? ☐ Yes ☐ No

26. Date employee first reported condition to supervisor Mo. Day Yr.

27. Date and hour employee stopped work Mo. Day Yr. Time ☐ a.m. ☐ p.m.

28. Date and hour employee's pay stopped Mo. Day Yr. Time ☐ a.m. ☐ p.m.

29. Date employee was last exposed to conditions alleged to have caused disease or illness Mo. Day Yr.

30. Date returned to work Mo. Day Yr. Time ☐ a.m. ☐ p.m.

31. If employee has returned to work and work assignment has changed, describe new duties

32. Employee's Retirement Coverage ☐ CSRS ☐ FERS ☐ Other, (Specify)

33. Was injury caused by third party? ☐ Yes ☐ No If "No," go to Item 34.

34. Name and address of third party (include street address, city, state, and ZIP code)

City | State | ZIP Code

Signature of Supervisor

35. A supervisor who knowingly certifies to any false statement, misrepresentation, concealment of fact, etc., in respect to this claim may also be subject to appropriate felony criminal prosecution.

I certify that the information given above and that furnished by the employee on the reverse of this form is true to the best of my knowledge with the following exception:

XXXXXX

Name of Supervisor (Type or print)

XXXX

Signature of Supervisor | Date

11/11/1

Supervisor's Title | Office phone

XXXX | (111)111-1111

Disability Benefits for Employees under the Federal Employees' Compensation Act (FECA)

The FECA, which is administered by the Office of Workers' Compensation Programs (OWCP), provides the following general benefits for employment-related occupational disease or illness:

(1) Full medical care from either Federal medical officers and hospitals, or private hospitals or physicians of the employee's choice.

(2) Payment of compensation for total or partial wage loss.

(3) Payment of compensation for permanent impairment of certain organs, members, or functions of the body (such as loss or loss of use of an arm or kidney, loss of vision, etc.), or for serious disfigurement of the head, face, or neck.

(4) Vocational rehabilitation and related services where necessary.

The first three days in a non-pay status are waiting days, and no compensation is paid for these days unless the period of disability exceeds 14 calendar days, or the employee has suffered a permanent disability. Compensation for total disability is generally paid at the rate of 2/3 of an employee's salary if there are no dependents, or 3/4 of salary if there are one or more dependents.

An employee may use sick or annual leave rather than LWOP while disabled. The employee may repurchase leave used for approved periods. Form CA-7b, available from the personnel off ice, should be studied BEFORE a decision is made to use leave.

If an employee is in doubt about compensation benefits, the OWCP District Office servicing the employing agency should be contacted. (Obtain the address from your employing agency.)

For additional information, review the regulations governing the administration of the FECA (Code of Federal Regulations, Title 20, Chapter 1) or Chapter 810 of the Office of Personnel Management's Federal Personnel Manual.

Privacy Act

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), you are hereby notified that: (1) The Federal Employees' Compensation Act, as amended and extended (5 U.S.C. 8101, et seq.) (FECA) is administered by the Office of Workers' Compensation Programs of the U.S. Department of Labor, which receives and maintains personal information on claimants and their immediate families. (2) Information which the Office has will be used to determine eligibility for and the amount of benefits payable under the FECA, and may be verified through computer matches or other appropriate means. (3) Information may be given to the Federal agency which employed the claimant at the time of injury in order to verify statements made, answer questions concerning the status of the claim, verify billing, and to consider issues relating to retention, rehire, or other relevant matters. (4) Information may also be given to other Federal agencies, other government entities, and to private-sector agencies and/or employers as part of rehabilitative and other return-to-work programs and services. (5) Information may be disclosed to physicians and other health care providers for use in providing treatment or medical/vocational rehabilitation, making evaluations for the Office, and for other purposes related to the medical management of the claim. (6) Information may be given to Federal, state and local agencies for law enforcement purposes, to obtain information relevant to a decision under the FECA, to determine whether benefits are being paid properly, including whether prohibited dual Payments are being made, and, where appropriate, to pursue salary/administrative offset and debt collection actions required or permitted by the FECA and/or the Debt Collection Act. (7) Disclosure of the claimant's social security number (SSN) or tax identifying number (TIN) on this form is mandatory. The SSN and/or TIN, and other information maintained by the Office, may be used for identification, to support debt collection efforts carried on by the Federal government, and for other purposes required or authorized by law. (8) Failure to disclose all requested information may delay the processing of the claim or the payment of benefits, or may result in an unfavorable decision or reduced level of benefits.

Note: This notice applies to all forms requesting information that you might receive from the Office in connection with the processing and adjudication of the claim you filed under the FECA.

Receipt of Notice of Occupational Disease or Illness

This acknowledges receipt of notice of disease or illness sustained by:
(Name of injured employee)

I was first notified about this condition on (Mo., Day, Yr.)

At (Location)

Signature of Official Superior	Title	Date (Mo., Day, Yr.)

This receipt should be retained by the employee as a record that notice was filed.

INSTRUCTIONS FOR COMPLETING FORM CA-2

Complete all items on your section of the form. If additional space is required to explain or clarify any point, attach a supplemental statement to the form. in addition to the information requested on the form, both the employee and the supervisor are required to submit additional evidence as described below. If this evidence is not submitted along with the form, the responsible party should explain the reason for the delay and state when the additional evidence will be submitted.

Employee (or person acting on the Employee's behalf)

Complete items *1* through 18 and submit the form to the employee's supervisor along with the statement and medical reports described below. Be sure to obtain the Receipt of Notice of Disease or Illness completed by the supervisor at the time the form is submitted.

1) Employee's statement

In a separate narrative statement attached to the form, the employee must submit the following information:

a) A detailed history of the disease or illness from the date it started.

b) Complete details of the conditions of employment which are believed to be responsible for the disease or illness.

c) A description of specific exposures to substances or stressful conditions causing the disease or illness, including locations where exposure or stress occurred, as well as the number of hours per day and days per week of such exposure or stress.

d) Identification of the part of the body affected. (If disability is due to a heart condition, give complete details of all activities for one week prior to the attack with particular attention to the final 24 hours of such period.)

e) A statement as to whether the employee ever suffered a similar condition. if so, provide full details of onset, history, and medical care received, along with names and addresses of physicians rendering treatment.

2) Medical report

a) Dates of examination or treatment.

b) History given to the physician by the employee.

c) Detailed description of the physician's findings.

d) Results of x-rays, laboratory tests, etc.

e) Diagnosis.

f) Clinical course of treatment.

g) Physician's opinion as to whether the disease or illness was caused or aggravated by the employment, along with an explanation of the basis for this opinion. (Medical reports that do not explain the basis for the physician's opinion are given very little weight in adjudicating the claim.)

3) Wage loss

If you have lost wages or used leave for this illness, Form CA-7 should also be submitted.

Supervisor (Or appropriate official in the employing agency)

At the time the form is received, complete the Receipt of Notice of Disease or Illness and give it to the employee. In addition to completing items 19 through 34, the supervisor is responsible for filling in the proper codes in shaded boxes a, b, and c on the front of the form. If medical expense or lost time is incurred or expected, the completed form must be sent to OWCP within ten working days after it is received. In a separate narrative statement attached to the form, the supervisor must:

a) Describe in detail the work performed by the employee. Identify fumes, chemicals, or other irritants or situations that the employee was exposed to which allegedly caused the condition. State the nature, extent, and duration of the exposure, including hours per days and days per week, requested above.

b) Attach copies of all medical reports (including x-ray reports and laboratory data) on file for the employee.

c) Attach a record of the employee's absence from work caused by any similar disease or illness. Have the employee state the reason for each absence.

d) Attach statements from each co-worker who has first-hand knowledge about the employee's condition and its cause. (The co-workers should state how such knowledge was obtained.)

e) Review and comment on the accuracy of the employee's statement requested above.

The supervisor should also submit any other information or evidence pertinent to the merits of this claim.

Item Explanation: Some of the items on the form which may require further clarification are explained below.

14. Nature of the disease or illness

Give a complete description of the disease or illness. Specify the left or right side if applicable (e.g., rash on left leg; carpal tunnel syndrome, right wrist).

19. Agency name and address of reporting office

The name and address of the off ice to which correspondence from OWCP should be sent (if applicable, the address of the personnel or compensation office).

23. Name and address of physician first providing medical care

The name and address of the physician who first provided medical care for this injury. If initial care was given by a nurse or other health professional (not a physician) in the employing agency's health unit or clinic, indicate this on a separate sheet of paper.

24. First date medical care received

The date of the first visit to the physician listed in item 23.

32. Employee's Retirement Coverage.

Indicate which retirement system the employee is covered under.

33. Was the injury caused by third party?

A third party is an individual or organization (other than the injured employee or the Federal government) who is liable for the disease. For instance, manufacturer of a chemical to which an employee was exposed might be considered a third party if improper instructions were given by the manufacturer for use of the chemical.

Employing Agency - Required Codes

Box a (Occupational Code), Box b. (Type Code), Box c (Source Code), OSHA Site Code

The Occupational Safety and Health Administration (OSHA) requires all employing agencies to complete these items when reporting an injury. The proper codes may be found in OSHA Booklet 2014, Record Keeping and Reporting Guidelines.

OWCP Agency Code

This is a four digit (or four digit two letter) code used by OWCP to identify the employing agency. The proper code may be obtained from your personnel or compensation office, or by contacting OWCP.

• U.S. GPO: 2001480-204/59062

Claim for Compensation

U.S. Department of Labor

Office of Workers' Compensation Programs

SECTION 1 **EMPLOYEE PORTION**

a. Name of Employee — Last: **XXXXX** First: Middle:

OMB No. 1240-0046
Expires: 01-31-2018

b. Mailing Address (*Including City State, ZIP Code*)
XXXXXXX

c. OWCP File Number
111111111

E-Mail Address *(Optional)*

d. Date of Injury
Month Day Year

e. Social Security Number
111-11-1111

f. Telephone No./FAX No.

SECTION 2 Compensation is claimed for:

		Inclusive Date Range From	To	Intermittent?	
a.	[x] Leave without pay			[ ] Yes [ ] No	*Go to Section 3*
b.	[ ] Leave buy back			[ ] Yes [ ] No	*Go to Section 3, and Complete Form CA-7b*
c.	[ ] Other wage loss; specify type, such as downgrade, loss of night differential, etc. Type:			[ ] Yes [ ] No	*Go to Section 3*
d.	[ ] Schedule Award (*Go to Section 4)*				

If intermittent, complete Form CA-7a, Time Analysis Sheet

SECTION 3 You must report **any and all** earnings from employment (**outside** your federal job); include any employment for which you received a salary, wages, income, sales commissions, or payment of **any** kind during the period(s) claimed in Section 2. Include self-employment, odd jobs, involvement in business enterprises, as well as service with the military. Fraudulently concealing employment or failing to report income may result in forfeiture of compensation benefits and/or criminal prosecution. ***Have you worked outside your federal job for the period(s) claimed in Section 2? Refer to the Instructions which provide further clarification.***

[ ] Yes — Name and Address of Business:

Name Address City State ZIP Code

[ ] No *Go to section 4*

Dates Worked: Type of Work:

SECTION 4 Is this the first CA-7 claim for compensation you have filed for this injury?

[ ] Yes *Complete Sections 5 through 7 and a Form SF-1199A, "Direct Deposit Sign-up"*

[ ] No If changes to dependent status, direct deposit information, or if a claim has been filed with the U.S. Civil Service Retirement, another federal retirement/disability law, or with Department of Veteran Affairs, complete Sections 5 through 7 or a new SF-1199A. If no, complete Section 7.

[ ] Yes - *Complete Sections 5 through 7 or a new SF-1199A to reflect change(s)* [ ] No - *Complete Section 7*

SECTION 5 List your dependents (including spouse). If additional space is necessary, provide same information requested below on separate page(s) and include your name/claim number at the top of the page(s).

Name	Social Security #	Date of Birth	Relationship	Living with you? Yes	No	
XXXXXXXX				[ ]	[ ]	*For dependents not living with you complete items a and b below.* ,
				[ ]	[ ]	

a. Are you making support payments for a dependent noted above or on your attachment(s)? [ ] Yes [ ] No If Yes, support payments are made to:

Name Address City State ZIP Code

b. Were support payments ordered by a court? [ ] Yes [ ] No If Yes, attach copy of court order.

SECTION 6 a. Was/Will there be a claim made against a 3rd party? [ ] Yes [ ] No

b. Have you ever applied for or received disability benefits from the Department of Veterans Affairs?

	Claim Number	Full Address of VA Office Where Claim Filed	Nature of Disability and Monthly Payment
[x] Yes [ ] No			

c. Have you applied for or received payment under any Federal Retirement or Disability law?

	Claim Number	Date Annuity Began	Amount of Monthly Payment	Retirement System (CSRS, FERS, SSA, Other)
[ ] Yes [ ] No				[ ] CSRS [ ] FERS [ ] SSA [ ] Other

SECTION 7 I hereby make claim for compensation because of the injury sustained by me while in the performance of my duty for the United States. I certify that the information provided above is true and accurate to the best of my knowledge and belief. Any person who knowingly makes any false statement, misrepresentation, concealment of fact, or any other act of fraud, to obtain compensation as provided by the FECA, or who knowingly accepts compensation to which that person is not entitled is subject to civil or administrative remedies as well as criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment, or both. In addition, a state or federal criminal conviction for FECA fraud will result in termination of all current and future FECA benefits. I understand that by signing this form, if evidence is received suggesting possible employment or earnings, I authorize OWCP to request verification of employment/earnings from the Social Security Administration.

Employee's Signature Date (*Mo., day, year*)

If you have a disability (a substantially limiting physical or mental impairment), contact OWCP for information on communication assistance (alternate formats or sign language interpretation), accommodations and/or modifications. See Instructions for Disability-Related Assistance under Federal disability nondiscrimination law.

CA-7 (Rev. 09-14)

Employing Agency Portion
For first CA-7 claim sent, complete sections 8 through 15.
For subsequent claims, complete sections 12 through 15 only.

SECTION 8 Show Pay Rate as of

Date of Injury: Base Pay
Date: _____ $ _____ per _____
Grade: _____ step: _____

Additional Pay: Type _____ $ _____ per _____
Additional Pay: Type _____ $ _____ per _____
Additional Pay: Type _____ $ _____ per _____

Date Employee Stopped Work:
Date: _____ $ _____ per _____
Grade: _____ step: _____

Additional Pay: Type _____ $ _____ per _____
Additional Pay: Type _____ $ _____ per _____
Additional Pay: Type _____ $ _____ per _____

Additional pay types include, but are not limited to: Night Differential (ND), Sunday Premium (SP), Holiday Premium (HP), Subsistence (SUB), Quarter (QTR), etc. (List each separately)

SECTION 9

a. Does employee work a fixed 40-hour per week schedule? ☐ Yes ☐ No

1. If Yes, circle scheduled days: ☐ S ☐ M ☐ T ☐ W ☐ T ☐ F ☐ S

2. If No, show scheduled hours for the two week pay period in which work stopped. Circle the day that work stopped.

FOR EXAMPLE ONLY

	S	M	T	W	TH	F	S
WEEK 1 From 5/14 to 5/20		8	4	6	(6)		
WEEK From 5/21 to 5/27		8		6	6		4

	S	M	T	W	TH	F	S
From _____ To _____							
From _____ To _____							

b. Did employee work in position for 11 months prior to injury? ☐ Yes ☐ No

If No, would position have afforded employment for 11 months but for the injury? ☐ Yes ☐ No

SECTION 10 On date pay stopped, was employee enrolled in:

a. Health Benefits under the FEHBP? ☐ No ☒ Yes Code **111**

b. Basic Life Insurance? ☐ No ☐ Yes

c. Optional Life Insurance? ☐ No ☐ Yes Class _____ *(D-Z only)*

d. A Retirement System? ☐ No ☐ Yes Plan _____ *(Specify CSRS, FERS, Other)*

SECTION 11 Continuation of Pay (COP) Received (*Show inclusive dates*):

From _____ To _____ Intermittent? ☐ Yes - Complete Time Analysis Sheet, Form CA-7a ☐ No

SECTION 12 Show pay status and inclusive dates for period(s) claimed:

			Intermittent?	
Sick Leave From	_____	To _____	☐ Yes ☐ No	If intermittent, complete Form CA-7a, Time Analysis Sheet.
Annual Leave From	_____	To _____	☐ Yes ☐ No	
Leave without Pay From	_____	To _____	☐ Yes ☐ No	If leave buy back, also submit completed Form CA-7b.
Work From	_____	To _____	☐ Yes ☐ No	

SECTION 13 Did employee return to work? ☐ Yes ☐ No
If Yes, date _____

If returned, did employee return to the pre-date-of-injury job, with the same number of hours and the same duties?

☐ Yes ☐ No If No, explain: _____

SECTION 14 Remarks:

SECTION 15 An employing agency official who knowingly certifies to any false statement, misrepresentation, or concealment of fact with respect to this claim (or impedes the filing of a claim) may also be subject to appropriate criminal prosecution.

I certify that the information given above and that furnished by the employee on this form is true to the best of my knowledge, with any exceptions noted in Section 14, Remarks, above.

Signature _____ Title _____ Date / /
(*Agency Official*)

Name of Agency **XXXXXXXX**

Date Claim Form Received from Employee / /

If OWCP needs specific pay information, the person who should be contacted is:

Name **XXXXXX** Title _____

Telephone No. **(111) 111-1111** Fax No. _____ E-Mail Address **11111111**

INSTRUCTIONS FOR COMPLETING FORM CA-7

If additional space is needed to respond to questions on this form, attach a separate sheet of paper and write, “see attachment” in the applicable portion of the form. Please ensure the claimant's full name and claim number appear on the separate sheet(s).

If the employee does not quality for continuation of pay (for 45 days), the form should be completed and filed with the OWCP as soon as pay stops. The form should also be submitted when the employee reaches maximum improvement and claims a schedule award. If the employee is receiving continuation of pay and will continue to be disabled after 45 days, the form should be filed with OWCP 5 working days prior to the end of the 45-day period.

The CA-7 also should be used to claim continuing compensation, when a previous CA-7 claim has been made.

Collection of this information is required to obtain a benefit and is authorized by 20 C.F.R.10.102, 20 C.F.R.10.103, and 20 C.F.R.10.404.

Requests for Disability-Related Assistance (Forms and Notices):
If you have a substantially limiting physical or mental impairment, Federal disability nondiscrimination law gives you the right to receive help from the OWCP, DFEC in the form of communication assistance, accommodation(s) and/or modification(s) to aid you in the FECA claims process. For example, we will provide you with copies of documents in alternate formats, communication services such as sign language interpretation, or other kinds of adjustments or changes to account for the limitations of your disability. Please contact our office or your OWCP claims examiner to ask about this assistance.

EMPLOYEE (or person acting on the employee's behalf) - Complete sections 1 through 7 as directed and submit the form to the employee's supervisor.

SUPERVISOR (or appropriate official in the employing agency) - Complete sections 8 through 15 as directed and promptly forward the form to the OWCP.

EXPLANATIONS - Some of the items on the form which may require further clarification are explained below:

Section Number	Explanation
2d. Schedule Award	Schedule awards are paid for permanent impairment to a member or function of the body.
3. Employment	An employee who either claims or is receiving compensation for partial or total disability must advise OWCP immediately of any return to work. An employee must report **all** outside employment, including any concurrent dissimilar employment held at the time of injury. The employee must report even those earnings which do not seem likely to affect benefits; failure to report earnings may result in forfeiture of **all** benefits paid during the period for which compensation is claimed. For example, include sales, farming, and operating (or keeping books for) a business including a family business. Report providing services (such as carpentry, mechanical work, child care, odd jobs) provided in exchange for money, goods, or other services. Report part-time or intermittent activities and any volunteer work for which any form of monetary or in-kind compensation was received. Passive investment in any public traded business is not a required reporting item.
4. Direct Deposit Information	The Department of the Treasury requires all Federal payments be made by electronic funds transfer (EFT), also called Direct Deposit. If you have not previously signed up to receive compensation with EFT, or desire to change your current account information, please submit SF-1199A, Direct Deposit Sign Up. If you do not have a bank account, you may be required to receive your payment through Direct Express Debit MasterCard. To request information on the Direct Express Debit MasterCard, go to www.usdirectexpress.com or call 1-800-333-1795. If directed to enroll in the Program, you may contact the Department of the Treasury at 1-888-224-2950 to address any questions or concerns you may have, as well as apply for a waiver from the process. NOTE: payments to residents of foreign countries are exempt from the Treasury requirements.
5. List your dependents	Your spouse is a dependent if he or she is living with you. A child is a dependent if he, or she either lives with you or receives support payments from you, and he or she: 1) is under 18, or 2) is between 18 and 23 and is a full-time student, or 3) is incapable of self-support due to physical or mental disability.
6a. Was/will there be a claim made against 3rd party?	A third party is an individual or organization (other than the injured employee or the Federal government) who is liable for the injury. For instance, the driver of a vehicle causing an accident in which an employee is injured, the owner of a building where unsafe conditions cause an employee to fall, and a manufacturer who gave improper instructions for the use of a chemical to which an employee is exposed, could all be considered third parties to the injury.
8. Additional Pay	''Additional Pay'' includes night differential, Sunday premium, holiday premium, and any other type (such as hazardous duty or ''dirty work'' pay) regularly received by the employee, but does not include pay for overtime. If the amount of such pay varies from pay period to pay period (as in the case of holiday premium or a rotating shift), then the total amount of such pay earned during the year immediately prior to the date of injury or the date the employee stopped work (whichever is greater) should be reported.
11. Continuation of pay (COP) received	If the injury was not a traumatic injury reported on Form CA-1, this item does not apply.
14. Remarks	This space is used to provide relevant information which is not present elsewhere on the form.

DO NOT SEND THE COMPLETED FORM TO THIS OFFICE

The authority for requesting this information is 5 U.S.C. 8101 et seq. The information will be used to determine entitlement to benefits. Furnishing the requested information is required for the claimant to obtain or retain a benefit. Information collected will be handled and stored in compliance with the Freedom of Information Act, the Privacy Act of 1974, as amended (5 U.S.C.552a). Failure to furnish the requested information may delay the process, or result in an unfavorable decision or a reduced benefit.

Public Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. Public reporting burden for this collection of information is estimated to average 13 minutes per response, including time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. The obligation to respond to this collection is voluntary (5 U.S.C. 8101 et seq.) to obtain or retain a benefit. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Workers' Compensation Programs, U.S. Department of Labor, Room S3229, 200 Constitution Avenue, N.W.,Washington, D.C. 20210, and reference the OMB Control Number 1240-0046. Note: Do not submit the completed claim form to this address.

Privacy Act

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), you are hereby notified that: (1) The Federal Employees' Compensation Act, as amended and extended (5 U.S.C. 8101, et seq.) (FECA) is administered by the Office of Workers' Compensation Programs of the U. S. Department of Labor, which receives and maintains personal information on claimants and their immediate families. (2) Information which the Office has will be used to determine eligibility for and the amount of benefits payable under the FECA, and may be verified through computer matches or other appropriate means. (3) Information may be given to the Federal agency which employed the claimant at the time of injury in order to verify statements made, answer questions concerning the status of the claim, verify billing, and to consider issues relating to retention, rehire, or other relevant matters. (4) Information may also be given to other Federal agencies, other government entities, and to private-sector agencies and/or employers as part of rehabilitative and other return-to-work programs and services. (5) Information may be disclosed to physicians and other healthcare providers for use in providing treatment or medical/vocational rehabilitation, making evaluations for the Office, and for other purposes related to the medical management of the claim. (6) Information may be given to Federal, state and local agencies for law enforcement purposes, to obtain information relevant to a decision under the FECA, to determine whether benefits are being paid properly, including whether prohibited dual payments are being made, and, where appropriate, to pursue salary/administrative offset and debt collection actions required or permitted by the FECA and/or the Debt Collection Act. (7) Disclosure of the claimant's social security number (SSN) or tax identifying number (TIN) on this form is mandatory. The SSN and/or TIN, and other information maintained by the Office, may be used for identification, to support debt collection efforts carried on by the Federal government, to verify earnings without further written authorization, and for other purposes required or authorized by law. (8) Failure to disclose all requested information may delay the processing of the claim or the payment of benefits, or may result in an unfavorable decision or reduced level of benefits.

Note: This notice applies to all forms requesting information that you might receive from the Office in connection with the processing and adjudication of the claim you filed under the FECA.

Authorization for Examination And/Or Treatment

U.S. Department of Labor
Office of Workers' Compensation Programs

The following request for information is required under (5 USC 8101 et. seq.). Benefits and/or medical services expenses may not be paid or may be subject to suspension under this program unless this report is completed and filed as requested. Information collected will be handled and stored in compliance with the Freedom of Information Act, the Privacy Act of 1974 and OMB Cir. No. 130. Persons are not required to respond to this collection of information unless it displays a currently valid OMB control number.

OMB No.: 1240-0046
Expires: 01-31-2018

PART A - AUTHORIZATION

1. Name and Address of the Medical Facility or Physician Authorized to Provide the Medical Service:

2. Employee's Identification (last, first, middle, SSN)	3. Date of Injury (mo. day, yr.)	4. Occupation

5. Description of Injury or Disease:

6. You are authorized to provide medical care for the employee for a period of up to sixty days from the date shown in item 3, subject to the condition stated in item A, and to the condition indicated in either 1 or 2, item B.

A. Your signature in item 35 of Part B certifies your agreement that all fees for services shall not exceed the maximum allowable fee established by OWCP and that payment by OWCP will be accepted as payment in full for said services.

B. ☐ 1. Furnish office and/or hospital treatment as medically necessary for the effects of this injury. Any surgery other than emergency must have prior OWCP approval.

☐ 2. There is doubt whether the employee's condition is caused by an injury sustained in the performance of duty, or is otherwise related to the employment. You are authorized to examine the employee using indicated non-surgical diagnostic studies, and promptly advise the undersigned whether you believe the condition is due to the alleged injury or to any circumstances of the employment. Pending further advice you may provide necessary conservative treatment if you believe the condition may be to the injury or to the employment.

7. If a Disease or Illness is Involved, OWCP Approval for Issuing Authorization was Obtained from: (Type Name and Title of OWCP Official)	8. Signature of Authorizing Official: 9. Name and Title of Authorizing Official: (Type or print clearly)
10. Local Employing Agency Telephone Number (Including Area Code):	11. Date (mo., day, year)
12. Send one copy of your report: **U.S. DEPARTMENT OF LABOR** DFEC CENTRAL MAILROOM P.O. BOX 8300 LONDON, KY 40742-8300	13. Name and Address of Employee's Place of Employment: Department of Agency Bureau or Office Local Address (including ZIP Code)

Public Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. Public reporting burden for this collection of information is estimated to average five minutes per response, including time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. The obligation to respond to this collection is voluntary (5 U.S.C. 8101 et seq.) to obtain or retain a benefit. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Workers' Compensation Programs, U.S. Department of Labor, Room S3229, 200 Constitution Avenue, N.W.,Washington, D.C. 20210, and reference the OMB Control Number 1240-0046. Note: Do not submit the completed claim form to this address.

DO NOT SEND THE COMPLETED FORM TO THIS OFFICE

Requests for Disability-Related Assistance (Forms and Notices): If you have a substantially limiting physical or mental impairment, Federal disability nondiscrimination law gives you the right to receive help from the OWCP, DFEC in the form of communication assistance, accommodation(s) and/or modification(s) to aid you in the FECA claims process. For example, we will provide you with copies of documents in alternate formats, communication services such as sign language interpretation, or other kinds of adjustments or changes to account for the limitations of your disability. Please contact our office or your OWCP claims examiner to ask about this assistance.

PART B - ATTENDING PHYSICIAN'S REPORT

14. Employee's Name (Last, first, middle)

15. What History of the Employment Injury or Disease Did The Employee Give To You?

16. Is there any History or Evidence of Concurrent or Pre-existing Injury, Disease, or Physical Impairment? (If yes, please describe)
☐ Yes ☐ No

16a. ICD Code(s)

17. What are Your Findings? (Include results of X-rays, laboratory tests, etc.)

18. What is the Diagnosed Condition(s)

18a. ICD Code(s)

19. Do You believe the Condition(s) Found was Caused or Aggravated by the Employment activity Described? (Please explain your answer if there is doubt)
☐ Yes ☐ No

20. Did Injury Require Hospitalization? If yes, date of admission (mo., day, year) Date of discharge (mo., day, year) ☐ Yes ☐ No

21. Is Additional Hospitalization Required?
☐ Yes ☐ No

22. Surgery (If any, describe type)

23. Date Surgery Performed (mo., day, year)

24. What (Other) Type of Treatment Did You Provide?

25. What Permanent Effects, If Any, Do You Anticipate?

26. Date of First Examination (mo., day, year)

27. Date(s) of Treatment (mo., day, year)

28. Date of Discharge from Treatment (mo., day, year)

29. Period of Disability (mo., day, year) (If termination date unknown, so indicate)
Total Disability: From To
Partial Disability: From To

30. Is Employee Able to Resume
☐ Light Work Date:
☐ Regular Work Date:

31. If Employee Is Able to Resume Work, Has He/She been Advised? ☐ Yes ☐ No If Yes, Furnish Date Advised

32. If Employee is Able to Resume only Light Work, Indicate the Extent of Physical Limitations and the Type of Work that Could Reasonably be Performed with these Limitations.

33. General Remarks and Recommendations for Future Care, if indicated. If you have made a Referral to Another Physician or to a Medical Facility, Provide Name and Address.

34. Do You Specialize? ☐ Yes ☐ No (If yes, state specialty)

35. SIGNATURE OF PHYSICIAN. I certify that all the statements in response to the questions asked in Part B of this form are true, complete and correct to the best of my knowledge. Further, I understand that any false or misleading statement or any misrepresentation or concealment of material fact which is knowingly made may subject me to criminal prosecution.

36. Address (No., Street, City, State, ZIP Code)

37. Tax Identification Number

39. Date of Report

38. National Provider System Number

MEDICAL BILL: Charges for your services should be presented on the AMA standard "Health Insurance Claim Form" (HCFA-1500, OWCP-1500, OWCP-04 or the UB-04). Physician services must be itemized by Current Procedural Terminology Code (CPT) using current CPT-4 coding schema; or, the UB-04 and the coding schemas acceptable on this form.

INSTRUCTIONS FOR AUTHORIZING OFFICIAL FOR COMPLETION OF PART A

SELECTION OF PHYSICIAN

- A Federal employee injured by accident while in the performance of duty has the initial right to select a physician of his/her choice to provide necessary treatment. The supervisor shall immediately authorize examination and appropriate medical care by use of Form CA-16 issued to either a United States medical office or hospital or any duly qualified physician/ hospital of the employee's choice.
- If an employee elects to be treated by a private physician; a copy of the American Medical Association Standard Billing Form (AMA) OWCP-1500 should be supplied together with the submitted Form CA-16.
- If an employee, in an emergency situation has to be sent and/or admitted to an Acute Care Facility for emergency surgery or care, a copy of the OWCP Uniformed Billing Form (UB-04-1450), should be supplied together with the submitted Form CA-16.
- A physician who is excluded from the FECA program as provided at 20 CFR 10.815-826 may not be authorized to examine or treat an injured Federal employee.
- Generally, a roundtrip distance of up to 100 miles from the place of injury, employing agency, or the employee's home is a reasonable distance to travel for medical care; however, other pertinent factors must also be considered. For non-emergency medical treatment, if roundtrip travel of more than 100 miles is contemplated, or air transportation or overnight accommodations will be needed, submit a written request to OWCP for prior authorization with information describing the circumstances and necessity for such travel expenses.

PERIOD OF AUTHORIZATION

- Form CA-16 is valid for up to sixty days from date of injury, and may be terminated earlier upon written notice from OWCP to the provider. It should not be used to authorize a change of physicians after the initial choice is exercised by the employee.

FEDERAL MEDICAL FACILITIES

- U. S. Medical Facilities include Army, Navy, Air Force or the VA. Federal health service facilities (health units) established under 5 USC 7901 are not U.S. medical facilities as used herein (see 20 CFR 10.300).

DEFINITION OF INJURY

- The term "injury" includes damage to or destruction of medical braces, artificial limbs and other prosthetic devices. Eyeglasses and hearing aids are included only if the damages were incidental to a personal injury which required medical services. Treatment for illness or disease should not be authorized unless approval is first obtained from OWCP. Simple exposure to a workplace hazard, such as an infectious agent, does not constitute a work place injury, entitling an employee to medical treatment under FECA.

DEFINITION OF PHYSICIAN

- The term "physician" includes doctors of medicine (MDs), surgeons, podiatrists, dentists, clinical psychologists, optometrists, chiropractors and osteopathic practitioners within the scope of their practice as defined by State law. The reimbursable services of chiropractors under the FECA are limited by statute to physical examination, related laboratory tests and X-rays to diagnose a subluxation of the spine; and treatment consisting of manual manipulation of the spine to correct a subluxation demonstrated by X-ray.

FORM COMPLETION

- Part A shall be completed in full by the authorizing official. The authorization is not valid unless the name and address of the physician or hospital is entered in Item 1 and the signature of the authorizing official appears in Item B. Check B1 or B2 in Item 6, whichever is appropriate.
- Send the completed form to the OWCP address shown in item 12. Send original and one copy of Form CA-16 to the medical officer or physician. If issued for illness or disease, a copy must also be sent to OWCP.

ADDITIONAL INFORMATION

- See 20 CFR and/or Publication CA-810, Injury Compensation for Federal Employees
- Requests for Disability-Related Assistance (Forms and Notices): If you have a substantially limiting physical or mental impairment, Federal disability nondiscrimination law gives you the right to receive help from the OWCP, DFEC in the form of communication assistance, accommodation(s) and/or modification(s) to aid you in the FECA claims process. For example, we will provide you with copies of documents in alternate formats, communication services such as sign language interpretation, or other kinds of adjustments or changes to account for the limitations of your disability. Please contact our office or your OWCP claims examiner to ask about this assistance.

INSTRUCTIONS FOR AUTHORIZED PHYSICIAN/MEDICAL FACILITY FOR COMPLETION OF PART B

YOUR AUTHORIZATION

- Please read Part A of Form CA-16. You are authorized to examine and provide treatment for the injury or disease described in Item 5, for a period of not more than 60 days from the date of injury, subject to the conditions in Item 6. A physician who is debarred from the FECA program as provided at 20 CFR 10.815-826 may not be authorized to examine or treat an injured Federal employee. Authorization may be terminated earlier upon written notice from OWCP. For extension of the authorization to treat beyond the 60 day period, forward your request to the address shown in Part A. Item 12.
- This form covers office visits and consultations, laboratory work, hospital services (including inpatient), x-rays, MRIs, CT scans, physical therapy, emergency services (including surgery) and chiropractic services. Chiropractic services are limited to charges for physical examinations and x- rays to diagnose a subluxation of the spine and treatment consisting of manual manipulation of the spine to correct a subluxation demonstrated by x-ray.
- This form does not cover elective and non-emergency surgery, home exercise equipment, whirlpools, mattresses, spa/gym membership and work hardening programs.

USE OF CONSULTANTS AND HOSPITALS

- You may utilize consultants, laboratories and local hospitals, if needed. A private room may be authorized only if the diagnosed condition is medically necessary as determined by the treating physician and concurred by the OWCP District Medical Advisor. Ancillary treatment may be provided to a hospitalized employee as necessary.

REPORTS

- After examination, complete items 14 through 39, of Part B, and send your report, together with any additional narrative or explanatory material, to the address listed in Part A, item 12. If the employee sustained a traumatic injury and is disabled for work, reports on Form CA 17, "Duty Status Report" may be required by the employing agency during the first 45 days of disability. If disability continues beyond 45 days, monthly reports should be submitted. Reports from all consultants are also required. Delay in submitting medical reports may delay payment of benefits.

RELEASE OF RECORDS

- Injury reports are the official records of OWCP. They shall not be released to anyone nor may any other use be made of them without the approval of OWCP.

BILLING FOR SERVICES

- OWCP requires that when services are provided by a private physician, charges be itemized using the AMA standard Health Insurance Claim Form, HCFA-1500/OWCP-1500. The form should contain appropriate International Classification of Disease (ICD-9) coding schemas in Block-21, and related correctly to the Diagnosis Pointers referenced in Block 24E. The form should also identify services rendered using the Current Procedural Terminology (CPT-4), and HealthCare Common Procedure Codes (HCPC) schemas.
- OWCP requires that when services are performed in an emergency situation, and in an Acute Care Facility for emergency surgery or care, a copy of the OWCP Uniformed Billing Form (UB-04-1450), should be supplied together with the submitted Form CA-16. The form should contain the appropriate International Classification of Diseases (ICD-9) coding schemas in Blocks 66-70, and reference any surgical procedures performed in the facility in Blocks 74a-74e using the International Classification of Disease ICD-9 Surgical Procedure Codes. The UB-04 should be itemized in Block #42 in a summarization listing all ancillary services performed during the stay, and each service; (radiology, Labs, pharmacy, supplies, etc;) should be referenced using Revenue Center Codes (RCC).
- Payment for chiropractic services is limited to charges for physical examinations, related laboratory tests, and X-rays to diagnose a subluxation of the spine; and treatment consisting of manual manipulation of the spine to correct a subluxation demonstrated by X-ray.

TAX IDENTIFICATION NUMBER

- The Provider/Facility Tax Identification Number (TIN) is an important identifier in the OWCP system. To ensure accurate processing and to reduce inaccuracy of payment, the provider billing on an OWCP-1500 billing form should reference the TIN (Employer Identification Number or SSN in Block #25, and indicate this identifier on all submitted reports and billings submitted consistently. The Tax Identification Number for Facilities billing on the UB-04 Billing form, should reference their Federal Tax Identification number in Block #5.

ADDITIONAL INFORMATION

- Contact the OWCP shown in Item 12 of Part A. Refer to Information for Medical Providers at http://www.dol.gov/owcp/dfec/
- Requests for Disability-Related Assistance (Forms and Notices): If you have a substantially limiting physical or mental impairment, Federal disability nondiscrimination law gives you the right to receive help from the OWCP, DFEC in the form of communication assistance, accommodation(s) and/or modification(s) to aid you in the FECA claims process. For example, we will provide you with copies of documents in alternate formats, communication services such as sign language interpretation, or other kinds of adjustments or changes to account for the limitations of your disability. Please contact our office or your OWCP claims examiner to ask about this assistance.

PRIVACY ACT STATEMENT

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), you are here by notified that: (1) The Federal Employees' Compensation Act, as amended and extended (5 U.S.C. 8101, et seq.) (FECA) is administered by the Office of Workers' Compensation Programs of the U. S .Department of Labor, which receives and maintains personal information on claimants and their immediate families. (2) Information which the Office has will be used to determine eligibility for and the amount of benefits payable under the FECA, and may be verified through computer matches or other appropriate means. (3) Information may be given to the Federal agency which employed the claimant at the time of injury in order to verify statements made, answer questions concerning the status of the claim, verify billing, and to consider issues relating to retention, rehire, or other relevant matters. (4) Information may also be given to other Federal agencies, other government entities, and to private-sector agencies and/or employers as part of rehabilitative and other return-to-work programs and services. (5) Information may be disclosed to physicians and other healthcare providers for use in providing treatment or medical/vocational rehabilitation, making evaluations for the Office, and for other purposes related to the medical management of the claim. (6) Information may be given to Federal, state and local agencies for law enforcement purposes, to obtain information relevant to a decision under the FECA, to determine whether benefits are being paid properly, including whether prohibited dual payments are being made, and, where appropriate, to pursue salary/ administrative offset and debt collection actions required or permitted by the FECA and/or the Debt Collection Act. (7) Disclosure of the claimant's social security number (SSN) or tax identifying number (TIN) on this form is mandatory. The SSN and/or TIN, and other information maintained by the Office, may be used for identification, to support debt collection efforts carried on by the Federal government, and for other purposes required or authorized by law. (8) Failure to disclose all requested information may delay the processing of the claim or the payment of benefits, or may result in an unfavorable decision or reduced level of benefits.

Note: This notice applies to all forms requesting information that you might receive from the Office in connection with the processing and adjudication of the claim you filed under the FECA.

Initial Claim Forms

CA-1	Federal Employee's Notice of Traumatic Injury
CA-2	Notice of Occupational Disease/ Illness
CA-35, a-h	**Occupational Disease Checklists** a. Occupational Disease b. Hearing Loss c. Asbestos d. Coronary Vascular e. Skin Disease f. Pulmonary/ Not Asbestos g. Psychiatric h. Carpal Tunnel
CA-2a	Notice of Employee's Recurrence of Disability
CA-5	Claim for Compensation by Widow, Widower and/or Children
CA-5b	Claim for Compensation by Parents, Brothers, Sisters, Grandparents or Grandchildren

Other Types of Forms

CA-6	Official Superior's Report of Employee's Death
CA-7	Claim for Compensation because of an accepted Traumatic Injury or Occupational Disease/ Illness claim
CA-7a	Time Analysis Form
CA-7b	Leave Buy-Back (LBB) Worksheet/Certification and Election
CA-16	Authorization for Examination and/or Treatment
CA-17	Duty Status Report
CA-20	Attending Physician's Report
OWCP-1500a	Health Insurance Claim Form

You can find the above forms on department of Labor's website at:
https://www.dol.gov/general/forms

BACKGROUND INFO ONLY - NO LONGER PRESENTED
The Regulated Industries:
Characteristics and Manufacturing Processes

OBJECTIVES

After completing this module, participants will be able to describe the characteristics of the regulated industry, the processes used, and manufacturing principles related to the meat and poultry industry.

INTRODUCTION

The purpose of this module is to give you a brief introduction to the meat and poultry industries. We will not be covering the details of how we regulate the industries; this is addressed in other modules. This module will give you an overview of the processes used and the products produced by the industries that we regulate. During the module, you'll see some video footage of different *production processes*. These are shown as examples, not as standards. Each establishment is unique, and the production processes used by establishments in your assignment are likely to differ in detail from the ones we present in this module. There are a wide variety of products produced and a number of different activities conducted by regulated establishments. The industry as a whole is dynamic, in that over time, production of products that are not favored by consumers are decreased or discontinued, and new products are created to meet consumer needs.

We have organized these materials by what FSIS calls *processing categories*. These processing categories are addressed and defined in the "*Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP)*" regulations, 417.2 (b). The 9 different processing categories that we will cover include the following:

- Slaughter
- Raw product – non-intact
- Raw product – intact
- Heat treated but not fully cooked - not shelf stable
- Heat treated – shelf stable
- Fully cooked - not shelf stable
- Product with secondary inhibitors - not shelf stable
- Not heat treated - shelf stable Heat treated - shelf stable
- Thermally processed - commercially sterile

There are some processes and technologies that are not specifically addressed by a processing category in the HACCP regulations as listed below:

- Mechanically Separated and Advanced Meat Recovery
- Irradiation
- Egg Products

The Agency developed and distributed generic HACCP models that addressed most of these processing categories. We will be referring to some examples given in these models as we discuss the processing categories.
Every product produced by an establishment (when the hazard analysis reveals any food safety hazard that is likely to occur) must be produced according to a written *HACCP* plan. Many different products may be grouped within a single processing category, as long as the food safety hazards, critical control points, and critical limits are essentially the same.

In this module, we will discuss both quality and safety issues. Both of these issues are important to both the agency and the industry. There are many quality issues, sometimes referred to as *non-food safety consumer protection*, which would render product adulterated. Some examples are products with low net weights or with water added above allowed limits. Safety or *public health protection* issues are given an extremely high priority because of the potential to cause food-borne disease outbreaks. The most common hazard to public health is the presence of harmful bacteria. Throughout this module, we will point out processes where quality or safety issues are important.

Definition of terms:

Before we go further, let's define a few terms:

- *Amenable* - accountable or liable to an order or regulation.
- *Product* - any carcass, meat, meat byproduct, or meat food product, poultry, or poultry food product capable of use as human food.
- *Process* - is a procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products.
- *Process flow diagram* - process flow diagrams provide a simple description of the steps involved in the process. The flow diagram covers all steps in the process which are directly under the control of an establishment. It may also include steps in the food chain which are before and after the processing occurs.

To give you an idea of the *production volume* of the meat and poultry industry, in FY 2008, there were 43.8 billion pounds of poultry slaughtered in federally inspected establishments. For the same period, there were 49.74 billion pounds of meat animals slaughtered.

SLAUGHTER

Slaughter is the process whereby healthy, live animals are humanely stunned, bled, dehided, dehaired and/or defeathered, and eviscerated. The resulting carcass may be split and/or fabricated in some fashion. During the process, inedible waste and products (e.g., products not used for human food such as the hides) are produced. Edible byproducts (e.g., livers and gizzards) are also produced. The establishment must keep

inedible materials separate from edible ones. We will cover byproducts when discussing another processing category.

SLAUGHTER - includes all amenable red meat species, and all poultry classes. Some examples are beef and pork carcasses, and ready-to-cook whole chickens and turkeys. Some of the products, such as whole poultry, will be distributed for sale following the slaughter process. However, most products go for further processing.

Beef slaughter process

Look at the *process flow diagram* (at the back of this handout) for the beef slaughter process. They are only examples of the slaughter process. These processes will vary from establishment to establishment. The examples we use are more typical of large establishments. Large establishments (large volume/many employees) are typically highly mechanized and may process thousands of carcasses daily. Smaller establishments follow many of the same steps, but with fewer employees and less automatic equipment.

Beef slaughter covers all market classes of cattle. Class is determined based on maturity and sex of the animal at the time of slaughter. The *classes* of beef carcasses are calves, steers, bulls, heifers and cows. There are a number of quality issues that are of concern to the producer, such as marbling, color, and texture of the meat, that do not affect the slaughter process.

Cattle are received, unloaded from trucks, and held in pens. Prior to slaughter, packers will usually require that animals be kept off feed to facilitate the dressing procedures. The amount of time animals are kept off feed will vary by establishment. The animals must have access to water in all holding pens. This is a requirement of the humane handling regulations.

A thorough inspection of the live animals before slaughter is called *ante mortem inspection*. The inspection is to identify any disease conditions in the cattle. Some disease conditions are unacceptable because they may affect human health. Others are unacceptable from an aesthetic standpoint.

Stunning is the first step in the slaughter procedure. This must be done in a way that complies with the Humane Slaughter Act. Most establishments use a mechanical method, such as a captive bolt, to render each animal completely unconscious with a minimum of excitement and discomfort. Because of the positive finding of Bovine Spongiform Encephalopathy (BSE) in the United States, the method of air injection stunning is prohibited.

Sticking is the second step in the process. A sharp blade is inserted into the neck, severing the carotid arteries and jugular vein, resulting in exsanguination and death. Typically, this is done while the animal is hanging head down from the rail. These overhead rails or tracks move at a controlled speed so that the carcass advances through the various slaughter processing steps.

The next step is *removing the hide*. This may be achieved through various methods, either using mechanical equipment or by hand (at small operations).

After the head and hide are removed, many establishments use *anti-microbial interventions*. Anti-microbial interventions include, but are not limited to, hot and/or ambient temperature water wash, organic acid wash, and steam vacuuming. The steam vacuuming system is used to remove contamination from the dehided carcass either before or after evisceration. Additionally, some of these interventions are used as a multi-hurdle methodology. These interventions can be done before or after evisceration of the carcass for the removal of visible contamination.

Bunging, when the rectum (bung) is secured to prevent contaminating the carcass with fecal material, happens prior to evisceration.

Evisceration is done to separate the internal organs from the carcass. Even in highly mechanized establishments, this is still done by hand. It is important that evisceration is done properly so as not to *contaminate* the carcass with the contents of organs such as the stomach or intestines. Fecal material or stomach contents *(ingesta)* contain many bacteria, and may possibly harbor certain harmful bacteria *(pathogens)* such as *E. coli* O157:H7, *Salmonella*, *Campylobacter jejuni*, etc.

At this point the carcass receives *post mortem inspection*. Similar to ante mortem inspection, the carcass is examined for disease conditions that cause the carcass or parts to be unacceptable for human consumption.

Next the carcass is *split* with a saw. At the trim rail, an inspection reveals whether the carcass is free from contamination or quality concerns that can be removed by *trimming*.

In the next step, the carcasses are weighed, *marked* with an official USDA inspected and passed brand, and washed. They are then moved to a chill box or cooler and *chilled* to a specified temperature. The chilling step helps inhibit the growth of spoilage and harmful bacteria. There are various methods and equipment used for chilling the carcass.

Carcasses are typically *stored* in large refrigerated warehouses called coolers until they are shipped. It is important that an appropriate temperature, humidity, and air flow be maintained in coolers. Generally, the colder the temperature in the cooler, the slower the bacteria grow. Proper temperature is essential for preserving the quality and maintaining the safety of the product.

From this point, the carcass halves are ready to be *fabricated*, which means cut into parts. This *further processing* may happen at the slaughter facility in a processing or fabrication department, or the carcasses may be shipped to another establishment.

Edible and inedible byproducts will be covered when we discuss the RAW PRODUCT – NON-INTACT processing category. Some establishments may include edible and inedible byproducts in their Slaughter HACCP plan.

Pork slaughter process

Now, let's look at the process flow diagram for pork slaughter (at the back of this handout). We will discuss the process for the skin-on pork carcass, which is most common. There are other pork slaughter processes, such as skinned, or hot boned.

Hog slaughter is somewhat similar to beef slaughter, but there are some major differences; we will highlight only the differences.

Hogs are usually stunned with an electrical shock or using CO_2 that renders them unconscious and insensible to pain.

Sometimes hogs will be hanging during the sticking and bleeding step. However, sticking and bleeding can also be done while the hog is lying on its side or being held on its back.

Instead of removing the hide, usually hogs are scalded and *dehaired*. Then, they are quickly singed with a flame to remove any remaining hairs.

The step called *"gambrelling"* refers to slicing the tendons on the back of the hock so that the carcass can be hung on a gambrel, or special type of hook.

Poultry slaughter process

In addition to the different *species* of poultry, such as chickens or turkeys, there are also different *classes* of poultry. Classes are groups based on physical characteristics like age or sex, such as fryers, roasters, or hens.

The process flow diagram (at the back of this handout) for the poultry slaughter process has many similarities to beef and pork slaughter. For example, there is holding, stunning (varies), bleeding, washing, evisceration, trimming, washing, and chilling. Some of the other steps are specific to poultry, such as picking, which removes feathers. The establishment may use a variety of methods and types of machinery to accomplish each of these steps, such as an automatic stunner, an automatic scalder, a picker, an outside bird washer, an eviscerating trough, oil sac cutter, etc., to allow it to process thousands of birds per hour.

The presentation step entails placing the carcass and its visceral organs in position to facilitate inspection for disease conditions.

The *salvage* and reprocessing steps refer to interventions the establishment employees would perform to remove contamination, bruises, or other unwholesome conditions from a carcass, so that the carcass is acceptable for human consumption and eligible for the marks of inspection.

Chilling for poultry is different than chilling for beef or swine. Poultry chilling is usually done in a large container of chilled water called a *chiller*, which holds a large number of poultry carcasses. It is very important that the chiller water does not become contaminated with fecal matter from any poultry carcass, because it could potentially contaminate *all* carcasses that enter the chiller. The amount of time birds spend in the chiller is a quality issue because the birds gain water weight.

The processing of byproducts may be covered either in the slaughter HACCP plan, or in another processing category.

RAW PRODUCT – INTACT

The RAW PRODUCT – INTACT processing category includes all raw products which are not ground in their final form. Some examples are beef trimmings, steaks, roasts, chops, poultry parts, fabricated products, and edible byproducts (e.g., livers, gizzards).

The process flow diagram (at the back of this handout) for this category uses the example products beef trimmings and beef tenderized cuts.

Notice that the first step is *carcass receiving*. Carcasses are chilled after slaughter for a specified period allowing them to become firm to facilitate a neat job of cutting.

Fabrication

Fabrication refers to creating the various cuts from the carcass to produce particular types of product. *Primal* or *wholesale* cuts are made first (refer to Figure 1, at the back of this handout). Their names usually identify where the meat comes from on the animal, such as the loin, the shoulder, etc. The establishment typically uses large mechanized saws to fabricate the carcass into primal cuts.

As denoted in Figure 1, *retail cuts* describe what part of the primal cut the meat comes from, for example, rib roast or round steak. Retail cuts may be made with a saw, especially if they include bone. Often, primal parts are boned before cutting into retail cuts, in order to produces boneless items. Establishments that produce portion controlled retail cuts for hotels, restaurants, and institutions are often called *HRI* (Hotel, Restaurant, and Institution) operations.

Packaging materials (such as wax treated paper or plastic film) protect the product from damage during refrigerated or frozen storage.

The final step is distribution, either to other departments in the same establishment, other establishments, or to retail markets.

Tenderization

Tenderization is another procedure used in some establishments. All cuts can be tenderized, but this is typically used on cuts from lower quality grades and less tender cuts of higher graded carcasses. There are several methods for tenderizing meat. They include aging (natural chemical process), the use of enzyme solutions (artificial chemical process), and use of mechanical tenderizers. Mechanical tenderizers typically press many thin blades through the meat pieces, cutting the muscle fibers. Not all tenderized products fall into this category. Products in this category are those tenderized by natural aging, and marination or tumbling without vacuum.

Byproducts

The processing category of RAW PRODUCT - INTACT includes edible byproducts. Consumer demand has had an effect on production levels of various byproducts. For example, vegetable oils have replaced animal fats like lard and tallow in the frying industry. Technological developments have also had an impact on the demand for

inedible byproducts. Synthetic materials have been developed to make many items that were once made of animal products.

Edible byproducts - Some of the edible byproducts include tongues, brains, sweetbreads, hearts, livers, and kidneys. These are called variety meats. Because variety meats are more perishable than carcass meat, they must be chilled quickly after slaughter and processed or moved quickly into retail trade. They may be sold as fresh or frozen items, or used to make other processed foods. There are exceptions to the use of edible byproducts derived from cattle 30 months of age and older, including brain, skull, eyes, trigeminal ganglia, spinal cord tissue, and dorsal root ganglia. As of January 12, 2004, new regulations and policies prohibited the use of the aforementioned materials for human consumption as a result of a positive case of BSE.

Some descriptions of the sources and uses of various edible byproducts are as follows:

- *Casings* for sausages are sometimes made from sheep or hog intestines. (Note: the distal ileum of beef small intestines are prohibited regardless of age)
- *Chitterlings* are made from thoroughly cleaned and cooked intestines of pigs, and consumed as a variety meat.
- *Blood* is used as an ingredient of certain specialty products.
- *Tripe* is obtained from the first (rumen) and second (reticulum) stomach compartments of cattle. It is consumed as a variety meat and used in specialty products.
- *Sweetbreads* are thymus glands obtained from the ventral side of the neck and inside the chest cavity of young cattle. They are used fresh or frozen.

Inedible byproducts - The uses for inedible byproducts are constantly changing based on the available technology and consumer interests. Next are some examples of the ways in which inedible byproducts are used:

- *Hides, skins, and pelts* are used to make leather goods and glue.
- *Fats* are used to produce industrial oils, lubricants, soap, glycerin and other cosmetic ingredients. Most inedible fats are processed by dry rendering.
- *Bones* are used to produce animal feed (except ruminant bones to feed ruminants) and fertilizer.
- Some *glands* are used to produce pharmaceuticals. For example, bovine ovaries yield estrogen. The pancreas glands yield insulin, which is used to treat diabetes.
- *Lungs* are used to produce pet foods.

These lists are by no means complete, but give a few examples of the uses of edible and inedible byproducts.

RAW PRODUCT – NON-INTACT

This processing category includes all raw products that are raw ground, comminuted or otherwise non-intact. Some of the common products are ground beef, hamburger, ground beef patties, ground pork, fresh sausage, Italian sausage, and ground poultry products. Beef, pork, veal, lamb, chicken, and turkey can all be ground and sold or used in other products. One of the favorite products served in this country is the hamburger patty, which is the example we will use in this section (refer to flowchart at the back of

this handout). However, the processing steps that are used to produce hamburger patties are also used for other products. Establishments differ in how they design their production processes, and you may see many variations of the basic processes that we illustrate.

Meat for use in non-intact products may come into the establishment from outside suppliers, or it may be produced within the establishment during fabrication and boning operations. Non-meat ingredients and packaging materials will come from outside suppliers. Many establishments use a combination of suppliers, depending on the cost and type of product available from each.

Written purchase specifications are developed by some establishments to ensure that a consistent product is received. Specifications are formal agreements between the supplier and the purchaser, and may include quality aspects, such as portions of lean and fat, and safety factors such as laboratory testing for pathogens.

After meat ingredients are received, they are stored in freezers or coolers until use. Meat products must be maintained at refrigeration temperatures adequate to prevent spoilage and growth of pathogens. *Refrigeration* achieves several purposes: it slows the growth of microorganisms, including spoilage bacteria and pathogens; slows the metabolic and enzymatic activities within the meat tissues that would lead to product deterioration; and also reduces moisture loss from the product.

Chiller or cooler temperatures in the range of 38° - 45°F will substantially retard most pathogen growth. However, certain types of bacteria, like *Yersinia* and *Listeria*, can grow at these temperatures and may be a significant hazard. Chiller storage is temporary because even at these temperatures, the spoilage organisms will continue to grow, although at a very slow rate. Freezers, generally maintained at -10° F or below, halt the growth of all bacteria. Product kept at these temperatures will maintain safety and quality for longer periods of time.

Dry ingredients and packaging materials are also received and stored prior to use.

Ground products are often made from *trimmings*. Trimmings are the pieces that are removed from carcasses while producing higher quality retail cuts of meat. Grinding is a way that establishments can use lower quality products that would not be saleable to a retail consumer. In addition to trimmings, ground beef is also commonly made from flanks, short plates, shank meat, briskets, chucks, rounds, or sirloins. Meat ingredients used may be fresh or frozen, or a combination.

Often products contain *non-meat ingredients*. Ground products are often seasoned with salt, sugar, spices, or other flavorings. Depending on the product being made, water may be added, and some product formulations include binders and extenders such as soy flour or non-fat dry milk.

Establishments use a specified recipe, called a *formulation*, to create a consistent product batch after batch. The formula lists the weights or percentages of ingredients to be used. Meats and other ingredients are weighed before use to ensure that the proper amount of each is added to the batch.

Comminution is the process of reducing the particle size of meats. Several different machines are used, including the grinder, the bowl chopper, and the flaker. Some producers use a combination of several of these in the production of a product.

The *grinder* consists of a hopper into which the meat chunks are placed. The meat then moves along an auger or screw, through a cylinder, at the end of which is a grinding plate and a knife. As the meat is pressed up against the plate the knife turns and cuts off small bits of the meat. The size of meat particle produced is determined by the size of the holes in the grinding plate.

Another method of reducing particle size is the *bowl chopper*. This machine consists of a metal bowl that revolves and a metal knife that rotates, cutting through the meat pieces in the bowl. The bowl chopper also mixes product as it chops it.

The *flaker* is used on large frozen blocks of meat or meat trimmings. Product is pressed against the knife blades, which shave off pieces of the still-frozen meat, enabling it to be used in formulation without thawing.

Sometimes meat ingredients go through several grinding processes. Often, fat and lean meat ingredients are ground separately and then combined.

After comminuting, products are mixed thoroughly. Often product is transferred to a separate piece of equipment, called a mixer or blender, in order to mix it. The *mixer* consists of a chamber that the ingredients are placed into, and blades or paddles that turn and mix the product, resulting in a uniform distribution of fat and lean particles. Non-meat ingredients, if used, are added at this stage.

After comminuting and mixing, the ground meat mixture is often *shaped* into different forms. Fresh sausage may be extruded into a casing. Hamburger or ground beef is often shaped into patties using a patty machine. After formation, the patties may be frozen.

Because of the moving metal parts common in these operations, there is a possibility of metal chipping or breaking. Proper maintenance of equipment is essential to reduce this possibility. Some establishments use a *metal detector* to identify product that may be contaminated with metal fragments.

The final step for ground products at the processing establishment is *packaging and labeling*. Product may be packaged into retail size packages, into larger containers for institutional use, or into bulk containers for sale to other establishments for further processing. Although there are many different combinations of packaging materials in use, plastic liners and cardboard boxes are some of the materials commonly used. Labels must accurately reflect the product.

After packaging and labeling, products must be held at proper refrigeration temperature during storage, and throughout distribution to the customer.

Many variations of these steps are used to produce the different products available in the marketplace. Ground products may be marketed in bulk or in patty form. Fresh sausage products are also included in this category, and these products may be sold in bulk or in casings. Poultry products are common today, and ground poultry products are

available in bulk, packaged into chubs (short plastic casings), or formulated into a variety of sausage products.

Mechanically Separated and Advanced Meat Recovery Product

Often, the industry searches for ways to yield the maximum edible, wholesome product from the meat or poultry carcass. The mechanical separation process is a technology that industry uses to obtain more usable product from bones from which the muscle has been removed. Often, you will see these products referred to as *"mechanically separated (species) or MS (species)"***.** Any species, **except** beef, can be used: lamb, pork, chicken or turkey. Use of beef in MS product is prohibited. Mechanically separated product falls under the Raw Product Non-Intact category.

The process begins with bones (refer to flow chart at the back of this handout). Bones for this process have usually already had most of the muscle tissues removed by hand boning, or they are bones, like neck bones, which are difficult to process. The bones are ground up, and the resulting mass is forced through a sieve. The softer muscle particles are thus separated from the hard bone particles, which remain behind the sieve. The resulting product has a paste-like consistency.

Great pressure is used to force the product through the sieve, and this result in a temperature rise in the product. Therefore, product must be processed quickly and the temperature immediately reduced, in order to prevent oxidation and microbial degradation of the product. Even with these precautions, this product will deteriorate quickly.

Although mechanically separated product has many of the characteristics of meat and may be used as a meat ingredient in the formulation of quality meat food products, it is not meat, as defined in the regulations. In particular, the consistency of mechanically separated livestock product and its mineral content are different from those of meat. The bone marrow, spinal cord, and a certain amount of fine bone particles are included in the finished product. This actually provides a readily absorbed source of valuable nutrients like calcium and iron. However, there are specific limits on the quantity and size of the bone particles included in the final product. There are also limits on how much of the mechanically separated product that can be used in meat or poultry products, and it must be identified in the ingredients statement of the label. As per 9 CFR 319.5(b) mechanically separated beef is prohibited for use as human food.

A similar technology used by industry is called *advanced meat recovery (AMR)*. This process obtains the meat tissues from the bones without incorporating significant amounts of bone and bone products into the final product. The resulting product consists of distinct particles of meat, with the typical color and texture of the species used. There are no special limits on the use of this product. Nevertheless, the presence of CNS-type tissue may be evident in product derived from AMR systems. Therefore, AMR derived products from cattle that contains central nervous system (CNS) tissue cannot be used as an ingredient of a meat food product. More specifically, Regulation 9 CFR 318.24 prohibits the use of skulls or vertebral columns (with exceptions) of cattle 30 months of age and older from use in AMR systems.

Irradiation

Food irradiation is a technology that exposes food to radiant energy in order to reduce or eliminate bacteria. Ionizing radiation will reduce, and in some circumstances eliminate, pathogenic microorganisms in or on meat and poultry (refer to flow diagram at the back of this handout). FSIS recognizes irradiation as an important technology for helping to ensure the safety of meat and poultry. FSIS has included ionizing radiation as an approved additive in pork carcasses and fresh, or previously frozen, cuts of pork that have not been cured or heat processed for the control of *Trichinella spiralis*, which causes trichinosis. Ionizing irradiation is also recognized as an approved additive in fresh or frozen, uncooked, packaged meat or poultry products for the purpose of reducing pathogenic microorganisms and extending shelf life.

Radiation is broadly defined as energy moving through space in invisible waves. Radiant energy has differing wavelengths and, hence, degrees of power. Forms of radiant energy include: microwave and infrared radiation, which heat food during cooking; visible light or ultraviolet light, which are used to dry food or kill surface microorganisms; and ionizing radiation, which penetrates deeply into food, killing microorganisms without raising the temperature of the food significantly. Food is most often irradiated commercially to reduce the numbers of pathogenic microorganisms, to extend shelf-life, or to prevent reproduction of insects. Food irradiation for these purposes is practiced in many countries, including the United States.

Treating product with irradiation could result in significant *reduction or even the elimination of pathogens*. Ionizing radiation has been shown to be effective at eliminating *Salmonella*, *E. coli* O157:H7, *Clostridium perfringens*, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Campylobacter jejuni*, among others. Irradiation also can significantly extend the shelf-life of meat and poultry food products through the reduction of spoilage bacteria.

Irradiation *dose* is measured in kilo Gray (kGy); the maximum dose for use on meat products is 4.5 kGy. The radiation dose necessary to reduce the initial population of bacterial pathogens by 90 percent (the D-value, or 1-$\log_{10}$) range from 0.1 kGy to 1 kGy. Higher radiation doses (above 1 kGy) are needed to accomplish the same anti-microbial effect in a frozen food versus a non-frozen food of the same type.

Irradiation does not significantly increase the temperature or change the physical, sensory, or nutritional characteristics of foods. Irradiation does not make food radioactive. During irradiation, the energy waves affect unwanted organisms but are not retained in the food. This is similar to the way that food cooked in a microwave oven does not retain those microwaves. Because irradiation does not raise product temperature, product is still raw and requires refrigeration.

The irradiation process requires a source of energy. The two types are radioisotopes (radioactive materials such as cobalt or cesium) or machines that produce high-energy beams. Specially constructed facilities are used to confine the beams so that personnel won't be exposed.

The Food and Drug Administration (FDA) regulates all aspects of irradiation: what products it can be used on, allowable dose, and how those products are labeled. The

USDA is responsible for the inspection and monitoring of irradiated meat and poultry products and for the enforcement of FDA regulations concerning those products.

The *"radura"* is an internationally recognized symbol identifying irradiated food. The FDA requires that both logo and a statement ("Treated with irradiation" or "Treated by irradiation") must appear prominently on the label of packaged foods, and on bulk containers of unpackaged foods.

Irradiation can be used within a *HACCP system*. Establishments that irradiate product probably would establish critical limits such as radiation dosage. By ensuring that specific limits for these parameters are met, establishments could be reasonably sure that a predetermined reduction in pathogens has been achieved within the irradiated product.

HEAT TREATED BUT NOT FULLY COOKED - NOT SHELF STABLE

Up to now, all of the processing categories that we discussed dealt with raw product - product that had not been heat treated. This section covers a group of products that receive a heat treatment, but they are *not fully cooked*. These products still need to be thoroughly cooked in order to be safely consumed.

The products included in this category vary quite a bit from each other. What they have in common is that *they have received some type of heat treatment, but not sufficient heat treatment to result in ready-to-eat product*. One well-known product is bacon, a cured and smoked pork product. Another product is cold smoked sausage, a product that has been smoked to add flavor, but is still raw. Partially cooked battered and breaded poultry is included in this category; it has been cooked only enough to "set" the breading. Char-marked patties are similar; they have been cooked only enough to add distinctive char marks on the meat surface, but are still essentially raw. Low temperature rendered products are heat treated to melt and remove some of the fat in the meat tissues, but again, they are not fully cooked. As you can tell, there are many different types of products grouped into this category.

We are going to discuss the processes involved, focusing on some of the most common products. There will be many variations of these processes used by establishments, and this module will only provide an introduction to the procedures used.

Bacon

Bacon is an example of a product that is cured and smoked. Let's study the process flow chart (at the back of this handout) for this product.

First, raw meat ingredients are *received*, either from another establishment, or from the fabrication department within a large establishment. In this case, the raw meat ingredient used is the pork belly.

The non-meat ingredients are weighed and combined. Bacon is a *cured* product, which means that *additives* are used to preserve the product and stabilize the color. Following are some of the most common additives:

- *Salt* is used for flavor and because it preserves the product by inhibiting bacterial growth.
- *Sugar* is sometimes used as a sweetener. It can counteract the harsh flavor of the high levels of salt used in some products.
- *Nitrite (or less commonly used nitrates)*- stabilizes the color of the meat, contributes to the characteristic flavor of cured meat, inhibits the growth of both pathogens and spoilage microorganisms, and retards rancidity (deterioration of the fat).

The amounts of nitrite and nitrate allowed are restricted by FSIS regulations. Additives that have regulatory limits are known as *restricted ingredients*. Because nitrates are reduced to nitrites and is further converted to nitric oxide which react with amines present in muscle fibers to form *nitrosamines* (are known to cause cancer), the nitrite and nitrates levels must be closely monitored. Also, nitrites can be very toxic to humans therefore the use of these ingredients is carefully controlled. Supplies of nitrites and mixtures containing them are kept securely under the care of a responsible employee of the establishment. Often, the nitrite is purchased pre-mixed with salt and colored pink to prevent its accidental misuse.

Nitrite is most important because of its role in the developing the cured meat color. Nitric oxide (the chemical reaction product of nitrite) reacts with *myoglobin*, a complex protein present in meat. Myoglobin is the pigment that is responsible for the red color of muscle tissue. A series of chemical reactions results in the formation of the stable pink color of cured meat.

These are just some of the most common curing ingredients. Many other ingredients are used by industry, and will contribute to the variety of formulations that you may encounter.

These cure ingredients are sometimes mixed with water to form what is known as a *pickle*, or a curing solution. The solution is often injected into the meat using an *injector*. This equipment carries the meat past a series of needles that pierce it and force the pickle solution into the interior of the meat pieces. This process is called *pumping*. This results in a fast and even distribution of the pickle. There are many other means of introducing the pickle; sometimes meat pieces are simply placed into a barrel or vat of the pickle. This is a much slower process than injection.

After injection, the meat pieces are hung onto racks called *trees* or *cages*, which hold the meat while it is further processed. The meat hangs in a cooler for a period of time to ensure that the cure ingredients have time to react with the meat, and to allow some of the solution to drain out, if necessary.

The next step is the *smoking* process. The racks of meat are loaded into a smokehouse. The establishment operator carefully controls the smokehouse. Time, temperature, and humidity are parameters that effect product. These parameters are

usually carefully monitored to ensure that the smoking step proceeds as designed by the establishment.

One common type of monitoring equipment used is the dry bulb/wet bulb thermometer. This device monitors the temperature inside the smokehouse with two thermometers set right next to each other, one dry, and one inside a moist piece of cloth. The difference between the two temperature readings is used to calculate the humidity of the environment.

The operator sets the smokehouse controls to run through a series of processes, in which the addition of steam and smoke will change the conditions inside the smokehouse. Although bacon receives some heat treatment in the smokehouse, it is not fully cooked. The smokehouse treatment is primarily designed to deposit the smoke onto the surface of the meat.

Smoke has several important effects on the meat product:

- It develops the characteristic smoke flavor.
- It results in a color change (browning effect), on the surface of the meat.
- It has some preservative effect.
- It protects the meat from *oxidation*, which is the development of off-flavors.

Smoke is a complex mix of chemical compounds, including phenols, alcohols, organic acids, carbonyls, hydrocarbons, and gases. The phenols and carbonyls produce the color and flavor of smoke. Smoke has a *bactericidal* action; that is, it kills some of the bacteria present. This is due to the combined effects of heating, drying, and depositing the chemical components of the smoke. Smoke is often produced from hardwood sawdust in a *smoke generator*. Liquid smoke is also used.

After the product has been smoked according to the establishment's desired process standards, it must be cooled down to safe product storage temperatures. This is often done initially in a *blast cooler* for maximum cooling effect. This cooler forces cold air at a very high velocity around the bacon pieces, quickly cooling them.

After the product is properly chilled, it may be sold in the bulk form. Most bacon, however, is sold as sliced product. The meat pieces are usually shaped in a press, or *blocked*, in order to produce uniform slices. The product is sliced, and packaged. *Net weights* are checked by establishment personnel to ensure that the net weight statement on the label is accurate. Other quality checks are often performed by the establishment on the finished product. The product is now ready for final distribution.

Other products in this category

Cold smoked sausage is similar to bacon, in that the product is smoked primarily for appearance and flavor. The process is called *"cold-smoked"* because the smoking does not result in high enough temperatures to cook the product. The smoke used is not actually cold; it is usually 90 - 120° F. The product must be quickly cooled to prevent bacterial growth.

Partially cooked battered, breaded poultry products are another product in this category. The raw poultry pieces are coated with *batter*, a liquid mixture of flour, egg, milk, or water; or with *breading*, a powder or granular mixture of cereal products, like breadcrumbs; or they are both battered and breaded. The pieces are then heat treated to "set" or precook this coating, usually in hot oil. The poultry product inside is still uncooked. The products are cooled, usually in a special *IQF (individually quick frozen)* freezer, and packaged.

Char-marked patties are also included in this category. These products received a heat treatment on the outside surface that produces a "char-mark" which imitates the marks created from cooking product on a grill. The product is still essentially uncooked, and it is important that product labeling distinguish this product from ready-to-eat products. It is crucial that this product be fully cooked by the final user, to ensure safety.

Low temperature rendered products are derived from the low temperature rendering of fresh meat. The products are usually ground, heated, then treated to a process that separates some of the fat from the lean portion. The temperature used must not exceed 120° F. The product is then cooled quickly to limit potential growth of bacteria at these warm temperatures. The heat treatment is not sufficient to eliminate pathogens or to result in a cooked appearance. The rendered product is frozen and used in further processing operations. If the raw meat trimmings had at least 12% lean meat prior to rendering, the resulting product is called *Partially Defatted Chopped (species***)**. If the fatty trimmings used as raw materials contain less that 12% lean meat, the resulting products are called *Partially Defatted (species) Fatty Tissue*.

There are, of course, many other products that you may encounter that would fall into this category. The common characteristic is that these products receive some heat treatment, but not enough to result in a fully cooked, ready-to-eat product.

FULLY COOKED - NOT SHELF STABLE

This processing category includes all food items that have been fully cooked, but are not shelf stable. *Fully cooked* means that these products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. This is also known as *"ready-to-eat"*. Please note, however, that many of these products are customarily eaten hot, and cooking instructions may be included on the label. This does not affect the classification of these products into this processing category. An example is the hot dog. This product receives sufficient heat treatment to be fully cooked, and does not necessarily need to be reheated by the customer. Most customers do, however, heat this product, and cooking instructions may be included on the label of the product. Another parameter that defines this category is that the products are not shelf stable. *Shelf stable* means that the product has received a treatment that renders it safe to store without refrigeration. This does not apply to this category. These products, although fully cooked, are not shelf stable, and must be kept refrigerated or frozen in order to maintain safety and quality. Again, the hot dog is a great example. It must be kept refrigerated by the consumer until it is eaten.

There are many different types of products that fall under this category. There are some major groups that we will closely examine, but there will be many other products that you will encounter in the industry. Keep in mind that what they all have in common is that

they are fully cooked, but they are not shelf stable. Some examples that we will discuss are the cooked and smoked sausages, cooked deli meats such as ham, roast beef, pastrami, corned beef, cooked chicken roll, and smoked turkey breast. Other meat and poultry products that fall under this classification are salads, such as chicken or ham salad, and frozen entrees.

Cooked and smoked sausage

One of the major product groupings that fall under this category is the cooked and smoked sausage. There are many different types of these sausages made; some common examples are bologna, cooked salami, polish sausage, and hot dogs. Let's take a closer look at hot dogs as an example of how these products are produced (refer to flowchart at the back of this handout).

The first steps are the same as we have previously covered: meat and/or poultry, other ingredients, and packaging materials are received and stored in the establishment until ready to use. Many establishments carefully control the quality of the incoming ingredients through purchasing specifications. Meat ingredients may have quality specifications such as percent fat, moisture, and protein. These are parameters that will affect the final quality of the product.

Raw meat ingredients used in these products will depend on the type of finished product desired. Not long ago, most hot dogs were either a combination of pork and beef, or they were all beef. Today, establishments still make these products, but many more combinations of ingredients are used. Many formulations include at least some *poultry* products, (turkey or chicken), and some products are made exclusively with poultry.

Many larger volume establishments use a system called *least cost formulation*. This is a computerized program that allows the processor to determine the specific allocation of ingredients required for a given product at a minimum cost. The product can be manufactured subject to ingredients available. These establishments carefully analyze samples of each batch of ingredients and enter the data into the computer program. The program determines how many pounds of each ingredient to use, in combination, to produce the desired product. Theoretically, each finished batch of product will then be identical to each other batch. Of course, the final retail label must have a list of ingredients in the correct *order of predominance*, despite any variations caused by the least cost formulation system.

The first step in the formulation process is weighing or measuring the meat and/or poultry ingredients. They are ground and mixed or blended with the non-meat ingredients. Often establishments will *pre-blend*, that is, they will grind and mix the meats with water and salt, and sometimes with the nitrite, and let it stand for a period of time in a cooler.
We have already discussed the most common non-meat ingredients used in hot dogs: water, salt, curing agents like sodium nitrite, and sugar. Let's take a look at some of the other ingredients that may be used, depending on the formulation.

Binders and extenders, such as dry milk powder, cereal flours, and soy protein, have a number of uses in a sausage formulation. They increase the overall yield, improve binding qualities, and add certain flavor characteristics.

Cure accelerators such as ascorbates and erythorbates are used to speed up the curing process. They also stabilize the color of the final product.

Phosphates are used to improve the water-binding capacity of the meat, and contribute to the flavor and color of the product.

Spices and flavorings are used to add flavor to the sausage. The wide range of available spices, seasonings, and flavorings is a primary reason for the variety available in sausages in the marketplace.

- *Spices* are any aromatic vegetable substance that is intended to function as contributing flavor to food, rather that as a nutritional substance. The active aromatic or pungent properties of spices that contribute the most to the flavoring effect are present in the volatile oils, resins, or oleoresins of the spice. Spices may be used whole or ground. White pepper, paprika, and nutmeg are common spices used to produce the characteristic flavor of the hot dog. Because paprika also adds color and makes meat look brighter red, it must be listed as “paprika” on labels.

- *Flavorings* are substances that are extracted from a food, and contribute flavoring, such as spice extracts.

After the non-meat ingredients are blended with the ground meats, the mixture is *emulsified.* This is done in an emulsifier, and further reduces the size of the meat particles to achieve a very fine texture. Fat, protein, salt, and water are mixed and combined into a semi-fluid emulsion. The meat muscle protein, myosin, is *solubilized*, or released from the muscle fibers, by salt. The solubilized protein and water combine and surround the fat globules, and suspend the fat particles within the mixture.

Careful control of the amount of each ingredient is essential to the quality of the final product. The manufacturer must select a mix of raw meat materials with the appropriate binding characteristics. Different meats vary in their ability to bind. Lean beef, for example, bull, cow, and shank meat, has high binding ability. Regular pork or beef trimmings with more fat, and poultry, have medium binding ability. Low binding meats contain high levels of fat, such as jowls and briskets. Organ meats have no binding qualities. The binding capabilities are directly proportional to the myosin (red) in the muscles. Thus, the paler the muscle, the less bind it contributes to the mixture.

Control of the emulsification process is also essential. Product defects result from too much chopping or from an increase in temperature during the process. Over-chopping makes the protein fibers too short. It also creates heat from friction that melts fat. This results in product defects such as pockets of fat in the final product.

After emulsification, the mixture (or “batter”) is *stuffed* into casings, usually artificial plastic casings that allow moisture to cook out and smoke flavors to penetrate. Natural casings such as sheep small intestines may also be used.

Following stuffing, the product is *linked* by pinching and twisting the casing to form separate units of sausage. The sausages are still held together by the casing. These lengths of casings are then placed on racks or trees, and are ready to be loaded into the smokehouse. Some establishments load trees into individual smokehouses, however, some large volume establishments use continuous smokehouses.

The smokehouse parameters that must be controlled are temperature, time, and humidity. The product must be exposed to a high enough temperature in order to produce a fully cooked, ready-to-eat product. The temperature inside the smokehouse and the internal temperature of the sausage, may be monitored by the establishment in order to verify that the critical limits are met. Cooking is a very important step, because it is here that any pathogens that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level.

After product has reached the final temperature desired, the cooling process begins. This product is often showered with cold water inside the smokehouse. This removes some of the heat from the product, and immediately halts the cooking process. The shower is usually not sufficient to complete the cooling process. Usually product is moved to another chiller or cooler to finish cooling. Some establishments use very cold water as a chilling medium, sometimes with salt added to lower the temperature below the normal freezing point of water. This is called a *brine chiller*. Other establishments may use cold air, and some use a combination of methods.

The cooling process is also known as *stabilization*. There are two types of bacterial contamination that must be addressed by the stabilization process:

- Spore-forming bacteria (*Clostridium perfringens* and *Clostridium botulinum*) can survive cooking when in the heat-resistant spore form, and these organisms need to be considered as the products are chilled. Growth (sometimes referred to as *"outgrowth"*) of these bacteria is slowed by rapid cooling. Cooling rates, or time/temperature relationships, must be carefully controlled in order to ensure that product does not remain at warm temperatures that would support the outgrowth.

- Recontamination with bacteria (e.g., *E. coli, Salmonella, L. monocytogenes*) must be considered as cooked products are exposed to the environment, food contact surfaces, or cross-contamination with raw product prior to final packaging. Proper chilling and cold storage temperatures are essential to limit the growth of these bacteria.

After product has been chilled to the desired temperature, it is removed from the artificial casings in a machine called a *peeler*. This equipment quickly runs the sausage through a tunnel that has a tiny blade that slices the casing. Steam or air is then used to blow the casing away from the sausage. The sausage links are now separate. If you closely examine the outside of a hotdog, you might see where the casing had been cut. This blade is a potential source of contamination, since it contacts every hot dog!

Sometimes a product that has partially or fully completed the production cycle is not sellable but is still wholesome, and can be used for food. For example, the casing of some sausages may split during the cooking or smoking cycle. Manufacturers may reuse these edible but unsalable products by removing the casing and adding the contents to the grinder to include in another run of the same product. This is called *rework*. Since the proteins are coagulated from cooking, rework has no bind capabilities. Of course, the ingredients of the rework must be compatible with the ingredients of the batch to which they are added.

The final steps are packaging, labeling, and storage. The product is ready for distribution to retail stores, restaurants, or institutions.

Deli meats

Deli meats such as ham, roast beef, and smoked turkey breast all have very similar processes. These products are produced by adding a solution of ingredients to the raw meat ingredient. Cured products, like ham, turkey ham, and corned beef, have nitrite in the solution. Other products, like roast beef or chicken roll, may have only salt and seasonings used. The solution is often added with an injector, but products may also simply be immersed in the solution.

Traditionally, these products were produced with whole muscle pieces, such as bone-in hams, pieces of beef round, whole briskets, or whole boneless turkey breasts. Today, many products are made with chunks of meats of various sizes, to make chopped and formed products.

Products may be *tumbled* or *massaged*, which increases both yield and tenderness. In this procedure, meat and solution are added to a chamber with baffles. The chamber or the baffles rotate, which subjects the meat pieces to a gentle beating process. This produces muscle fiber disruption, with a corresponding release of salt-soluble protein, which in turn coats the meat pieces. The protein is then coagulated by cooking to form a matrix between the individual pieces, thus giving the product an intact muscle appearance.

The meat pieces are often formed into uniform shapes. This can be done by stuffing them into nets, casings, or molds. The product takes on the shape of the mold when cooked.

The cooking and cooling of these products is similar to the cooked sausage procedure. Some of these products, however, are cooked in a water bath or in a steam chamber.

After chilling, many of the products are packaged as whole roasts, for the retail deli market. Other products are sliced and packaged in retail consumer sized portions. Most are vacuum packed, which helps to protect the product quality and increases the shelf life.

Salads

Another type of product in the FULLY COOKED - NOT SHELF STABLE category is the meat salad. Ham and chicken salad are some of the common salads produced. The establishment starts with fully cooked product. The fully cooked meat is chopped or ground, and mixed with other ready-to-eat ingredients such as mayonnaise, salt, spices, onions, celery, or pickle relish. The finished salad is packed into containers, and may be distributed fresh or frozen.

These products are rarely reheated; most consumers eat them cold. Therefore, there is no chance that any pathogens present will be eliminated by consumer re-heating. Whatever bacteria are in the product when mixed, or contamination of the product during mixing, will remain in the product when eaten. The temperature of this product must be carefully controlled to ensure that bacteria in the mixture do not have a chance to grow.

Fresh or frozen entrees

Another group of products that fall within this category are the fresh and frozen entrées. These range from pre-cooked chicken pieces, barbecue beef, to prepared dinners with meat or poultry along with rice, pasta, sauce, and vegetables. There are many of these convenience type items produced today, and new products are introduced almost daily.

The processing procedure for all of these products is very similar. Fully cooked meat or poultry portions are combined with sauces, vegetables, pasta, or other ingredients. Each of the ingredients is individually weighed or portioned, to result in the desired finished proportions.

Most of these products are designed to be re-heated by the customer. Most packages will include instructions for re-heating. This does offer some degree of safety to the consumer, in that the re-heating may eliminate some bacteria if present. However, this re-heating must not be depended on, as consumers may vary greatly in how well they re-heat the product. These products are intended to be fully cooked and must be safe to eat without the re-heating step.

These are some of the major product groups that fall within the FULLY COOKED - NOT SHELF STABLE category. There are other products that we did not mention that you might encounter in the marketplace or being produced in an establishment. These products all have some things in common: they are fully cooked and ready-to-eat by the consumer; and they require refrigeration or freezing in order to maintain product safety and quality.

PRODUCT WITH SECONDARY INHIBITORS - NOT SHELF STABLE

Finished products produced under this regulatory processing category can be not-ready-to-eat (NRTE) or ready-to-eat (RTE) meat and poultry products that have been processed in a manner that utilizes strategies which produce results that will inhibit secondarily the growth of pathogenic bacteria. Finished products in this regulatory processing category may or may not have had heat applied to the product. The finished products in this category are *not shelf stable products* and require special handling to maintain their wholesome condition. In other words, the product may be heat treated, but not fully cooked, and a secondary inhibitor gives a cumulative effect (heat plus a food additive that affects the product) so that the product is RTE, yet it would *not* be ready-to-eat in the *absence* of the secondary inhibitor. The NRTE products must be kept refrigerated or frozen to maintain product quality and safety. Refrigeration, therefore, is still the primary inhibitor of the growth of pathogens and spoilage bacteria in NRTE products. RTE products need to be kept refrigerated to inhibit growth of spoilage organisms that are still present and capable of growth at ambient, non-refrigerated temperatures.

Secondary inhibitors are usually ingredients or processes such as fermentation or drying that when used, in combination or alone, assists in inhibiting, or slowing the growth of possibly harmful bacteria. Primary microbial growth inhibitors include lowered water activity (a_w) and higher acidity. Salt or sugar in quantities that effectively lower the water

activity of the finished product is an example of a secondary inhibitor. We will discuss each of the inhibitors and then concentrate on one product example - country-style ham.

Water activity (a_w) - Microorganisms in food need water in order to live and grow. The water must be in a form that is available to the microorganisms. Water activity is a measurement of how much water is available in a product. The water activity can be reduced by removing water (drying) or by increasing the concentration of solutes dissolved in the water (adding salt or sugar).

Acidity - Most bacteria grow best in a medium that is neutral or slightly acidic, and the growth of most bacteria is significantly inhibited in very acidic foods. The ionic hydrogen concentration (pH) is measured on a scale from 1 to 14, with 7 being neutral; pH levels above 7 are basic, or alkaline, while those below 7 are acid. Foods that are highly acidic are seldom the vehicles for pathogens. Many foods are acidified to prevent the growth of undesirable microbes. This may be done by adding acidic ingredients, like tomatoes, or by adding the acid directly, like vinegar. The acidity of products may also be increased by the process of fermentation.

The process of using secondary inhibitors is a very complex system. Often several different inhibitors are used, each depending on the others in order to result in a safe product. You will learn more about this topic in the Inspection Methods (IM) training.

Some examples of products that may fall into this processing category include products that are uncooked, cured, fermented, dried, salted, or brine treated, which are not shelf stable but can be RTE or NRTE, such as sliced country style ham, salt pork, and semi-dry fermented sausage. The product standards, processing methods, and labeling are all factors that must be considered in determining the regulatory processing category for the 03I products

Let's look at the example of the perishable sliced country-style ham (refer to flowchart at the back of this handout).

Country-style Ham or Shoulder

Sliced country-style ham or shoulder is a cured, dried product, traditionally made from a single piece of raw meat from a pork shoulder. The example shown is for a NRTE, cured product (refer to flowchart at the back of this handout).

Dried whole muscle products are mostly dry cured. An initial process for manufacturing whole muscle products consists of dry mixing the non-meat ingredients with the meat. Curing is the addition of salt, saltpeter, nitrites, sugars, spices, and flavorings. Nitrate and nitrite contribute to the characteristic cured flavor and reddish-pink color of the cured pork. All ingredients added are carefully weighed, in order to conform to the product formula.

The entire exterior of the ham or pork shoulder is coated or rubbed by the dry application of salt combined with the other ingredients. Additional salt or dry-cure mixture of salt may be reapplied to the product as necessary to insure complete penetration. The high salt level and the colder temperatures are the only measures protecting against the growth of spoilage and pathogenic microorganisms.

After the initial salting, the product is held for some period of time at refrigeration temperatures (at 40 ˚F) for the salt mix penetration and equilibration ("burning" period). This period often takes many weeks (at least 28 days) to achieve uniform salt distribution to greater than 4.5% with a water activity below 0.96. The goal is to eventually lower the water activity sufficiently to inhibit microorganisms to a point at which the temperature can be elevated. The product undergoes a maturation period (during this stage, the product is held at elevated temperatures for drying and flavor development), air drying and smoking (if desired), and storage. During these periods at higher temperatures, the humidity and air circulation is lowered, with further moisture loss. This final step in the process can be from 3 to 12 months in duration. The final product is then sliced and vacuum packaged for sale.

This is an example of a system of inhibitors. The nitrite and the salt are both inhibitors, they work together to achieve a certain amount of preservation of the product. This also extends the shelf life of the product, because spoilage organisms are inhibited. The lethality of the process for pathogens achieved in a salt-cured product will depend on the interaction of salt content, time and temperature of curing, drying, and aging. In addition, this product does not receive the amount of drying or reduction in water activity needed to make it shelf-stable. Therefore, the product is not completely preserved, and still requires refrigeration for safe storage. Products that are shelf stable will be covered in other sections.

NOT HEAT TREATED - SHELF STABLE

The NOT HEAT TREATED - SHELF STABLE processing category includes products controlled by water activity, pH, freeze dried, and dehydrated product, such as salami, pepperoni, or prosciutto. What defines this category is that the product is shelf stable, and while heat may be applied, it is not the *primary* means of achieving lethality. Many processors of products, such as pepperoni, include a low temperature heat treatment step in order to safely produce this type of product. We will examine the processing steps that are necessary for this type of product.

The process flow diagram (at the back of this handout) for this category represents salami/pepperoni. These are dry sausages that are ready-to-eat without any further cooking. Pepperoni was traditionally made with pork, while salami was made of pork along with some beef. Today, of course, many combinations of meat ingredients are used.

Many of the processing steps are similar to the processes we have already discussed. Raw meat ingredients are ground and mixed with non-meat ingredients. The meat mixture is stuffed into casings. Let's take a look at some of the unique aspects of these processes.

Starter cultures - Bacterial fermentation is used to produce the lactic acid that results in the tangy flavor associated with this type of sausage. The acid inhibits bacterial growth. The resulting lower pH causes the proteins to release water, which assists in the drying process, and further inhibits bacterial growth in the finished product. Producers typically use a commercial lactic acid bacteria starter culture. Commercial starter cultures consist of a blend of harmless bacteria strains such as *Lactobacillus*. Simple sugars, such as

dextrose or corn syrup, are added. They help promote lactic acid bacterial growth by serving as food to the bacteria during fermentation.

Fermentation - This step is an important one for pathogen control. During this step, the pH level of the product is reduced by the starter culture activity and by appropriate time/temperature factors. The starter culture is added to the meat mixture, along with the sugar. The mixture is stuffed, and held in an environment optimum for their growth. These rooms are sometimes called *green rooms*. The temperature and humidity are carefully monitored. The starter culture bacteria actively reproduce, and as they do they give off lactic acid, which decreases the pH of the product. It is important that lactic acid is produced quickly, because it inhibits undesirable bacteria, like the toxin-producing *Staphylococcus*. The pH is monitored over time to determine when the process is complete. During fermenting, the establishment will probably want to achieve a pH of 5.0 or less within a certain time.

Most microorganisms thrive on pH near neutral (7.0) although there are exceptions. Meat processors can control pH to limit microbial growth and give meat a longer shelf life. Muscle tissues are close to 7 in the live animal. At slaughter, lactic acid builds up and the pH is lowered. The pH of fresh meat ranges between 5.3 and 6.4. At pH between 6.0-6.4 meat spoils faster than meat in the lower pH range (5.3 to 5.7), because the spoilage bacteria are more active at the higher pH.

Heating (optional) - Both *Salmonella* and *E. coli* O157:H7 have been isolated from fermented sausage products. Consequently, many dry/semi-dry fermented sausages, particularly in the United States, have a significant “heat step” in the process to assure lethality of high numbers of bacterial pathogens.

Drying - At this stage, the salami/pepperoni is hung in a dry room to dry. Again, temperature and humidity are controlled. One of the factors that affect microbiological growth is moisture. Bacteria need moisture to survive and grow. Drying is the simple process of dehydration in which osmosis withdraws water from the cell of the spoilage organisms, shriveling or inactivating the cells. The product must be dried to the point at which bacteria are inactive or destroyed in order to create a safe, shelf stable product.

FSIS product standards state that dry sausage must have a *Moisture Protein Ratio (MPR)* of 1.9:1 or less, in order to qualify as a shelf stable product. This is a calculation that compares the percentage of moisture to the percentage of protein. For comparison, fresh meat has a MPR of about 4.0:1.

At this point, the finished sausage sticks are dry and ready to be packed for storage and distribution. Some product is *sliced* so that it can be used for purposes such as sandwiches, pizza, or salads. This step is another one where the potential for cross-contamination of product must be controlled by the establishment.

Validation for E. coli - In light of food-borne outbreaks of *E. coli* O157:H7 linked to dry fermented ready-to-eat beef sausage products, FSIS strongly recommends that all procedures for dry and semi-dry fermented sausages be validated to show a 5-log reduction of *E. coli* O157:H7. Full documentation is required.

This process category contains all products that are shelf stable, which may or may not have been heat treated. These products are rendered safe by a combination of processes, such as fermentation, heating, and drying.

HEAT TREATED - SHELF STABLE

The HEAT TREATED - SHELF STABLE processing category includes rendered products, popped pork skins, bacon bits, snack sticks or jerky, summer sausage, kippered beef, and pickled sausages. These products are considered ready-to-eat, meaning they can be consumed as packaged. This category contains products that are shelf stable, and have received a full lethality treatment. Cooking is generally the primary method for achieving all or most of the lethality in these products.

Rendering

Rendering refers to the extraction of edible and inedible fats and oils from meat after slaughter. The rendering process can be either wet (usually through steam) or dry. It yields products such as tallow and lard.

Summer sausage

Summer sausage is a semi-dry sausage. It is not as dry as the “hard” sausages such as salami and pepperoni. This product is made ready-to-eat by a combination of fermentation (pH), smoking, cooking, and drying. Just one or two of these steps is not enough to produce a safe, shelf stable product.

The formulation for summer sausage typically includes lean beef, lean pork, sage or ground mustard seed, salt, sugar, pepper, and sodium nitrite. It may include a starter culture. The meat ingredients are ground, and seasonings and preservatives are added. Then the mixture is stuffed into casings. Next it is placed in a cooking chamber and heated at a low temperature (100º to 110º F) to quickly ferment the product. Often a smokehouse is used, although generally no smoke is applied. When the required pH is reached, the temperature is raised, and product is heated to a desired temperature for lethality. This also kills off the lactic acid bacteria and stops the fermentation. The product is then placed in a drying room until it dehydrates to the specified level. Sometimes a smokehouse is used as the drying room.

Snack sticks and jerky

Different types of snack sticks are made (refer to flow chart at the back of this handout). Some are fermented, with either a low or high moisture level. Some are not fermented, with a very low moisture level. They are usually ground, and are similar to a dry sausage. Jerky is not fermented; it is often beef, but turkey and other products are also found in the marketplace. Jerky may be made from either solid pieces of muscle or chopped product. Processing steps are similar to dry sausage and summer sausage:

- *Acidifiers* such as citric acid, lactic acid, and glucono delta-lactone may be used to reduce the pH of the product.

- *Antioxidants* such as butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), or propyl gallate may be used to prevent oxidation and rancidity.

- The *thermal processing* step, which involves cooking the product for a specified amount of time, is designed to control bacterial growth, both spoilage and pathogens. The cooking process also helps to shorten the drying time.

- The *drying* step helps reduce the moisture in the product to the desired level. Reducing the moisture helps control *Trichinae* and enteric pathogens such as *E. coli* O157:H7 and *Salmonella*.

FSIS has established *product standards* for certain dried products that specify a moisture protein ratio (MPR) needed to achieve shelf stability and ensure the product meets the standard established for that product. For example, a "dry sausage" must have a MPR of 1.9:1 or less, in order to be labeled as a "dry sausage" and also ensure shelf stability. Likewise, a non-refrigerated, semi-dry, shelf-stable sausage must have an MPR of 3.1:1 or less and a pH of 5.0 or less to ensure shelf stability. However, for most type of salt cured dried products, the water activity (available moisture) of the product is the primary factor affecting shelf stability and safety.

These products may be stored and shipped at frozen, refrigerated, or ambient temperatures. Storing product below ambient temperature is usually done for quality reasons.

THERMALLY PROCESSED - COMMERCIALLY STERILE

The THERMALLY PROCESSED - COMMERCIALLY STERILE processing category includes canned meat products, products in reportable pouches and semi-rigid containers. Common examples are stew, chili, soup, canned hams, Vienna sausage, hash, potted meat product, and pasta sauce with meat. Although there are several types of packaging options available, such as pouches, plastic cups and plastic pans, the metal can is still the most common package used. For this reason, these products are usually referred to as *"canned".*

This category contains all products that have been thermally processed in order to achieve commercial sterility. The term *commercially sterile* does not mean that the product is completely sterile. Complete sterility is not achievable with canned products, because the *thermal processing* required to assure absolute sterility is so severe that the quality of the product would suffer. Certain types of microorganisms survive the thermal processing, but remain dormant or are inhibited from growth by some other factor. Thermally processed, commercially sterile product is ready-to-eat. It can be eaten directly from the container, although most consumers heat the product as a matter of personal taste.

Thermal process

Our example product is pasta with meat sauce (refer to flow chart at the back of this handout). You'll notice some familiar processing steps, such as receiving, storage, assembling ingredients, and formulation. Because we've covered steps very similar to these earlier, we will not cover them now. Let's focus on some of the items that are unique to thermal processing:

- *Filling* - involves adding product, which has been mixed and formulated, to the product container. The typical container is a metal can. In most operations, filling is done with high-speed machines.

- *Types of cans* - there are several types of cans used most frequently in the meat industry. Three basic types of cans are round sanitary, drawn aluminum, and oblong. The *round sanitary* can holds a variety of meat-base products, such as pasta with meat sauce. *Drawn aluminum* cans are used most often for Vienna sausage and meat spreads. Their use is increasing, because they use less metal and are more economical. *Oblong* cans are used for canned luncheon meats.

  To prevent an interaction between the meat product and the metal, cans are generally *coated* on the inside. The kind of coating that is typically used with meat products is sulfur-resistant. It prevents the sulfur released from meat proteins during retorting from staining the tinplate black.

- *Sealing* - lids are placed on the filled cans and a *hermetic* seal is formed. This seal prevents air from getting in or out. It is this seal which will preserve the integrity of the can after it has been thermally processed, so it is critical that the seal is formed correctly.

- *Thermal processing* - involves placing the filled and sealed cans in a *retort* so that they can be thermally processed. A retort is a steel tank in which metal crates or baskets containing the cans are placed for subsequent cooking and cooling. The retort operates under pressures of 12 to 15 pounds per square inch (psi). This pressure cooking raises the cooking medium (usually steam) to temperatures above the normal boiling point of water, 212°F. Three minutes at 250°F is an example of a minimum process. The retort subjects product to a high temperature for a sufficient duration to destroy the organisms that might adversely affect consumer health, as well as more resistant organisms that cause spoilage under normal storage conditions. These procedures are based on the destruction of all vegetative cells and all spores of the deadly, toxin-producing bacteria *Clostridium botulinum*.

- *Cooling* - after the heat process has been completed, all canned meat products should be cooled as quickly as possible to stop the cooking process and to lower the temperature below the range at which any heat tolerant bacteria can grow. Because the cans are wet, it is best to permit some heat to remain to evaporate any remaining moisture, in order to prevent rust. When cans are being cooled, they contract and even well-made seams may permit some inward leakage. Therefore, the water used for cooling must be as near sterile as possible. Canning cooling water is chlorinated, and rust inhibitors may be added.

- *Incubation* - after product is cooled, some establishments will hold it for 10 to 30 days before the cans leave the establishment. This holding time is used to test a sample of the retort load. A sample of each processing lot is held at a temperature that would promote bacterial growth. This is done in an *incubator*. At the end of this incubation period, cans are examined for evidence of spoilage. If none is found, canned products are shipped.

- *Storage* - canned meats should be stored in a cool, dry place because relative humidity and temperature influence their shelf life. Canned meat and poultry will maintain quality 2 to 5 years if the can remains in good condition and has been stored in a cool, dry place.

Here are some terms you commonly hear with regard to thermal processing:

- *Critical Factor* - any characteristic, condition, or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

- *Processing authority* - the person(s) or organization(s) having expert knowledge of thermal processing requirements of canned foods and utilizing procedures recognized by the scientific community as being adequate to properly calculate and assign thermal processes.

- *Process calculation* - scientifically defined procedures that determine the process time and temperature as adequate under specific conditions of manufacture for a given product.

- *Process deviation* - any change in a critical factor of the scheduled process that reduces the sterilizing value of the process.

- *Scheduled process* - the time, temperature, and critical factor controlled process, selected by the process authority and scientifically determined to yield commercial sterility under conditions of manufacture for a given product.

- *Sterilizing value* - this is normally expressed as "$F_{\circ}$" and is the number of minutes required to destroy a given number of microorganisms at a given temperature. The $F_{\circ}$ value is used to compare the sterilizing values of different processes.

- *Vacuum* - Removal of air from the can to prevent oxidation of the product.

This category contains many different types of canned product. Although we discussed metal cans, you will also see plastic cups and flexible pouches on the grocery shelf. These items are processed in a similar fashion. This category groups all products that are thermally processed in order to achieve commercial sterility.

EGG PRODUCTS

What Are Egg Products?

The term "egg products" refers to eggs that have been removed from their shells for processing. The processing of egg products includes breaking eggs, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying and packaging.

Basic egg products include whole eggs, whites, yolks and various blends with or without non-egg ingredients that are processed and pasteurized. These products may be available in liquid, frozen, and dried forms.

Who Inspects Egg Products?

On May 28, 1995, USDA's Food Safety and Inspection Service (FSIS) became responsible for the inspection of egg products. FSIS inspects all egg products, with the exception of those products exempted under the Act that are used by food manufacturers, food service, institutions, and retail markets.

Whole eggs in the shell are now regulated by FDA, not FSIS.

How Are Egg Products Made?

The initial step in making egg products is breaking the eggs followed by separating the yolks and whites from the shells. Eggs are processed by automated equipment which: moves the eggs from flats; washes and sanitizes the shells; breaks eggs and separates the whites and yolks and/or makes mixtures of them. The liquid egg product is filtered, mixed, and then chilled prior to additional processing.

Why and How are Egg Products Pasteurized?

The 1970 Egg Products Inspection Act requires that all egg products distributed for consumption be pasteurized. This means that they must be rapidly heated and held at a minimum required temperature for a specified time. This destroys *Salmonella*, but it does not cook the eggs or affect their color, flavor, nutritional value or use. Heating in the dried form pasteurizes dried whites, again for a specified time and at a minimum required temperature.

FSIS Egg Products Inspection

There are currently about 76 egg products processing plants under FSIS jurisdiction. Because of the EPIA requirement for continuous inspection, about 110 egg products inspectors oversee the day-to-day operations at these plants. In fiscal year 1998, the total of shell eggs produced was 79.7 billion. Of those, 20.3 billion were processed for egg products (25.5%). In 1999, the percent increased to 28%.

On the Horizon

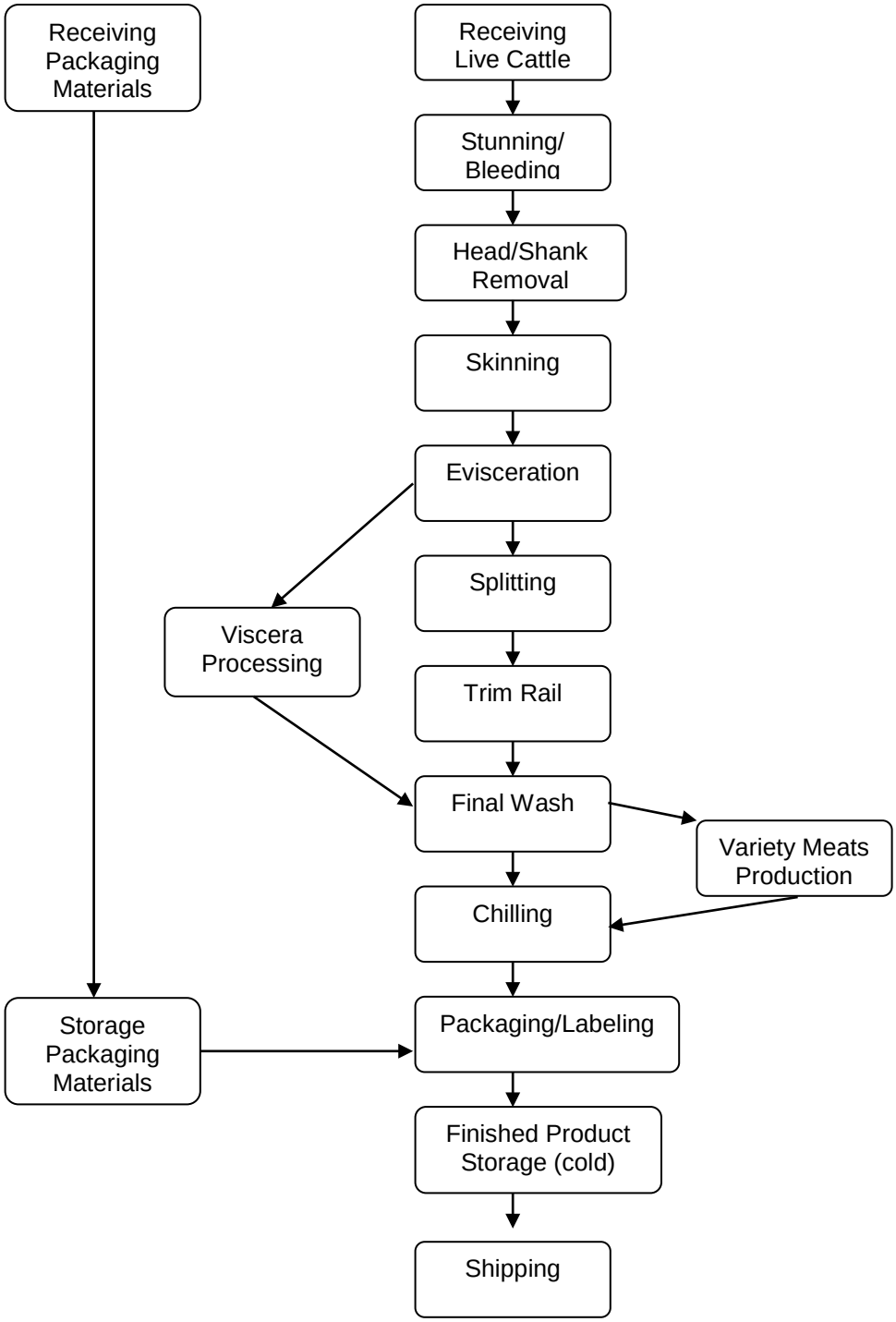
Egg products are not currently covered under the Sanitation SOP (Sanitation Standard Operating Procedures) or HACCP (Hazard Analysis and Critical Control Point) regulations to which meat and poultry ascribe. A task group is reviewing egg products regulations and policies to move egg products toward the Sanitation SOP and HACCP requirements. Instructions and guidelines are slowly being revised and issued as either directives or notices within the standard FSIS issuance framework.

APPENDICES

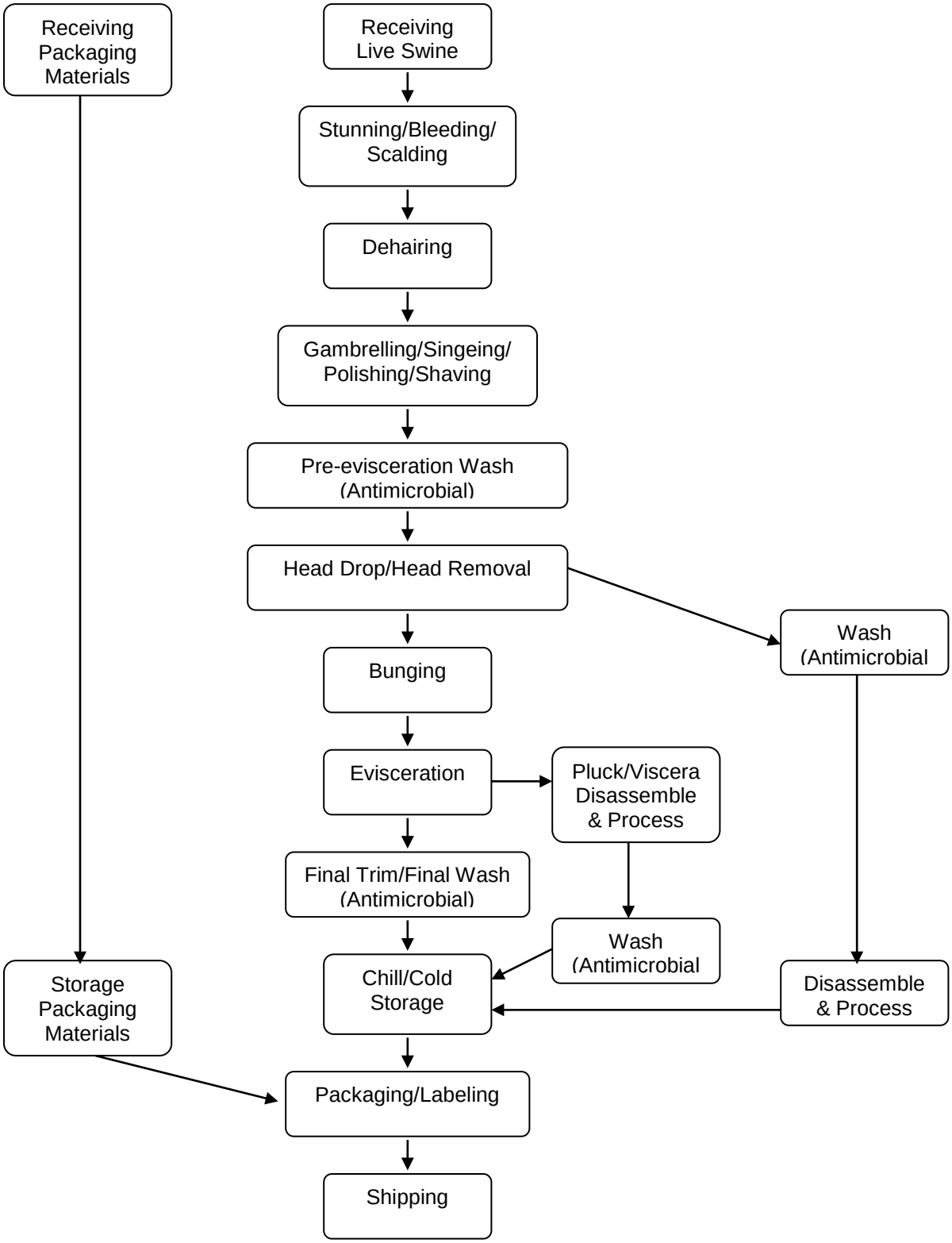
Process Flow Diagrams

The following process flow diagrams are examples of the variety of formats that you will see in use by the industry. Please keep in mind that these are to be used as a classroom aid only.

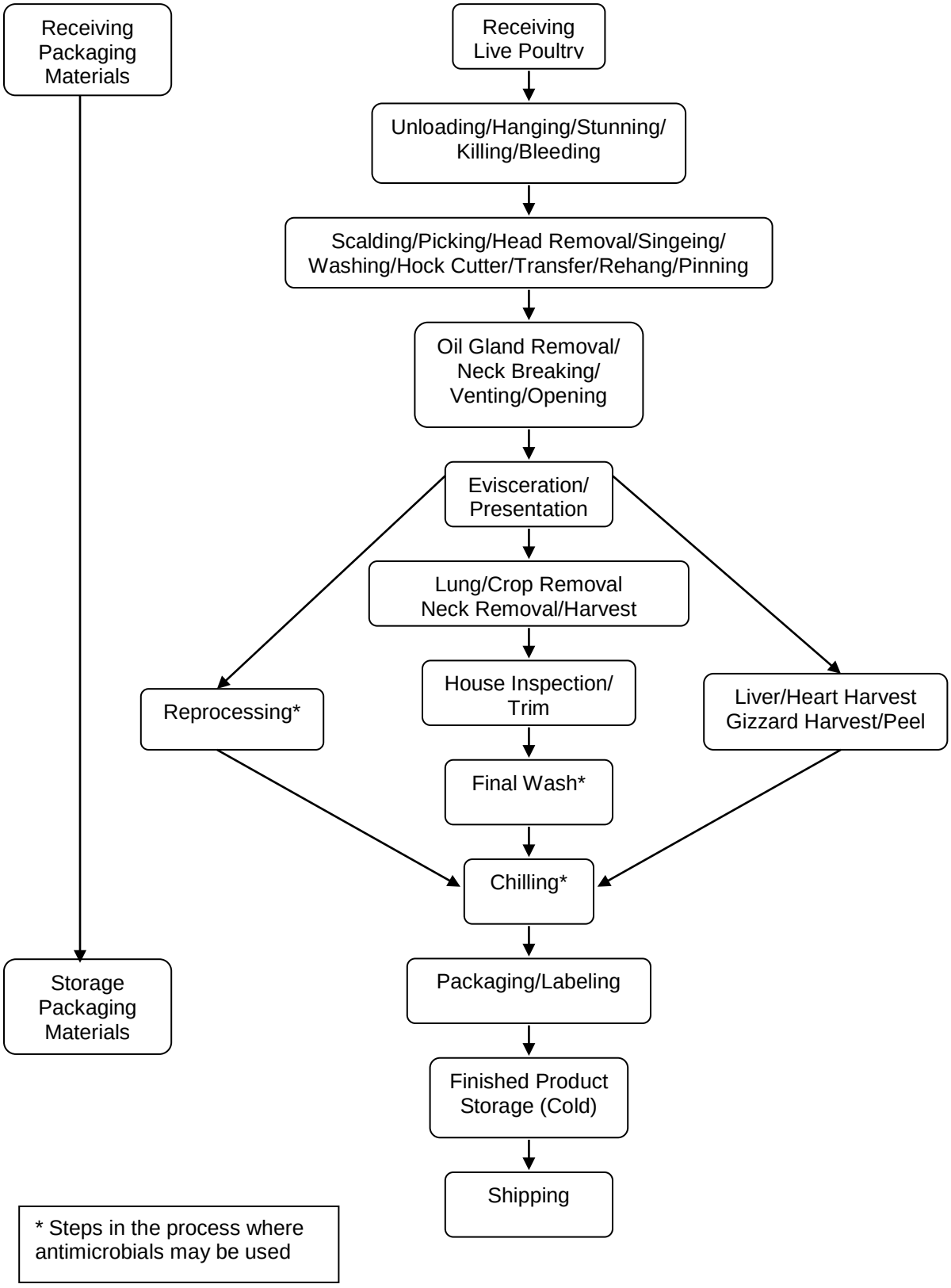
SLAUGHTER : FLOW CHART
Example product: **Beef (carcasses)**



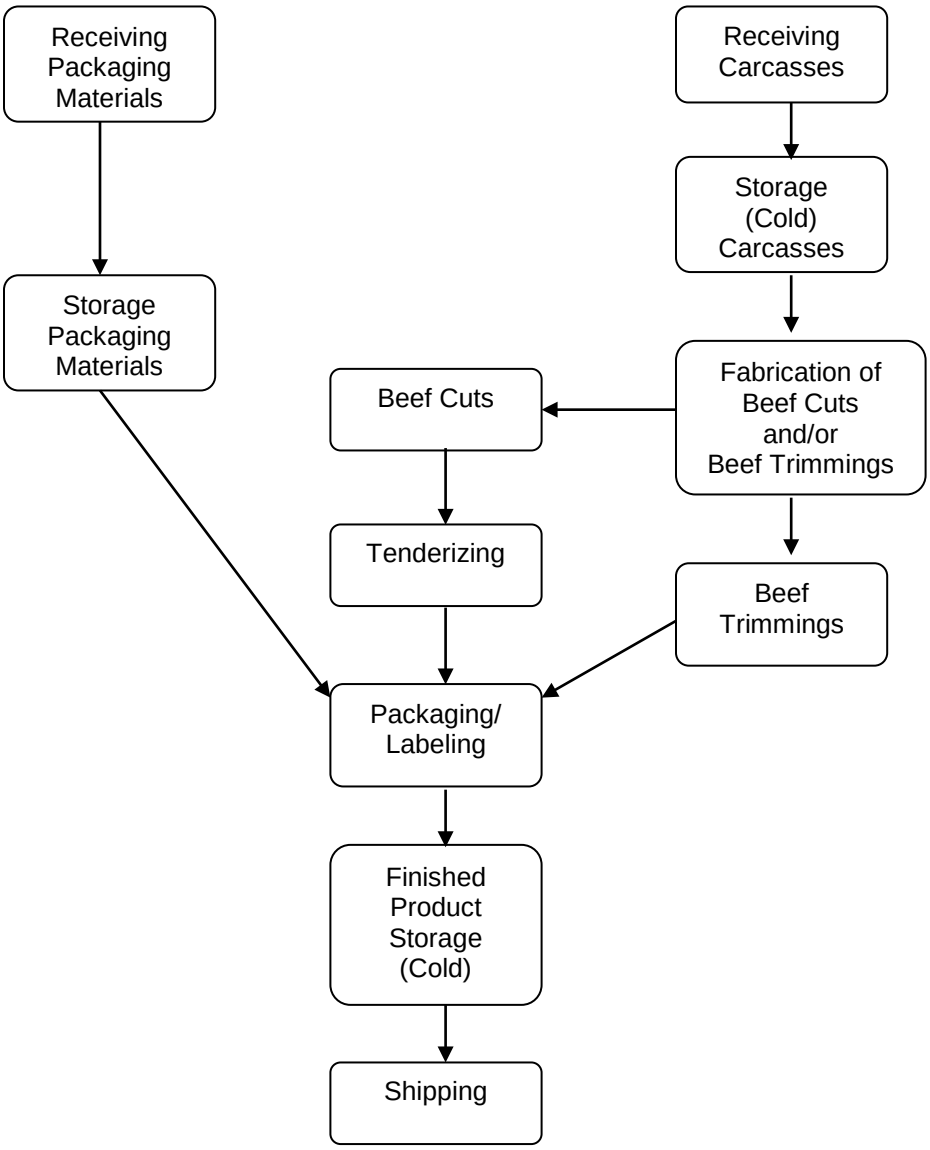
SLAUGHTER : FLOW CHART
Example product: **Pork (carcasses)**



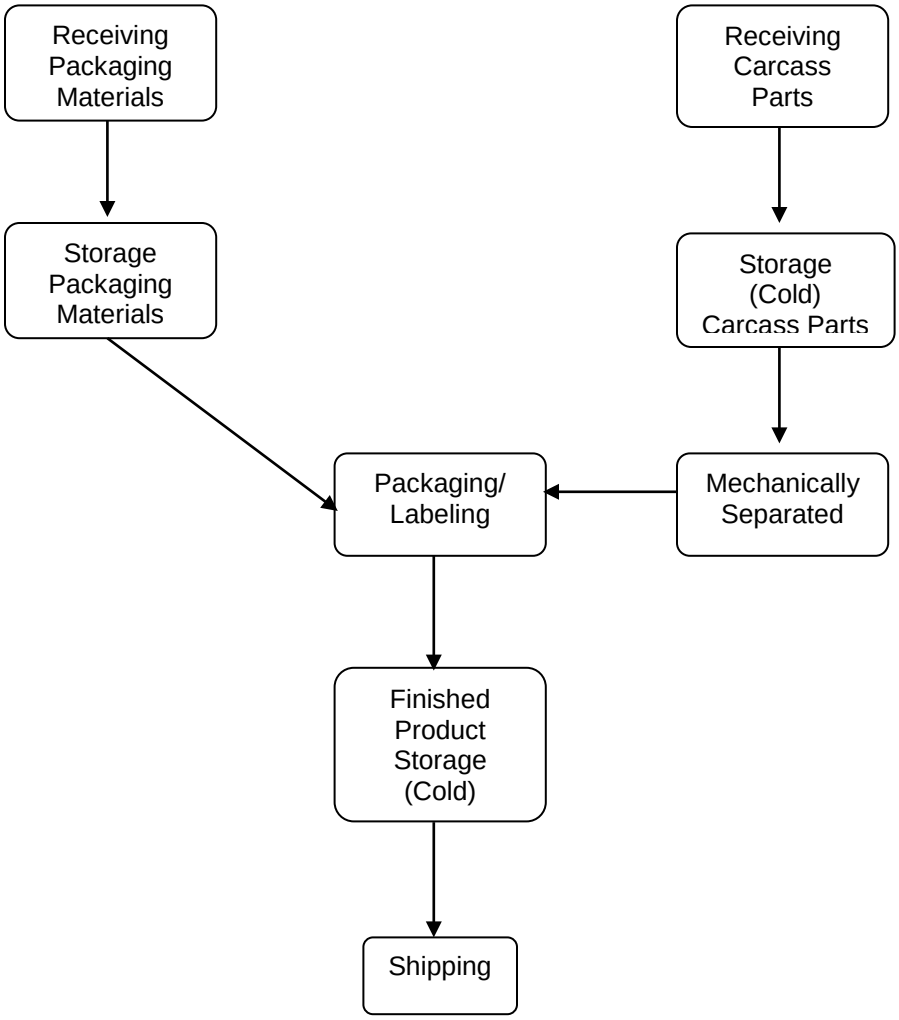
SLAUGHTER : FLOW CHART
Example product: **Young Chicken**



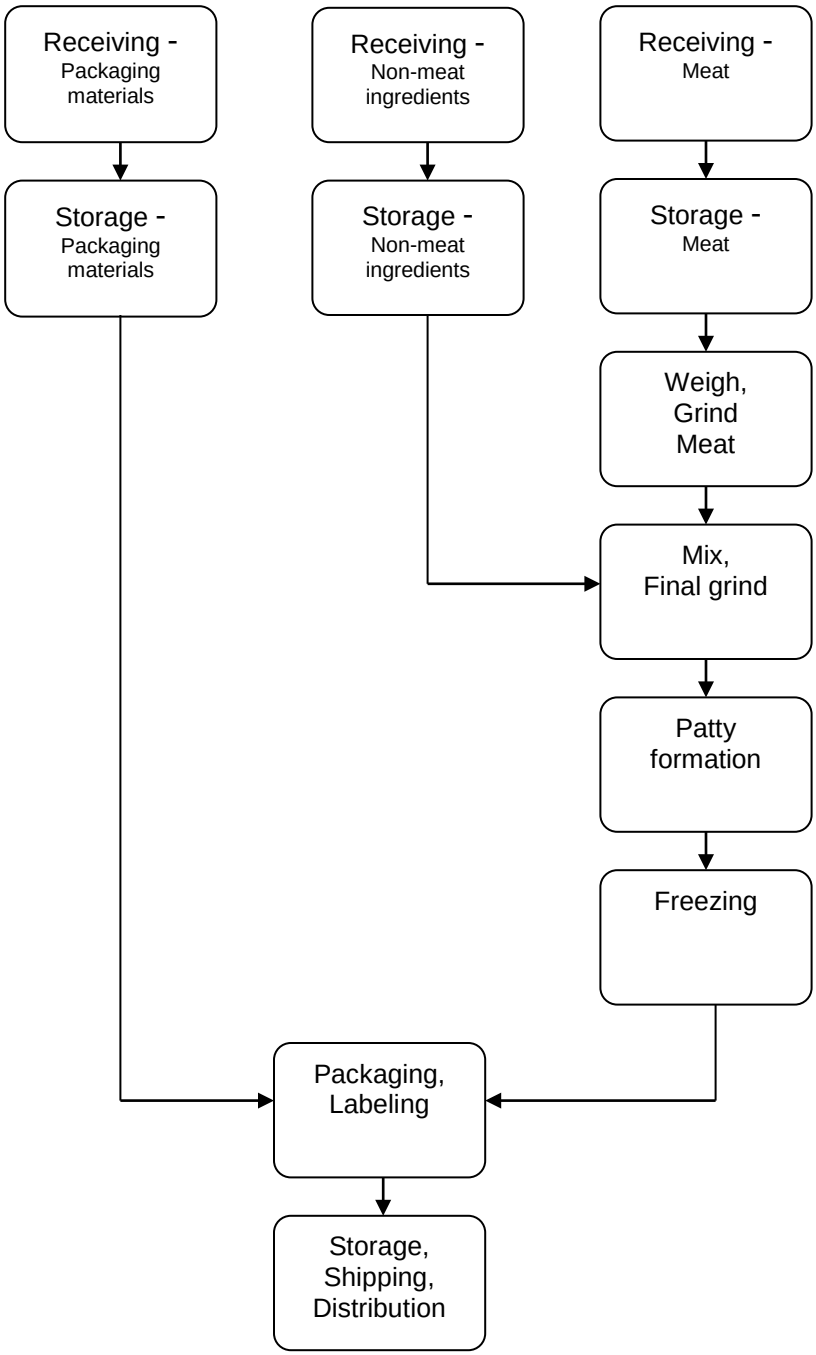
RAW PRODUCT- INTACT : FLOW CHART
Example product: **Beef Trimmings and Roasts**



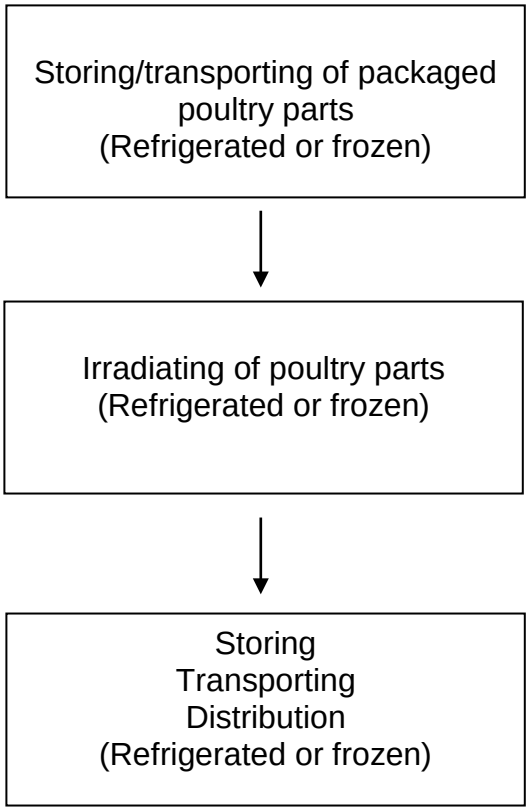
MECHANICALLY SEPARATED PRODUCT: FLOW CHART
Example product: **Mechanically Separated Pork**



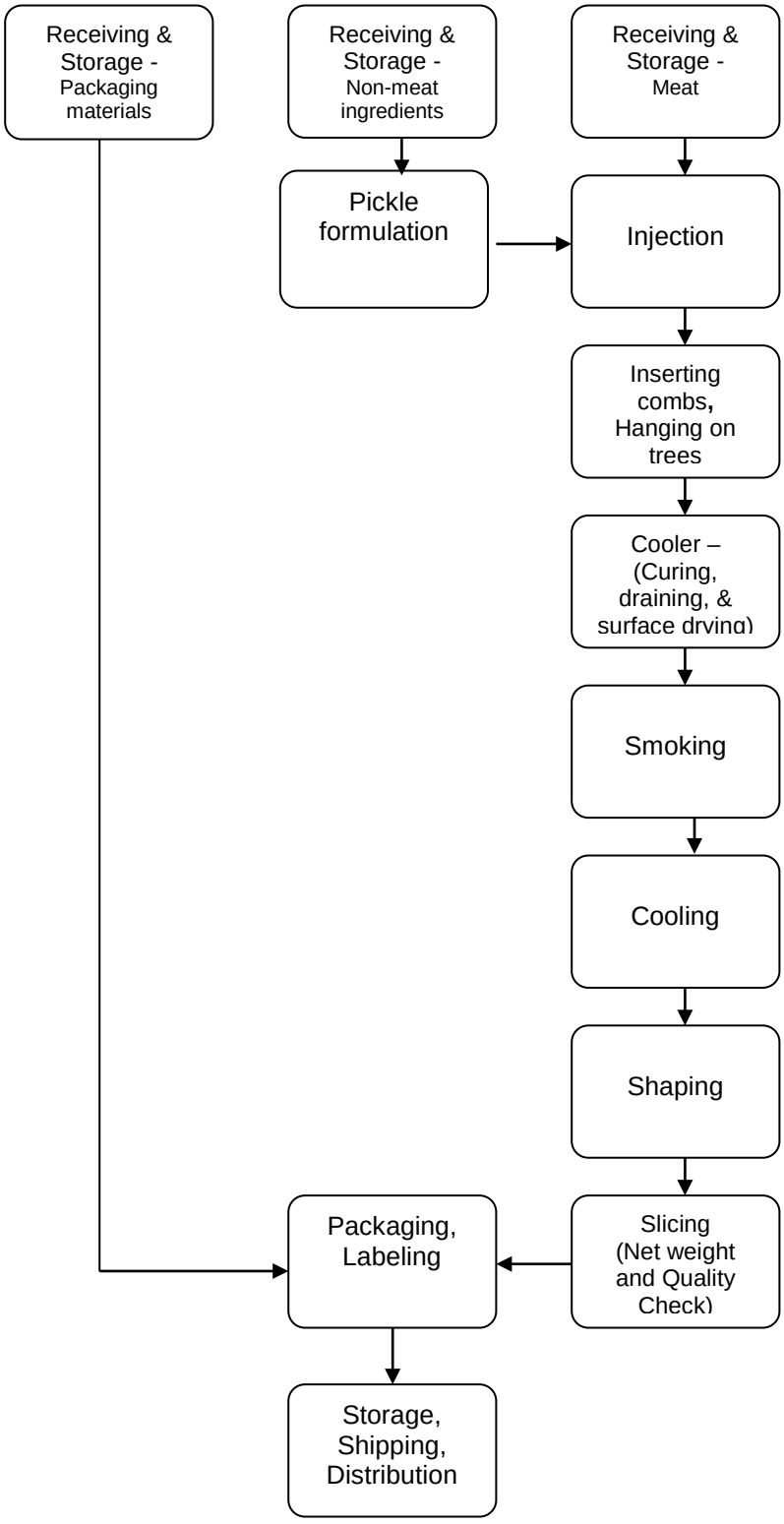
RAW PRODUCT- NOT-INTACT: FLOW CHART
Example product: **Ground beef patties**



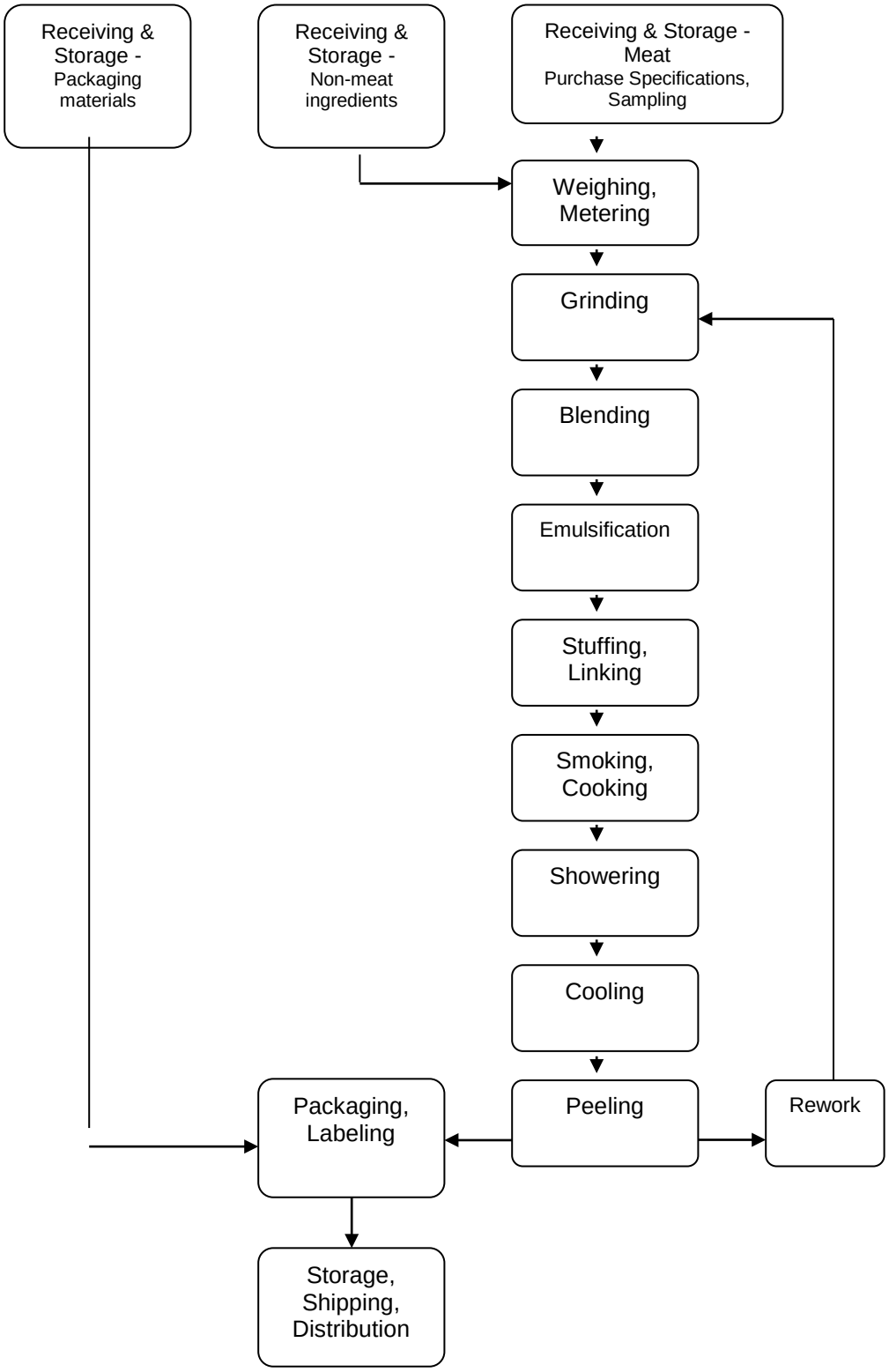
IRRADIATION: FLOW CHART
Example product: **Poultry parts**



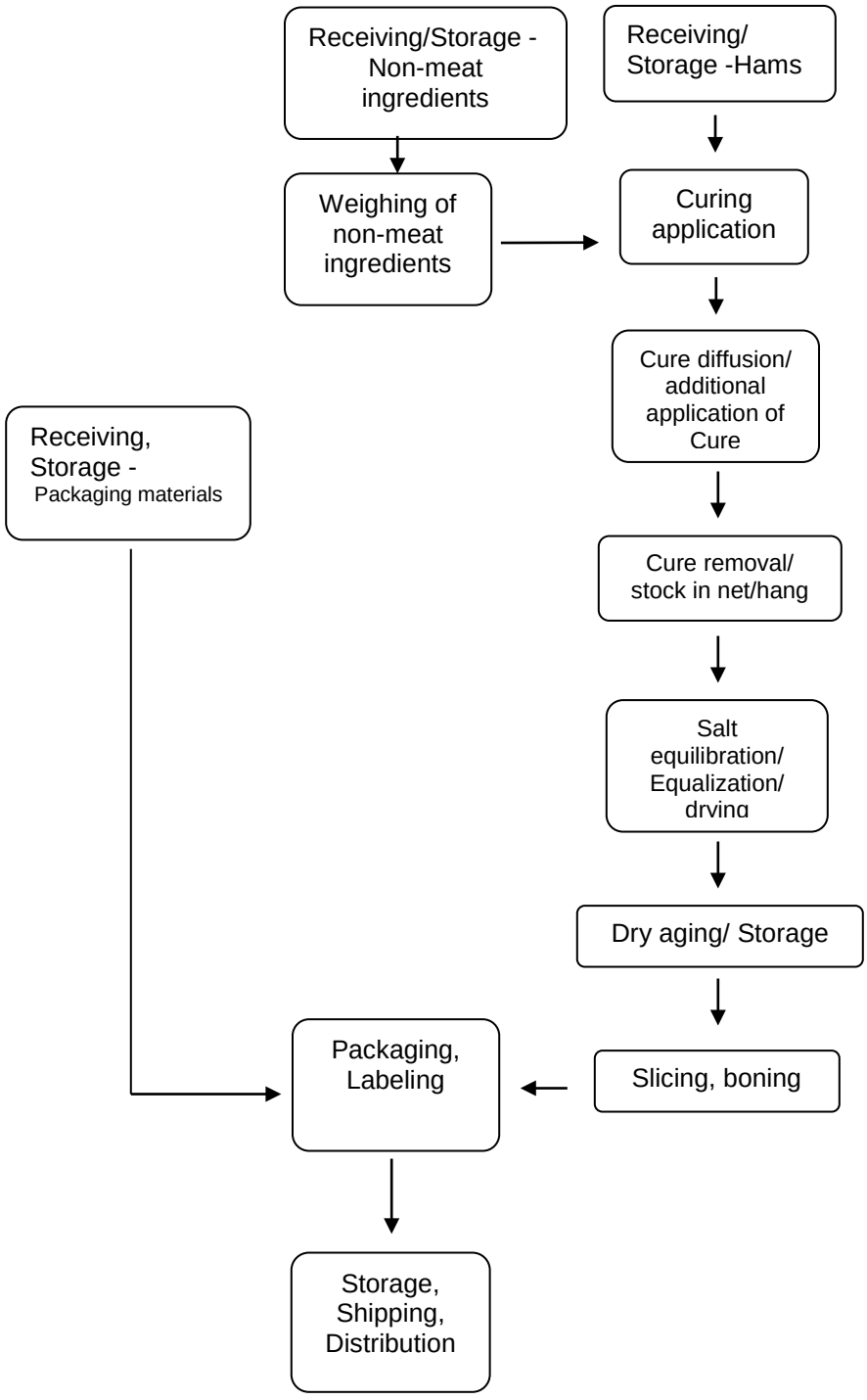
HEAT TREATED BUT NOT FULLY COOKED- NOT SHELF STABLE :
FLOW CHART
Example product: **Bacon**



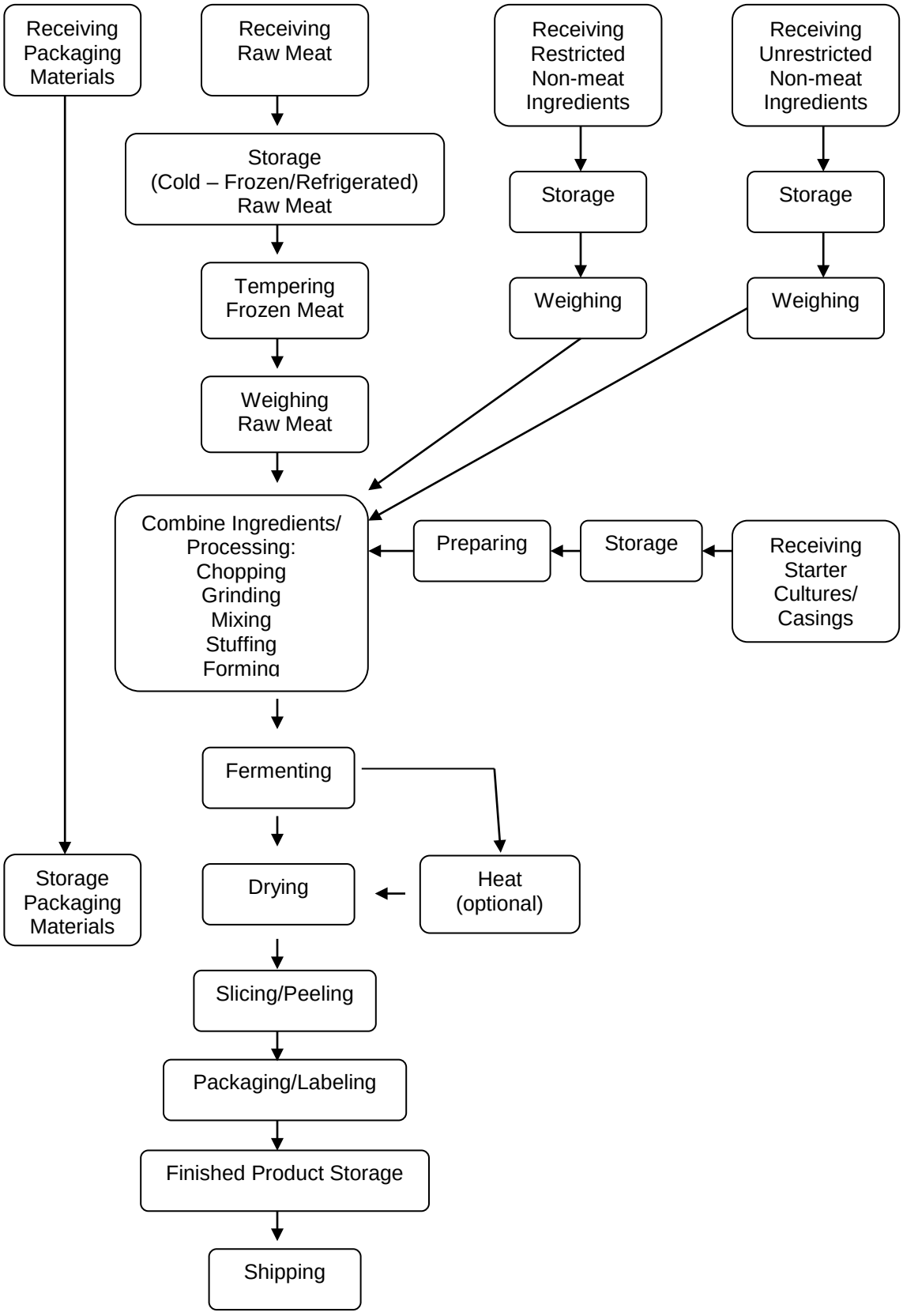
FULLY COOKED- NOT SHELF STABLE : FLOW CHART
Example product: **Hot Dogs**



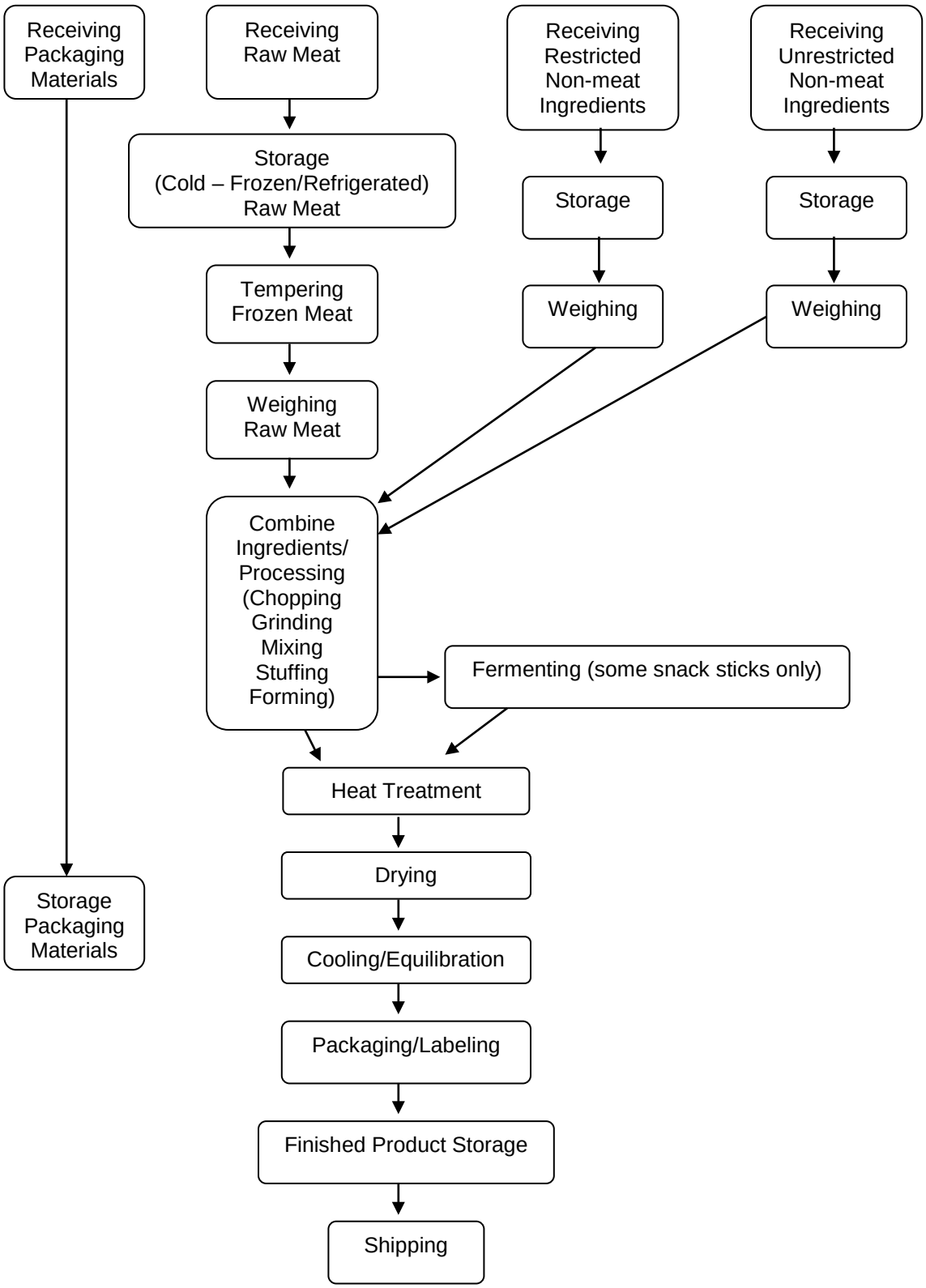
PRODUCT WITH SECONDARY INHIBITORS - NOT SHELF STABLE :
FLOW CHART
Example product: **Sliced Country-Style Ham**



NOT HEAT TREATED- SHELF STABLE : FLOW CHART
Example product: **Pepperoni**



HEAT TREATED- SHELF STABLE : FLOW CHART
Example product: **Jerky or Snack sticks**



THERMALLY PROCESSED - COMMERCIALLY STERILE : FLOW CHART
Example Product: **Pasta Sauce with Meat**

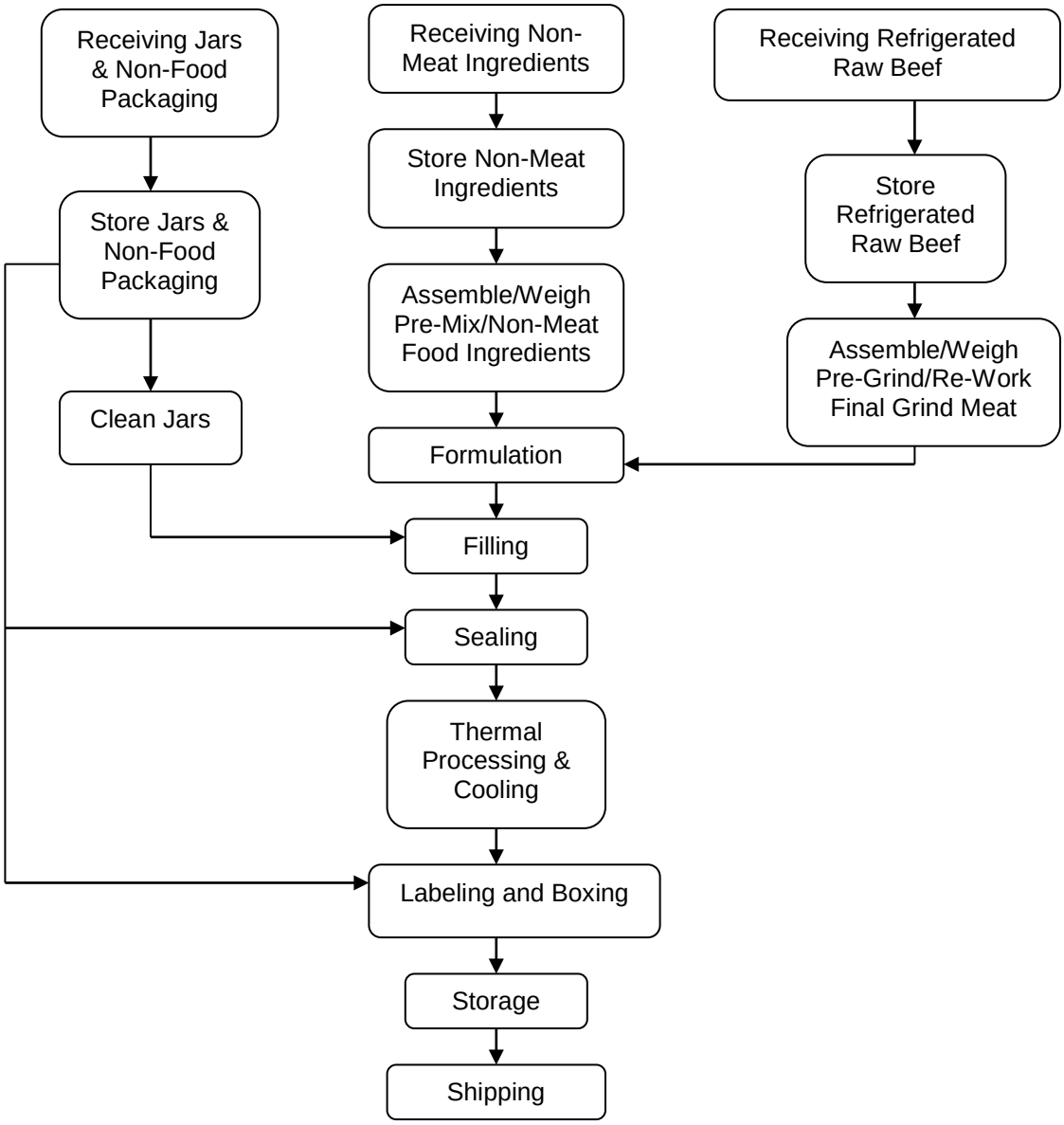
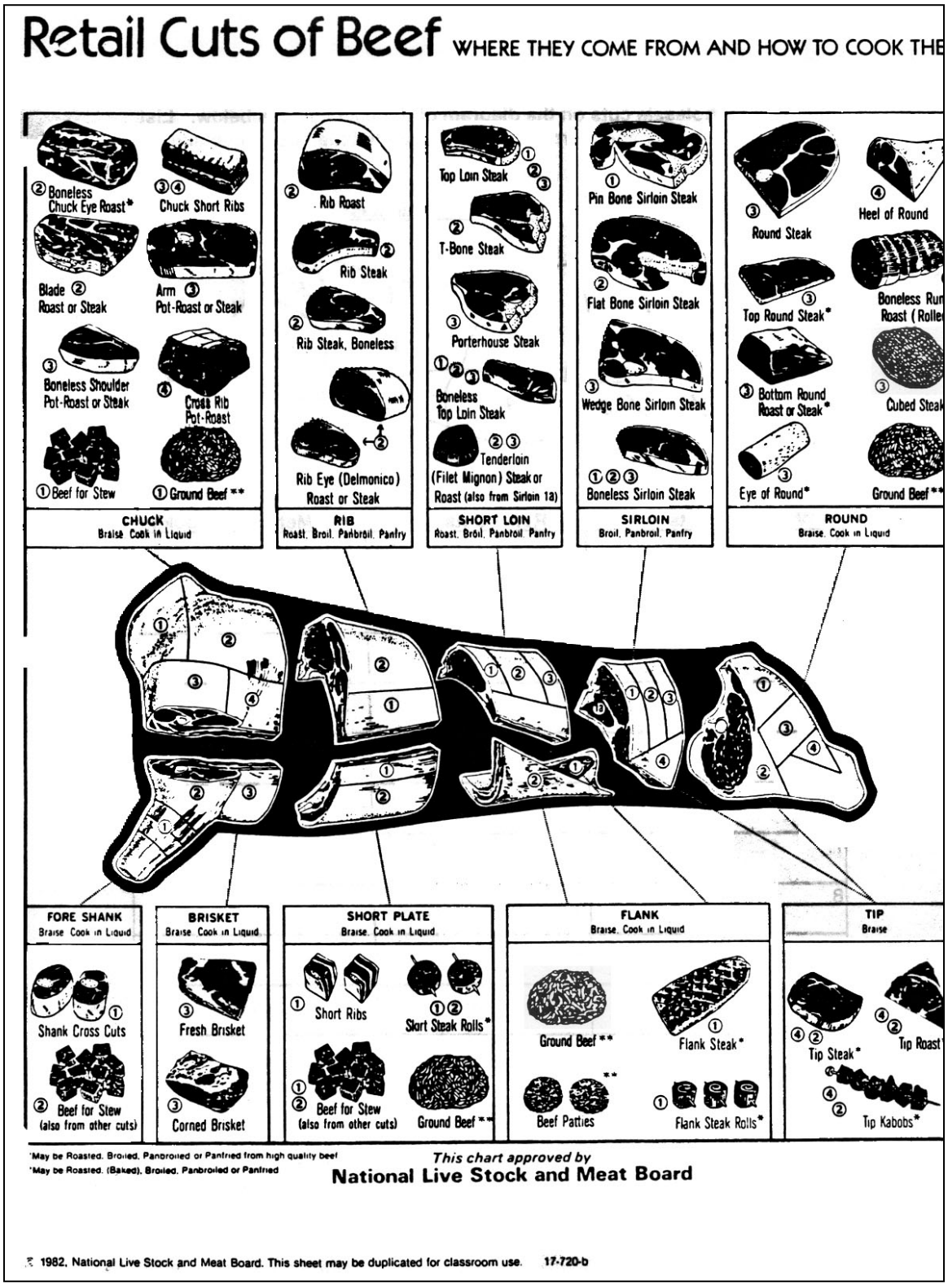


FIGURE 1: Wholesale cuts and Retail cuts



WORKSHOP

A. For each product listed below, identify the appropriate processing category.

Product	Processing category
1. Beef liver	_____
2. Sliced Ham	_____
3. Pork chops	_____
4. Beef jerky	_____
5. Canned Luncheon Meat	_____
6. Ground beef patties	_____
7. Bologna	_____
8. Whole chicken	_____

B. Define the following industry terms:

Stunning-

Pathogens-

Sticking-

Trimmings-

Comminution-

Formulation-

C. What is the food safety significance of the following procedures? (What is it about this step that must be controlled in order to ensure safety?)

Cooking-

Chilling-

Evisceration-

Grinding-

Drying-

Ante-mortem Inspection

OBJECTIVES

Upon completion of the ante-mortem inspection module the trainee will be able to:

1. Describe the following:

    a. ante-mortem inspection
    b. delayed slaughter ante-mortem inspection for livestock
    c. voluntary segregation (previously referred to as alternative ante-mortem inspection) procedure for livestock
    d. U.S. Suspect
    e. U.S. Condemned
    f. Non-ambulatory disabled
    g. the reasons for ante-mortem inspection

2. Identify the establishment's responsibilities for:

    a. livestock pens
    b. U.S. Suspect pen for livestock
    c. floors in livestock pens
    d. assistance for ante-mortem livestock inspection
    e. batteries or coops for ante-mortem poultry inspection

3. Identify the equipment and supplies that are needed to perform livestock ante-mortem inspection.

4. Describe the appropriate methods for conducting ante-mortem inspection:

    a. for livestock
    b. for poultry

5. Complete, given a list of information, the following in livestock inspection:

    a. a pen card
    b. FSIS Form 6150-1
    c. FSIS Form 6200-16 (formerly MP Form 402-1)

6. Given a list describing methods used to dispose of a livestock carcass condemned on ante-mortem, select those methods that are approved by FSIS.

Ante-mortem Inspection

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 (9 CFR 381.70(a)). IPP follow OFO supervisory instructions as to how often **daily** ante-mortem of poultry is performed (e.g., per lot). AM inspection is performed either by an FSIS PHV or a Food Inspector under veterinary supervision. However, if a Food Inspector performs AM inspection, the PHV must be notified of disease conditions that are observed.

Authorities

The Agency’s authority for conducting ante-mortem inspection can be traced to the statutes. The authority for conducting ante-mortem inspection in livestock is found in 21 U.S. Code (USC), Chapter 12, Section 603, of the Federal Meat Inspection Act (FMIA). The authority for conducting ante-mortem inspection in poultry is found in 21 USC, Chapter 10, Section 455(a), of the Poultry Products Inspection Act (PPIA).

The regulations covering ante-mortem inspection of livestock are found in Title 9 - Animals and Animal Products, Chapter III - Food Safety and Inspection Service, Department of Agriculture of the Code of Federal Regulations. Part 307.2 addresses the requirements for facilities for inspection. Part 309 covers ante-mortem inspection. Part 313 addresses the requirement for humane slaughter of livestock. Although we will cover the requirements for humane handling briefly, they are covered more extensively in the next module of this training.

The regulations covering ante-mortem inspection of poultry are found in Title 9 - Animals and Animal Products, Chapter III - Food Safety and Inspection Service, Department of Agriculture of the Code of Federal Regulations. Part 381.36(b) addresses the facilities for Inspection. Parts 381.70 through 381.75 cover ante-mortem Inspection.

There are some FSIS Directives and Notices related to ante-mortem inspection.

1. FSIS Directive 6000.1, “Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions”
2. FSIS Directive 6020.1, Rev. 1, “Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak”
3. FSIS Directive 6100.1, Rev. 2, “Ante-mortem Livestock Inspection”
4. FSIS Directive 6100.3, “Ante-mortem and Post-mortem Poultry Inspection”
5. FSIS Directive 6170.1, “Ratite Ante-mortem and Post-mortem Inspection
6. FSIS Directive 6240.1, Rev 2, “Inspection, Sampling, and Disposition of Animals for Tuberculosis”
7. FSIS Directive 6100.8, “Instructions for Verification of Improvest® Hogs”
8. FSIS Directive 6900.2, Rev. 3, “Humane Handling and Slaughter of Livestock”
9. FSIS Directive 9530.1, “Importation of Live Canadian Cattle, Sheep, and Goats into the United States”
10. FSIS Notice 66-16, “Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves”

Remember, Directive and Notices are instructions to inspection personnel.

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 healthful, safe 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 postmortem examination by an FSIS PHV. It is the first line of defense in protecting the public from potentially harmful meat products. Those animals and birds that exhibit abnormal signs must be withheld from normal slaughter and segregated for closer examination.

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. Be aware of this as we continue. We'll cover the humane handling requirements later.

Establishment responsibilities for 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. Let's review each of the requirements.

<u>Livestock</u>

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 313, the humane handling regulation. Let's review each of them. The pens must be satisfactory for conducting ante-mortem inspection, and maintained in a sanitary condition (307.2(a)). Pens must be kept clean and be well drained (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 (313.1(a)). The floors of pens, driveways, and ramps must be well constructed and maintained and provide good footing for animals (313.1(b)).

The lighting must be sufficient for inspection (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 suspect and condemned (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 (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 typically

also provides 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 (307.2(a)). 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 way 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 (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 have 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, 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 (307.2(a)). Do not allow yourself to become the establishment foreman in the ante-mortem areas. You must closely monitor establishment personnel to assure that they use humane animal handling practices at all times. You must also observe safe 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 may take will vary from withholding inspection of a single pen of animals until the pen is properly identified, or to withholding inspection of all animal pens because the establishment has failed to provide an employee to move and restrain the animals. There are more specific details for documenting noncompliance with the humane handling regulations that we will cover later.

Poultry

The establishment responsibilities for facilities and conditions for ante-mortem inspection of poultry are much simpler. The regulatory requirements identified in 9 CFR 381.36 state that the batteries, coops, or other facilities in which live poultry is presented for ante-mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out adequate inspection. Remember that ante-mortem inspection will be done on a daily basis while poultry are in the batteries or coops before or after their removal from trucks.

Supplies for performing ante-mortem inspection

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. You should have access to a thermometer, U. S. Suspect and U. S. Condemn tags, tagging pliers and hog rings, and a pencil for writing. You may also want to have a pad of paper and a clipboard for taking notes. Many inspectors keep all of 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 be commonly using 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. You can also order one from the Beltsville Supply Center.
2. Pliers- the tagging pliers, commonly called "hog ringers"; the hog rings are used to attach the suspect and condemn 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. Reject/Retain 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-I (Identification Tag-Ante-mortem), and may also use the FSIS Form 6200-16 (Summary of Ante-mortem Examination) at the discretion of the Frontline Supervisor, to record your ante-mortem findings. You will also record your findings on the pen card (a establishment form, discussed earlier). Remember that the pen card is a part of the procedure used to identify animals as having received ante-mortem inspection.

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." If the official establishment serves a dual purpose, such as a public stockyard or sale barn, as well as a slaughter facility, separate pens must be designated for animals presented for ante-mortem inspection and those destined for resale. You would only inspect those intended for slaughter. Livestock ante-mortem must be done by a PHV or a Food Inspector under the supervision of a PHV.

Ante-mortem inspection consists of two parts:

1. observe animals at rest
2. 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, the PHV must use his or her 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 may be in high pathology cattle establishments with a greater incidence of acti, epithelioma, or injection site reactions which all can be unilateral in nature.

When you perform at-rest inspection, position yourself at various locations outside the pen. Observe all of the animals and note their general behavior while they're at rest. Determine if any of the animals show abnormal behavior patterns 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 of 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. If the pen size permits, you may want to position yourself inside the pen and direct the establishment employee to move the animals past you in the pen. Do this only if it is safe. In general, it is only safe to position yourself inside the pen when inspecting small livestock such as sheep, market-sized hogs (up to 250 lbs.) and calves. 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, wearing your safety helmet during ante-mortem inspection is a good safety practice.

IPP are to verify that ante-mortem inspection has occurred at a minimum of once per 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 call the District Office for guidance.

Voluntary segregation, delayed, and emergency ante-mortem inspection

In addition to the manner in which ante-mortem inspection has just been described, there are other ways for performing it. They include voluntary segregation, (previously referred to as alternative ante-mortem), delayed, and emergency ante-mortem inspection.

Voluntary Segregation procedure 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.

Be aware that FSIS Directive 6100.1 states that **voluntary segregation is not permitted for cattle**.

Remember that inspection program personnel, under the Federal Meat Inspection Act, perform an ante-mortem examination and inspection on all animals prior to slaughter to determine that an animal is fit for slaughter for human food purposes. If an establishment fails to present animals for ante-mortem inspection in accordance with 21 USC 603 and 9 CFR 309.1, inspection program personnel will be unable to determine that carcasses are not adulterated during postmortem inspection, and therefore cannot permit the carcasses to be marked as "inspected and passed."

Provided the establishment properly presents animals for ante-mortem inspection and properly follows the Humane Slaughter Act, 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 Directive 6100.1, FSIS will only permit 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 continue 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
- all animals are presented to inspection program personnel for examination and inspection prior to slaughter
- procedures in the prerequisite program and related records are available to inspection personnel upon request (as per FSIS Directive 5000.2)

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 inspection program personnel 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. 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 the regulations (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 Frontline Supervisor is needed before delayed slaughter can be implemented. For example, a low-volume establishment may be planning to slaughter two hogs on Friday morning at a time when the PHV will be conducting inspection duties at another establishment. If the establishment is approved for delayed slaughter, it is permissible for you to perform ante-mortem inspection late Thursday afternoon when you are at the establishment. **Delayed slaughter is not permitted for cattle** (9CFR 309.1(a) and 311.27).

Special provisions have been made to allow the **emergency slaughter** of seriously injured animals other than cattle, during other than normal inspection time. As an example, on a Sunday a truck headed for a slaughtering establishment overturns and several of the animals are seriously injured. As a result, the establishment wants to slaughter the animals immediately rather than have them suffer pain until slaughtering operations begin on Monday morning. 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. One very important thing to remember about emergency

slaughter: it is NOT intended to cover the slaughter of sick or dying animals, only those that are seriously injured. So animals that are sick or dying from a disease are not covered by emergency slaughter. In addition, emergency slaughter is not permitted for cattle. **Emergency slaughter is not permitted for cattle.**

Poultry

Poultry ante-mortem inspection must be performed on the day of slaughter. It can be performed by either a Food Inspector or PHV, unless the birds originate from a control area or the establishment is located in a control area during an outbreak of Highly Pathogenic Avian Influenza (HPAI), in which case the PHV must examine every truck load of birds during ante-mortem inspection, and follow all instructions in FSIS Directive 6020.1, Rev. 1. It is performed on a group basis, while the birds are in coops or batteries before or after removal from trucks. 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, and
3. condemned

Let's discuss each of these outcomes in more detail. 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 diseases and conditions listed in the regulations must be condemned. This means that they are clearly not fit for human food, and they must be destroyed and not allowed to enter commerce as human food. 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. After you inspect the animals, you sign the card and write the time the animals received inspection. Signing the card indicates that the animals have received

ante-mortem inspection and are ready for slaughter. One commonly used option is that the pen card is taken from the pen and delivered to the postmortem inspector by a establishment employee prior to or at the time the animals are driven inside the establishment for slaughter. The post-mortem inspector can then collect all of the pen cards and compare the number of animals recorded on the cards with the number of animals being slaughtered. This is a method used to determine that all animals being slaughtered have received ante-mortem inspection. 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 on a daily basis. Keep this document in the FSIS inspection office for one week following the end of the respective slaughter week.

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 (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. We’ll cover some signs that will cause you to suspect animals of diseases and conditions listed in the regulations in the next section, and in great detail in the section on multi-species dispositions. But for now, 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 as per FSIS Notice 66-16. Section 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 (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. Alternately, 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, making the final disposition during post-mortem inspection.

Section 309.2 (p) provides for occasions when the establishment requests and receives permission to hold an animal for treatment in an effort to improve the animal's condition to the point that it may become eligible for slaughter. 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-premise, 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 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. **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, 309.3 indicate that dead, dying, disabled, or diseased livestock are to be condemned. It is your responsibility to identify the animal so that it is neither slaughtered nor used for human food. This is accomplished by placing a U. S. Condemned tag in the animal's ear. The FSIS Form 6150-1 must also be completed. The word "Suspect" is crossed out 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.

Section 309.13 covers the regulatory requirements for the disposition of condemned livestock. Any livestock that is condemned must have a U. S. Condemned tag placed in its ear. The FSIS PHV must complete FSIS Form 6150-1, and must ensure that the establishment properly disposes of the condemned animal.

Since the establishment cannot slaughter a condemned animal nor use it for human food, the establishment must promptly and humanely kill the animal and immediately dispose of the carcass in one of two ways that have been approved by regulation. Many establishments have their own disposal equipment and facilities. When a carcass is disposed of in this way, it is termed "on-premises rendering." Establishments that do not have their own disposal equipment and facilities have the carcass sent to some other place. This is called "off-premises disposal.” Regardless of the establishment's method of disposal, inspection personnel have certain responsibilities.

Section 314.3 covers the regulatory requirements for disposition of condemned products at official establishments having no tanking facilities. It states that condemned products or carcasses shall be destroyed in the presence of an inspector by incineration, or denatured with crude carbolic acid, or cresylic disinfectant, or a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella or any other proprietary material approved by the Administrator in specific cases.

Here’s an example. Obviously, 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 is an adequate control 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.

FSIS Form 6150-1

As stated earlier, 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” 9CFR 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, 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 6150-1 form 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 all non-ambulatory disabled livestock, TB reactors, mastitis elimination cows, and all 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 postmortem report section may or may not be completed.

2. The lower section is the postmortem 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 postmortem examination findings

Disposal – enter the disposition of the carcass and parts based on the postmortem findings.

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

FSIS Form 6200-16

The FSIS Form 6200-16 (formerly MP Form 402-1) (Summary of Ante-mortem Examination) is used to record daily ante-mortem activities. This form is completed at the discretion of the Frontline Supervisor. The form is completed by a PHV and only on the days of slaughter. Following are instructions for completing the form:

a. The date of the last slaughter day for this species.

b. The establishment number.

c. Today's date.

d. The name of the species inspected (use a separate 6200-16 form for each species inspected on this date).

e. The number of animals passed for regular slaughter (does not include suspects).

f. The number of animals the PHV identified as "U.S. Suspect" from the previous day, but the establishment did not slaughter.

g. The number of animals the PHV identified as "U.S. Suspect" today.

h. The total of lines 6 and 7.

i. The number of animals identified by the PHV as "U.S. Suspect" but later the PHV released the animal as not being a "U.S. Suspect".

j. The number of animals that died in pens after the PHV identified the animal as being a "U.S. Suspect".

k. The number of animals the PHV identified as "U.S. Suspect" and the establishment slaughtered on this date.

l. The total of lines 9, 10, and 11.

m. The number of animals the PHV identified as “U.S. Suspect” that the establishment chooses not to slaughter and the PHV is holding as U.S. Suspect.

n. The number condemned on ante-mortem plus dead animals (do not include suspects that died in pens – they are reported on line 11).

o. Write in “dead” or cause for condemnation and the number of animals disposed of in that category.

p. The first “U.S. Condemn” tag number and the last “U.S. Condemn” tag number used.

q. The signature of the PHV completing the report.

General signs of diseases and conditions identified in the regulations that can be detected at ante-mortem inspection

You will learn in detail about the signs of diseases and conditions identified in the regulations that can be detected during ante-mortem inspection during the Multi-species Disposition Basics section of this training. 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. 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 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.

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. Depression or disinterest may be a sign that the animal is in a dying or moribund state. A moribund animal may not respond to noises or other stimuli. Animals in a moribund condition are not eligible for slaughter.

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. 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.

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) permanently replaces the term “downer” with non-ambulatory livestock. 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. The PHV may choose to examine these animals where they are rather that 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, Rev. 2 provides guidance on re-examination of bovines that become non-ambulatory after passing ante-mortem inspection. On March 18, 2009, FSIS published a final rule, “Requirements for the disposition of cattle that become non-ambulatory disabled following ante-mortem inspection.” The final rule requires that all non-ambulatory cattle, including those that have passed ante-mortem inspection, must be condemned and properly disposed of, and that establishment personnel must notify FSIS when cattle become non-ambulatory disabled after passing ante-mortem inspection.

    The presence of the PHV in the livestock pen area is of critical importance. Establishments may have devices like hobbles to assist with ambulation, hip hoists to lift recumbent animals, or prods to urge the animals from a recumbent position. 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 such mechanical devices.

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). 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, or grinding of teeth. You may also see animals that have difficulty drinking and swallowing or appear to be blind. All of 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 (“cancer eye”). The PHV must examine all U.S. Suspect animals.

Abnormal signs on the body’s 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 in the tongue Epithelioma

(commonly referred to as "cancer eye" or "bug 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 by far the breed most commonly affected.

Abnormalities of the skin and mucus 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 maggots, notify the PHV because he or she will have to collect samples and send them to the laboratory. The laboratory will examine the maggots 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 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 the PHV 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 the PHV can conduct is to take the temperature of the animal. This chart 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. This chart is given as a reference.

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

Biological residues

Section 309.16 of the regulations 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 condemned unless the following options are exercised. They 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 period has passed, the animal must be returned for slaughter and be re-examined in 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, the PHV is 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. You will learn more about the details of residue testing in an upcoming module.

Animals used for research

Section 309.17 covers livestock that have been used for research purposes. The regulations prohibit 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. 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. You will learn more about how to deal with these situations in the Residue module.

Poultry

Condemned

Regulation 381.71 states that birds plainly showing any disease or condition in 381.80 to 381.93 that would cause condemnation of the carcass on post mortem inspection are condemned on ante-mortem. We will cover the specific regulations and conditions in the Multi-species Postmortem Disposition module. For now, just remember that you should ante-mortem condemn those poultry that would clearly be condemned on postmortem inspection.

According to 9 CFR 381.71, they 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 (DOAs) are identified, counted, and weighed, and the number is recorded in the Public Health Information System (PHIS) Animal Disposition Reporting function.

Suspect

Birds that do not plainly show but are suspected of being affected by any disease or condition in 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 under post-mortem (381.72). The PHV should verify that the establishment releases birds for treatment under the control of appropriate State of Federal officials. PHVs are to notify the District Office and follow instructions in FSIS Directive 6000.1, Responsibilities Related to Foreign Animal Diseases and Reportable Conditions, when he/she suspects a reportable or foreign animal disease. PHVs should also follow instructions in FSIS Directive 6020.1, Rev. 1, Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak, when FSIS issues specific instruction via an FSIS user notice. Section 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:

- slaughter separately if further handling does not create a health hazard, or
- release for treatment if practicable (and if further handling is a hazard), or
- condemn if treatment is not practicable (when further handling is determined to be hazardous)

Poultry suspected of having biological residues

Regulation 381.74 covers the requirements related to poultry suspected of having biological residues. There are three options. They 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.

Poultry used for research

Regulation 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 it is condemned.

Abnormal signs

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 may be observed 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

These abnormal signs will be covered in more detail in the dispositions section of the training.

Veterinary Services

Veterinary Services (VS) is an organizational unit of the Animal and Plant Health Inspection Service (APHIS). The overall mission of VS is to control or eradicate specified animal diseases in this country. Your role will be to contact VS when you suspect animals or poultry of having a reportable or foreign animal disease. Reportable diseases include anthrax, bluetongue, cysticercosis, scabies, tuberculosis, contagious ecthyma, myiasis (screwworm), scrapie, and vesicular diseases. Of these diseases anthrax, cysticercosis, tuberculosis, and contagious ecthyma are transmissible to humans. Foreign animal diseases include bovine spongiform encephalopathy (BSE), foot and mouth disease, rinderpest, African swine fever, hog cholera, contagious bovine pleuropneumonia, and Teschen's disease. In most cases, VS will want the livestock or poultry held so they can examine it. For example, in the case of livestock, the PHV 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. We will cover reportable and foreign animal diseases in more detail in a separate module later in the training.

WORKSHOP

Write your answers in the space provided.

1. State the body temperature at which each of the following species must be condemned.

Cattle _____ Sheep _____ Swine _____

2. The establishment disposes of dead or condemned livestock carcasses by sending them to a rendering establishment away from the official premises. FSIS requires these carcasses be properly denatured. From the following list of denaturants, identify those denaturants that are approved for this purpose.

_____ Crude carbolic acid

_____ Kerosene

_____ Cresylic disinfectant

_____ A formula consisting of 1 part FD&C green #3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella.

3. Which tag should be used for tagging an animal found dead in the pens?

_____ Silver U. S. Suspect tag

_____ Red U. S. Condemned tag

_____A tag is <u>not</u> necessary

4. Non-ambulatory disabled animal is

_____ unable to rise or walk

_____ showing signs of an abnormal condition

_____ found dead in the pens

5. U.S. Suspect is an animal

_____ that is obviously sick

_____ that will not respond to stimuli

_____identified with a U.S. Suspect tag in its ear or one that has been segregated into the U.S. Suspect pen because of an abnormal condition

6. U.S. Suspect tag is

_____ "U.S. Rejected."

_____ A serially numbered metal tag bearing the term "U.S. Suspect" and is silver in color

7. U.S. Condemned tag is

_____ A serially numbered metal ear tag bearing the term "U.S. Condemned"- usually red in color

_____The paper tag used to identify equipment or product as "U.S. Retained" or "U.S. Rejected"

8. Emergency slaughter is

_____The humane slaughter of an animal which has become sick or is in a dying state during the time an inspector is *not* on duty or *not* available for inspection

_____The humane slaughter of animals other than cattle, which are injured at night, on a holiday, or during a weekend, and an inspector is *not* on duty or *not* available for inspection

9. Select those that the official establishment is required by regulation ot provide:

_____Restraining device in suspect pen (or other acceptable method)

_____ Covered suspect pen

_____20 foot-candles lighting in suspect pen.

_____Suspect and condemned tags

_____ An accurate thermometer for inspection use

_____Curbs at least 12" high around the ante-mortem pens

_____ Adequate personnel to handle and drive livestock, drinking water for livestock in each pen

_____ Maintain pens in a sanitary manner and in good repair, free from sharp objects that may cause injury

10. Use the following information to complete the pen card below:

You just performed ante-mortem inspection on 24 animals (13 Holstein cows, 5 Angus steers, and 6 Hereford heifers) in pen #16. They are in Lot #39. One of the 13 cows had a vaginal prolapse, therefore, you made her a U. S. Suspect.

PEN CARD

DATE _____ PEN#_____

SPECIES: _____ LOT _____

BREED: _____

NUMBER: _____

TIME_____SIGNATURE_____

11. What happens to the above pen card when the animals are sent to slaughter?

12. Complete the FSIS Form 6150-1 using the following information:

You performed ante-mortem inspection on this date at Est. 38. The PHV condemned one Hereford bull (back tag #999 and condemn tag #456) for epithelioma.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION OPERATIONS

IDENTIFICATION TAG-ANTE MORTEM

SLAUGHTER AT EST. NO.

CONDEMNED OR SUSPECT TAG NO.

KIND OF ANIMAL	SEX

TAGGED FOR

TEMPERATURE	WEIGHT

REMARKS

INSPECTOR	DATE

POST MORTEM REPORT

FINDINGS

DISPOSAL

INSPECTOR	DATE

FSIS FORM 6150-1
(9/99)

REPLACES MP 402-2
9/83 WHICH MAY BE
USED UNTIL EXHAUSTED

13. Complete the FSIS Form 6150-1 using the following information:

You performed ante-mortem inspection on this date at Est. 38. You detected three Hereford cows with actinobacillosis to the extent that this condition would be readily detected on postmortem. Back tag #333 was attached to one animal, #334 to another animal, and #335 to the remaining animal.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION OPERATIONS

IDENTIFICATION TAG-ANTE MORTEM

SLAUGHTER AT EST. NO.

CONDEMNED OR SUSPECT TAG NO.

KIND OF ANIMAL	SEX

TAGGED FOR

TEMPERATURE	WEIGHT

REMARKS

INSPECTOR	DATE

POST MORTEM REPORT

FINDINGS

DISPOSAL

INSPECTOR	DATE

FSIS FORM 6150-1
(9/99)

REPLACES MP 402-2
9/83 WHICH MAY BE
USED UNTIL EXHAUSTED

14. Complete the FSIS Form 6150-1 using the following information:

You performed ante-mortem inspection on this date at Est. 38. You found one Holstein cow TB reactor with back tag #336, reactor tag #337, and a 103 degree temperature.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION OPERATIONS

IDENTIFICATION TAG-ANTE MORTEM

SLAUGHTER AT EST. NO.

CONDEMNED OR SUSPECT TAG NO.

KIND OF ANIMAL	SEX

TAGGED FOR

TEMPERATURE	WEIGHT

REMARKS

INSPECTOR	DATE

POST MORTEM REPORT

FINDINGS

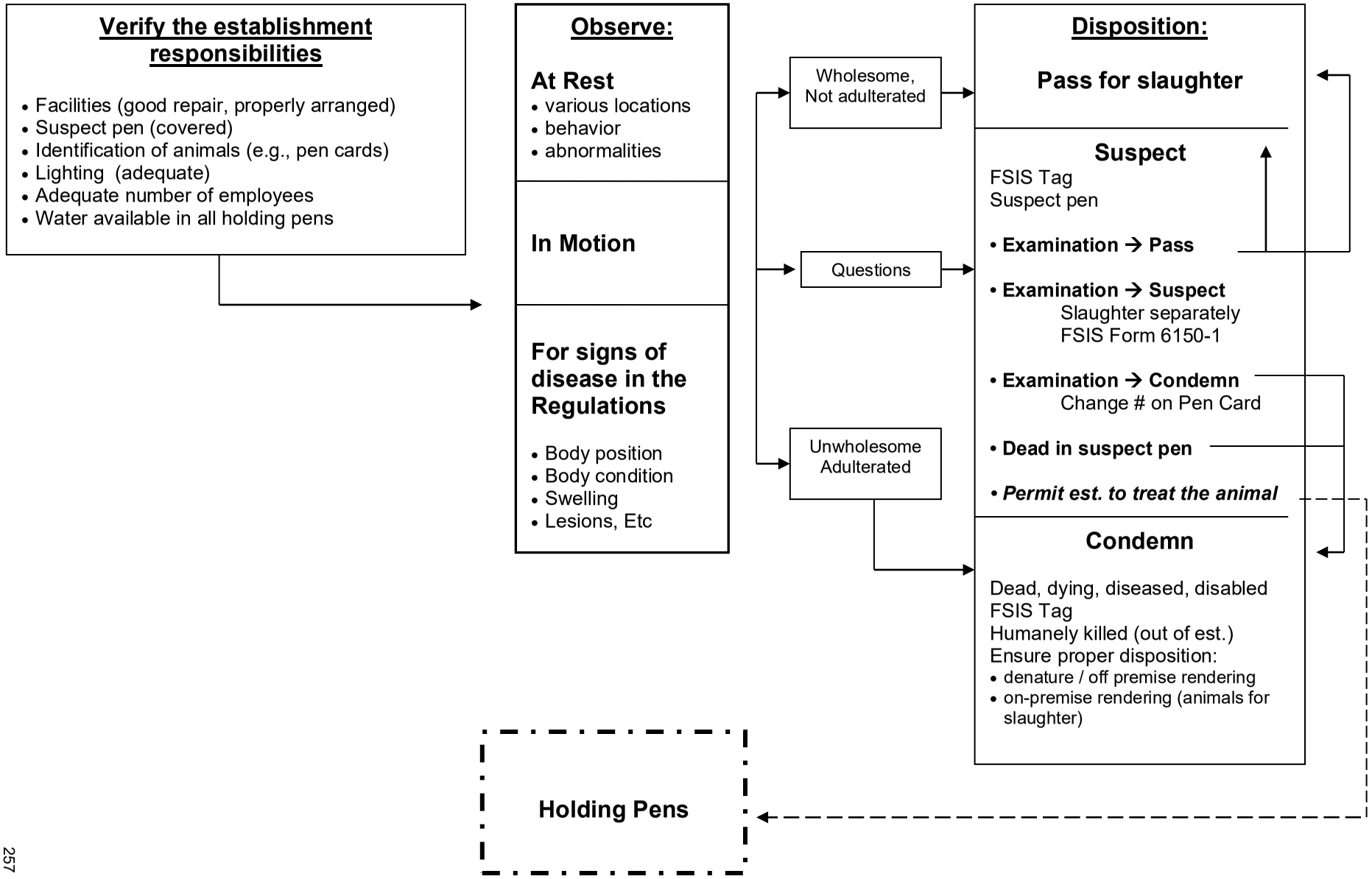
DISPOSAL

INSPECTOR	DATE

FSIS FORM 6150-1
(9/99)

REPLACES MP 402-2
9/83 WHICH MAY BE
USED UNTIL EXHAUSTED

ANTE MORTEM INSPECTION PROCESS



Humane Handling of Livestock and Good Commercial Practices in Poultry

OBJECTIVES

Upon completion of this module, you will be able to accomplish the following without the aid of references:

1. Select from a list of definitions the one that best describes the terms:
    a. Surgical anesthesia.
    b. Ritual slaughter.
2. Describe the four approved methods for stunning animals as identified in the Humane Slaughter Act and the Regulations.
3. Select, from a list of general humane slaughter or handling responsibilities, those that are applicable to the establishment, to FSIS, or both.
4. Determine if a description of the way an animal is stunned complies with the federal humane slaughter law.
5. Describe a method of slaughter that is exempt from stunning.
6. Select acceptable methods used to move a conscious disabled animal from one area to another area.
7. Determine if the way an animal is handled is compliant with the Humane Slaughter Act and the humane handling regulations.
8. Identify, from descriptions of establishment conditions in or around the livestock holding pens, those that might cause injury to animals.
9. Describe the establishment's responsibilities for animals that are withheld from slaughter for longer than 24 hours.
10. Describe the action an inspector should take when he/she observes an incident of inhumane treatment in an official establishment as a result of:
    a. Facility deficiencies, disrepair, or equipment breakdown.
    b. Establishment employee actions in the handling or moving of the livestock.
    c. Improper stunning.

REFERENCES

1. 9 CFR 313: Humane Slaughter of Livestock
2. 9 CFR 352.10: Exotic Animals; Voluntary Inspection; Ante-mortem inspection
3. Humane Methods of Livestock Slaughter Act of 1978
4. Federal Meat Inspection Act Section 603
5. FSIS Directive 6900.2, “Humane Handling and Slaughter of Livestock”
6. FSIS Directive 6100.1, “Ante-Mortem Livestock Inspection”
7. FSIS Directive 6110.1, “Verification of Poultry Good Commercial Practices”
8. FSIS Directive 6910.1, “District Veterinary Medical Specialist (DVMS) – Work Methods
9. FSIS Notice 09-18, Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves
PHV Intern 2
10. Federal Register Notice Docket No. 04-013N – A Systematic Approach to Humane Handling
11. Poultry Products Inspection Act Section 453(g)(5)
12. 9 CFR 381.65 (b): Poultry Products Inspection Regulations

13. Federal Register Notice, Docket No. 04-037N, Treatment of Live Poultry Before Slaughter
14. FSIS Directive 6100.3, “Ante-mortem and Post-mortem Poultry Inspection”
15. FSIS Directive 6110.1, “Verification of Poultry Good Commercial Practices”
16. Humane Interactive Knowledge Scenarios (livestock and poultry)
17. askFSIS

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 a significant financial loss to meat packers. Prior to 1958, there were no laws in the United States governing humane slaughter practices. The majority of the meat industry recognized the benefits of humane slaughter practices and their use was widely accepted. Primarily there were economic incentives; humane treatment generally resulted in less bruising and therefore less trimming of the dressed carcass. Still there was concern from many Americans over isolated, but persistent reports of continued cruelty to livestock at a few establishments.

The first law passed to address these concerns was the Humane Slaughter Act in 1958. This law was voluntary for meat packers who did not sell meat to the federal government. It required that livestock be rendered insensible to pain by a blow, gunshot, or electrical or chemical means that is rapid and effective before shackling, hoisting, casting, or cutting.

The law currently enforced by the USDA is the Humane Methods of Livestock Slaughter Act of 1978 (HMSA). The 1978 Act made mandatory the humane slaughter and handling of livestock in connection with slaughter of all food animals slaughtered in USDA inspected establishments. This includes cattle, calves, horses, mules, sheep, goats, swine, and other livestock. 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.

FSIS Notice 09-18, set forth policy to improve compliance with the HMSA and the humane slaughter regulations. Nonambulatory disabled cattle, including veal calves that are offered for slaughter must be condemned and promptly euthanized. Prohibiting the slaughter of all non-ambulatory veal calves removes a provision in 9 CFR 309.13(b), that formerly permitted establishments to set apart and hold for treatment veal calves that were unable to rise from a recumbent position and walk because they were tired or cold.

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. Additionally, Section 1906 exempts the handling or other preparation of livestock for slaughter from the terms of the Act. What this means is that 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. 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 the Title 9 Code of Federal Regulations (CFR) Part 313, titled *Humane Slaughter of Livestock*. Additional Agency guidance is detailed in the "References" section above. You and other in-plant personnel (IPP) will verify that establishments are meeting regulatory requirements by performing the Humane Activities Tracking System (HATS) task during every livestock slaughter shift. At this time, 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. GCP for poultry will be discussed later in this material.

Systematic Approach

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, has to include a written animal handling program. If the establishment has a robust systematic approach, FSIS will take that into

consideration should it be necessary to determine how to proceed 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. As a part of performing your daily HATS verification procedures, observe the establishment employees handle and slaughter animals. Verify that establishment employees are following their animal handling program and are implementing effective corrective actions when appropriate.

Recognize that 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 humane handling program that the establishment considers as systematic. 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 claims to have implemented a robust systematic approach, but you observe that the establishment is not following the written animal handling program, first discuss your observations with establishment management and document this discussion on an MOI. If you continue to observe ineffective implementation of the animal handling program, notify the DO (DVMS or DDMs if the DVMS position is vacant) and your immediate supervisor of your concerns by email. This notification serves as documentation of your concerns.

Ritual Slaughter

As previously mentioned, slaughtering is permitted without a stunning device in accordance with ritual requirements (kosher and halal slaughter being the most prominent examples). In common practice, each animal is shackled by a hind leg and hoisted into the air, or the animal is cut while restrained in a special pen prior to hoisting. The animal is fully conscious when the stick or cut takes place. In kosher slaughter, the cut is done by a shochet (slaughterer) chosen from the community, trained in the laws of the orthodox religion, and supervised by a rabbi in his area. 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.

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 to religious freedom. This does not mean that Agency personnel are to ignore completely what happens within in 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 District Veterinary Medical Specialist (DVMS) 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 HAT categories except stunning effectiveness. An exception to this is when stunning methods are an accepted part of that religious slaughter protocol. Therefore, 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

Establishment personnel are required to meet the regulatory requirements for humane handling and slaughter of livestock from the time the livestock are in conjunction with slaughter 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 premises, 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.

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 Animal and Plant Health Inspection Service (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 (AVIC) 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 conduct an investigation. IPP should also prepare a Memorandum of Interview (MOI) to document what was observed and all actions taken.

IPP can enter onto transport vehicles to conduct antemortem inspection if establishment employees cannot humanely remove disabled livestock from the vehicles. The decision to enter a transport vehicle to conduct antemortem inspection or to conduct antemortem inspection from outside the vehicle is made by each inspector individually and is voluntary. Inspection personnel may enter onto the transport vehicle or perform antemortem inspection from outside the transport vehicle if, in his or her professional opinion, he or she can safely and adequately conduct the antemortem inspection. No adverse or disciplinary action can or will be

taken against any inspection program personnel choosing not to conduct antemortem inspection of disabled livestock on or from outside of a transport vehicle.

Livestock pens, driveways, and ramps

Personnel responsible for moving livestock from the livestock trailers to 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 violation of humane practices.

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

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 to run before deciding if there is regulatory noncompliance. The key here is whether human actions caused the animal 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 of appropriate for the age and species of animal being fed. For example, feeding hay to bob veal calves held more than 24 hours would not meet the regulatory requirement for access to feed. If held overnight, they 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. Suspect must be segregated into a separate pen. The pen must protect these animals from adverse weather conditions until

you make your antemortem disposition, because the weakened state of these animals renders them less resistant to even “normal” weather conditions. This means that you need to take into account 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.

The regulations strictly prohibit dragging 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.

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 is 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.

It is important to recognize that 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 VII – 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 a regulatory control action 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 a regulatory control action and document a noncompliance record in as specified in the “Enforcement” section later in this module.

Stunning

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 animal to begin bleeding out ("sticking") after being 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 (electrical current)

<u>Carbon Dioxide</u>

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

There are two types of mechanical captive bolt stunners—penetrating and nonpenetrating—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 (a blank cartridge) 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. 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 statutory and 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.

After a Bovine Spongiform Encephalopathy (BSE) positive cow was found in Washington State in December 2003, a number of policies were issued to protect the public health against BSE. One of these policies involved the prohibition of air-injection stunning of cattle. Air-injection stunning is a method of deliberately injecting compressed air into the cranial cavity as a part of the stunning process. Therefore, 9 CFR 313.15(b)(2)(ii) states *"Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle."* to ensure that portions of the brain are not translocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process.

Many establishments will use the non-penetrating type of captive bolt in order 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 is important post-stun to ensure the animal does not regain consciousness.

Mechanical – gunshot

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

Remember that the standard is that every animal is rendered insensible to pain (unconscious) by a single gunshot, regardless of the type of projectile used. 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, 310.18(b) of the Regulations 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

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 as well as 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 but 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 method 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 postmortem 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 timeframe, but 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 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.
4. There is no vocalization—mooing, bellowing, baaing, 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. This sign is not used for electrically stunned animals. Also, be very aware of 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 vocalize. It may also show a “righting reflex”. The term “righting reflex” is used to describe the physical actions taken by an animal to move itself into a normal sternal 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. Do not mistake this sideways spasm 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.

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

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 establishment managers. 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 (the edge of a shovel, a pointed metal prod) 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. So, take care of the animal first.

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 warrants an immediate suspension of the assignment of inspectors under the authority of the Rules of Practice (9 CFR 500.3(b)).

<u>Non-egregious Noncompliance</u>

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 a noncompliance report (NR) in the Livestock Humane Handling Verification task in PHIS.

If necessary, take a regulatory control action to prevent further injury to the animal or to prevent injuries from occurring to other animals. You will also take the appropriate regulatory control action if you do not receive an adequate response or corrective actions to the NR or if the noncompliance observed continues to occur. The appropriate regulatory control action

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. Retained/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, inspection personnel must document the incident on a NR and send a copy to the DVMS at the District Office. It is important that it clearly and specifically describe exactly what was observed, including any response by the animal (if the noncompliance involved animal discomfort or injury). Specify all the relevant regulations that pertain to the incident. Somewhere in your narrative in Block 10 (where the noncompliance is described) of the NR, list the HATS category you were verifying when you saw the noncompliance. If the noncompliance is covered by a second HATS category, note both categories on the NR. Many IPP still write the HATS category (or categories) at the *top* of Block 10, before narrating the description of the incident, but this practice is no longer required.

If the establishment continues to have non-egregious humane handling noncompliances or does not adequately correct previously documented non-egregious humane handling noncompliances, the IIC is to communicate this to the FLS and DVMS. The IIC will work with the FLS and DVMS to determine if a Notice of Intended Enforcement (NOIE) should be issued for multiple noncompliances.

Egregious Noncompliance

Under the Rules of Practice, 9 CFR 500.3(b), FSIS can suspend assignment of inspectors to an establishment without prior notification for certain humane handling noncompliance. Humane handling noncompliance for which immediate suspension is 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." Actions or conditions FSIS considers egregious are listed in FSIS Directive 6900.2, Rev. 3, Chapter I, Section V.B.:

1. Making cuts on or skinning conscious animals;

2. Excessive beating or prodding of ambulatory or nonambulatory 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 electric 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.

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 regulatory control action. Your next set of actions will depend on whether or not you are the IIC.

If you are the IIC, after you place a U.S. Retained/Rejected tag at the appropriate place, inform establishment managers that you are communicating with the FLS, District Office and DVMS to discuss the incident and recommend that a suspension without notification is imposed in accordance with 9 CFR 500.3(b).

If you are not the IIC, after you attach a U.S. Retained/Rejected tag at the appropriate place, inform establishment managers that you are taking a regulatory control action 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.

The IIC will immediately notify the FLS, District Office and the DVMS of the incident to discuss and recommend a suspension action. The IIC will also document the facts that serve as the basis of the suspension action in a noncompliance record (NR) and promptly provide that information electronically to the DO and the DVMS for their use. The NR will form the basis of the Notice of Suspension documented by the DVMS and DO staff and of the Administrative Enforcement Report (AER).

Delayed Implementation – Egregious Noncompliance

The IIC may also delay implementing the suspension action if immediate action is likely to result in inhumane treatment of additional animals until he/she 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 the establishment is 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?

The IIC needs to let the DO know that the suspension action will be delayed. Also, 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 her or his own authority. This is not intended for a “kill-out” or “kill-off” 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 animals will not be subjected to inhumane handling, the suspension must be promptly implemented in coordination with the FLS and the District Office.

Enforcement Discretion – Egregious Violations

When certain conditions are met, the IIC can recommend that the egregious act be subject to enforcement discretion and recommend issuance of a Notice of Intended Enforcement (NOIE) rather than a Notice of Suspension. This would be when the establishment:

- Does not have any recent humane handling related enforcement actions;
- Has consistently been meeting the humane handling regulatory requirements;

• Has been operating under a written animal handling program that establishment management has proffered as a robust systematic approach and made accessible to IPP; and
• Has demonstrated the robustness of the program to IPP by effectively and consistently implementing all aspects of its program.

The decision to recommend this enforcement action is based on the Rules of Practice regulation (9 CFR 500.3(b)) that states: "FSIS also *may* impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely." In determining whether the egregious act is an anomaly, and whether the establishment should be allowed to continue to operate, the IIC, FLS, DO, and DVMS are to consider:

• Whether the establishment is operating under an animal handling program that provides for how the establishment will respond if an unforeseeable event of this type occurs;
• Whether there is any basis for concern that the planned response in the establishment's animal handling program will not effectively address the problem; and
• Whether the establishment has implemented their animal handling program consistently and effectively over time.

In 2003, the Agency began to incorporate the new Administrative Enforcement Reports (AER). The AER applies in all situations including humane handling. It is a reporting method that demonstrates that FSIS has an effective and efficient means to document and maintain administrative enforcement actions taken under the Rules of Practice.

An AER is started when the Agency initiates further enforcement actions, such as a Notice of Intended Enforcement (NOIE) or a Suspension without Prior Notification. Although in-plant PHVs are not responsible for maintaining the AER, documentation developed by in-plant PHVs is integral to the successful management and effective outcomes of those further enforcement actions. This means that in-plant documentation, including NRs, notes of weekly USDA/Company meetings, memoranda of conversations/interviews, needs to be complete, accurate, and clear.

Exotic species

Exotic animals (voluntary inspection) are covered under 9 CFR 352.10. This section includes regulations that address humane handling during antemortem inspection and stunning practices to render the animals unconscious. The regulation states, "Humane handling of an exotic animal during antemortem 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 and 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.

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

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 a regulatory control action 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 noncompliance, and District Office personnel may initiate a denial of service action.

Custom Exempt Operations

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.

When FSIS 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 observe inhumane handling or slaughter practices of custom exempt livestock, they are to take the following actions:

- Immediately notify establishment management of their observations and request that establishment management address the issue;
- Document their observations 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 5930.1, “Custom Exempt Review Process”.

Humane Activities Tracking System (HATS)

You will be verifying that establishment facilities and the activities of establishment personnel comply with humane slaughter laws. The amount of time that Agency inspection program personnel (IPP) spend verifying compliance with the humane handling statutes and regulations is captured in the HATS tab within the Livestock Humane Handling Verification task in PHIS. Agency IPP must perform HATS verification each day and shift that livestock slaughter occurs in federally inspected facilities.

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 and statutory 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. 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 antemortem inspection and slaughter. It is important to focus on doing complete, quality verifications of each category.

If you are in a multi-IPPS assignment, conduct one or more HATS category verifications whenever you visit an establishment to perform AM and PM 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.

If the establishment has an identified robust systematic approach, verify that the establishment is following its written animal handling program. If the establishment is not following its program, first discuss your observations with establishment management. Document the discussions on an MOI. If the establishment continues to implement its written animal handling program ineffectively, notify your immediate supervisor and the DVMS of your concerns by email.

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. The bottom line here is that 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.

<u>HATS Categories</u>

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.
   - Animals may slip or fall because of wet floor conditions or because of the build-up snow and ice.
   - Animals may not have access to water when water buckets or troughs freeze over.
   - Livestock are overheated because of a lack of proper shade or because of a lack of water for cooling.
   - Disabled livestock may not be placed in a covered pen.

II. Truck Unloading (9 CFR 313.1 and 313.2): Under this category, IPP record their verification of the establishment's humane handling procedures during livestock unloading activities.

- The condition of the facilities may injure or is injuring animals.
- Vehicles or ramps may not be properly positioned, leading to the injury of animals
- Animals may be forced to move faster than a normal walking speed.
- Animals may slip and fall.
- Disabled or U.S. Suspect animals may not be separated from normal ambulatory animals.
- During unloading and driving, animals may be excessively prodded or not driven with a minimum of excitement and discomfort.

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.

- Water may not be accessible to livestock in holding pens.
- Food may not be provided to livestock being held for longer than 24 hours.

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

- Livestock may be excessively prodded with an electric prod.
- Livestock may be injured because of handling practices.
- Livestock may be 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.

- Conscious animals may be dragged.
- Disabled animals may not be separated from normal ambulatory animals.

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 or the use of sharp objects *after* antemortem inspection has occurred (9 CFR 313.2).

- Livestock may be excessively prodded, causing them to become overexcited or injured.
- Livestock may be prodded with sharp objects.
- This procedure includes direct observation at multiple locations (e.g., pens, alleyways, single-file chutes, stunning areas) involving animal movement.

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.

- Livestock may slip and fall due to inadequate footing or improper handling practices.
- Livestock may slip and fall because of poor footing or lack of slip resistant flooring.\

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 may not be rendered unconscious with a single application of the stunning methodology.
- There may not be records for carbon dioxide gas concentrations.

IX. Conscious Animals on the Rail (9 CFR 313.5, 313.15, 313.16, and 313.30): Under this category, IPP (usually a Public Health Veterinarian) record their verification that the establishment ensures that animals do not regain consciousness 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.

- Establishments may further process (e.g., shackle, hoist, cut) livestock not rendered unconscious by the method of stunning.
- Animals may regain consciousness after being stunned.

<u>Odd-hours verification visits</u>

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 District Veterinary Medical Specialist (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 that 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 antemortem inspection.
• Non-ambulatory disabled animals are being delivered to the establishment outside the regular tour of duty when inspection program personnel (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 off-hour inspection will be paid as non-reimbursable overtime. Document your observations on FSIS Form 8100-1, and record time in PHIS under the appropriate HATS category on the date the odd-hours inspection occurs.

If noncompliance is identified, document the NR on the date of the odd-hours inspection.

Poultry Good Commercial Practices (GCP)

At this time, there is no statute requiring humane handling in poultry. However, there is a regulatory requirement that poultry are slaughtered using good commercial practices (GCP).

Introduction

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, 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 unfit for human food. These cadavers are automatically condemned on postmortem inspection per 9 CFR 381.90.

On September 28, 2005, the Agency published a Federal Register 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 good commercial practices. 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. Recognize that this approach is voluntary on the part of industry; also recognize that it signals a change by the Agency to 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. It discusses the observation of still breathing chickens entering the scald tank and identifies the enforcement actions that taken by IPP when noncompliance with regulatory requirements is observed.

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 bird’s 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 that stunning of poultry is not explicitly required by regulations, but it is an almost universal practice in the poultry slaughter industry).

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 the line inspectors report increased numbers or clusters of cadavers at inspection stations or increased numbers of bruised wings or legs.

Once a week, select a day at random to review establishment records documenting adherence to good commercial practices. This review takes the place of observation in the receiving through pre-scald areas. Recognize that establishments are not required to maintain written records of good commercial practices. 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 good commercial practices. 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.

Enforcement

If the establishment is not following good commercial practices, 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 a 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 Humane Methods of Livestock Slaughter Act, 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 Poultry Mistreatment MOI (see below).

Writing a GCP NR

1. IPP are to document loss of process control by the establishment, and thus not operating in accordance with GCPs. When there is repeated occurrence of birds:

    a. Dying otherwise than by slaughter (repeatedly entering the scalding tank while still breathing); and
    b. Not being appropriately bled out (as evidenced by equipment malfunction that results in increased numbers or clusters of cadavers being condemned); or
    c. Being intentionally and repeatedly mistreated by establishment personnel

2. IPP should consider the following questions to determine if there has been a loss of process control:

    a. What is the problem?
    b. How long did the problem last?
    c. How did the establishment react?
    d. How did they correct the problem, and did it reoccur?
    e. What were the periods of control?

3. IPP are to document the noncompliance with 9 CFR 381.65(b) when the establishment is not following GCP. Remember that an isolated incident does not represent a loss of process control and should be documented in a mistreatment MOI, not an NR.

Poultry Mistreatment MOIs

Poultry MOIs are primarily issued when the establishment is mistreating birds up until the kill step, but the mistreatment event does not demonstrate that the establishment's process is out of control. The MOI documents the discussion between IPP and the establishment management about the poultry mistreatment event. In addition, you are to document the discussion and any planned actions on the part of the establishment in a MOI. Give a copy of the MOI to establishment managers, keep a copy in the inspection file, and send a copy to the DVMS.

1. IPP should document poultry mistreatment MOI when: for example,

    a. Isolated instances of a bird still breathing when entering the scalder
    b. Unusually high number of injuries to birds such as broken legs, wings, but no evidence of intentional mistreatment

2. After observing poultry mistreatment, IPP should:

    a. Notify the establishment immediately
    b. Discuss the mistreatment after the event is resolved and advise the establishment that preventing mistreatment decreases the production of adulterated carcasses.
    c. Document the discussion, and any establishment's planned actions

DVMS Review of GCP NRs and Poultry Mistreatment MOIs

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

WORKSHOP

Mark your choice(s) with an "X" in the space provided.

1. Which of the following could be noncompliances that could cause injury or discomfort to animals during unloading, weighing, or driving to the stunning area?

   _____ an unloading ramp with a 2-inch section of the planking missing

   _____ several bolts protruding from the pen posts

   _____ ante-mortem pens not covered

   _____ icy runways

   _____ floors in the pens are smooth concrete

2. "Surgical Anesthesia" is best described as:

   _____ Drug or implement used to render the animal unconscious.

   _____ A state where the animal feels no painful sensations

3. "Ritual Slaughter" is best described as:

   _____ A method of slaughter dictated by a religious group

   _____ A method of slaughter that requires the animal to be bled prior to loss of consciousness

   _____ Both of the above

4. In your opinion, which implements or methods if not used in excess could be used to drive or move livestock and be acceptable under Part 313 of the Regulations?

   _____ Canvas slapper

   _____ Wooden club

   _____ Battery- operated prod

   _____ Bullwhip

   _____ Electric prod attached to AC current (transformer available)

   _____ Whistle

   _____ Electric prod attached to AC current (no transformer available)

   _____ Flat- blade shovel

_____ Light leather strap, 2 inches wide

_____ Hand- held metal prod

_____ Lead goat

5. List the four approved methods for humanely stunning animals.

6. Animals that are delivered to the slaughter establishment at 3:30 p.m. on Monday are intended to be slaughtered no later than noon on Tuesday would require both water and feed.

   _____ True

   _____ False

7. From the following list of responsibilities, write the letter "I" opposite those that are inspector's responsibilities and the letter "E" opposite those that are the establishment's responsibilities.

   _____ Provide adequate pens in good repair

   _____ Adhere to all humane slaughter requirements

   _____ Frequently observe stunning procedures to determine whether livestock are insensible to pain before shackling and bleeding

   _____ Provide water and feed when necessary for animals

   _____ Report any noncompliance of humane handling regulatory requirements.

   _____ Provide acceptable means to move disabled animals

   _____ Reject areas/ equipment when inhumane treatment is observed

8. You are performing the antemortem assignment and you observe an establishment employee driving animals with a sharp pointed implement. Which of the following statements best describes the action you should take as identified in the Regulations?

   _____ Tell the establishment employee to stop using the pointed implement

   _____ Inform the establishment management of the incident and request that they take the necessary steps to prevent a recurrence

   _____ Notify the district manager and the Humane Society

9. An animal that is conscious and not able to stand or walk, should be moved by which of the following methods?

   _____ Loading the animal onto a skid, stone boat, bucket lift, or any other method that will not, in your opinion, cause undue excitement and/ or pain

   _____ Allow the establishment to stun the animal then allow it to be dragged

   _____ Either of the above

   _____ None of the above

10. An injured alert U.S. suspect may be dragged from the suspect pen to the knocking box.

    _____ True

    _____ False

11. The establishment is using firearms to stun livestock. Which of the following is a true statement?

    _____ Condemn both the heads and the tongues if hollow-pointed bullets are used

    _____ Condemn the tongues but save the heads if frangible bullets are used

    _____ Condemn the heads but may save the tongues regardless of the type of bullets used

12. Can an establishment's inspection service be suspended if it has a history of treating livestock inhumanely?

    _____ Yes

    _____ No

How to Determine Insensibility

(Revised August 2007)

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In both captive bolt and electrically stunned animals kicking will occur. Ignore the kicking and look at the head. To put it simply, THE HEAD MUST BE DEAD. When cattle are shot with a captive bolt, it is normal to have a spasm for 5 to 15 seconds. After the animal is rolled out of the box or hung up its eyes should relax and be wide open.

Below are the signs of a properly stunned animal:

1. The legs may kick, but the head and neck must be loose and floppy like a rag. A normal spasm may cause some neck flexing, but the neck should relax and the head should flop within about 20 seconds. Check eye reflexes if flexing continues. Animals stunned with gas stunning equipment should be limp and floppy though they may exhibit slow limb movement.
2. The tongue should hang out and be straight and limp. A stiff curled tongue is a sign of possible return to sensibility. If the tongue goes in and out, this may be a sign of partial sensibility.
3. When the animal is hung on the rail, its head should hang straight down and the back must be straight. It must NOT have an arched back righting reflex. When a partially sensible animal is hung on the rail it will attempt to lift up its head. It will be stiff. Momentary flopping of the head is not a righting reflex.
4. When captive bolt is used the eyes should be wide open with a blank stare. There must be no eye movements. Immediately after electrical stunning the animal will clamp its eyes shut, but they should relax into a blank stare.
5. When captive bolt is used the animal must NEVER blink or have an eye reflex in response to touch. In electrically stunned pigs eye movements can be misinterpreted when untrained people indiscriminantly poke at the eyes. It is often best to observe without touching the eye. If a pig blinks with a natural blink where the eye closes and then re-opens it is not properly stunned. If you are not sure what a natural blink looks like, go and look at live pigs in the yards (lairage) before assessing insensibility.
6. Rhythmic breathing must be absent. Gasping is a sign of a dying brain and is OK. A twitching nose (like a rabbit) may be a sign of partial sensibility.
7. In captive bolt stunned animals, insensibility may be questionable if the eyes are rolled back or they are vibrating (nystagmus). Nystagmus is permissible in electrically stunned animals, especially those stunned with frequencies higher than 50 or 60 cycles.
8. Shortly after being hung on the rail, the tail should relax and hang down.

9. No response to a nose pinch. Animals entering a scauld tub must not make a movement that is in direct response to contact with the hot water. For all types of stunning this is an indicator of possible return to sensibility.
10. No vocalization (moo, bellow or squeal)

The above methods can be used for determining insensibility for all types of stunning and for ritual slaughter which is done without stunning. Just remember, kicking reflexes are normal in captive bolt stunned animals, electrically stunned animals and after ritual slaughter. They should be absent or very feeble for $C0_2$. Captive bolt stunning induces instant insensibility by both concussion and physical destruction of the brain. Stunner maintenance is essential to maintain maximum hitting power.

Electrical stunning, renders an animal instantly insensible by inducing a grand mal epileptic seizure. Scientific research has shown, that in order to induce the seizure the electric stunner must be set at a minimum of 1.25 amps for market weight pigs and l amp for sheep. Large sows will require 2 or more amps. If' lower amperages are used the stunner may induce cardiac arrest but the animal will feel the shock because the seizure was not induced. Electrical frequencies up to 800 hz (cycles) can be used. Frequencies over 800 hz should not be used. Research has shown that 1500 cycles failed to induce instant insensibility. Animals that are dehydrated may have high electrical resistance and be difficult to stun.

In some plants, cattle or sheep are immobilized after electric stunning with a small electric current to stop kicking. This immobilizer current completely masks signs of return to sensibility. To assess return to sensibility the immobilizer current MUST be turned off. Electric immobilization is highly distressful to animals and it must never be confused with electric stunning, which induces instantaneous insensibility by passing a high amperage current through the brain.

If an electrically stunned animal blinks within 5 seconds after stunning this is a sign that the amperage is too low. In electrically stunned animals, blinking should be checked within 5 seconds and after 60 seconds. In most plants blinking will not be found immediately after stunning, because the plant is using the correct amperage. After it has been verified that the amperage is set correctly, the most important point to observe for signs of return to sensibility is 60 seconds after electrical stunning. This provides time for the eyes to relax after the epileptic seizure. Checking for signs of return to sensibility after bleeding insures that the animal will not recover.

When stunned animals are viewed from a distance, the most important signs to look for in a properly stunned animal are:

1. A floppy head
2. Tongue hangs straight out and is limp
3. The back and head hang straight down. There is no arched back righting reflex.

Animals that show all three of the above signs will be insensible and blinking and other eye reflexes will be absent.

Order of the events which indicate Return to Sensibility:

1. Single feeble eye reflex in response to touch (probably still insensible and not conscious).
2. Return of rhythmic breathing. This is a primary indicator of poor stunning and it may occur before the corneal reflexes.
3. Spontaneous natural blinking without touching (recommended sign for determining return to sensibility for regulatory purposes). In large plants this is easier to assess than rhythmic breathing.
4. Response to a painful stimulus such as pricking the nose with a pin. The stimulus must be applied to the head to avoid confusion with spinal reflexes.
5. Righting reflex and raises it's head.
6. Fully conscious and sensible. Complete return to sensibility can occur within 15 to 20 seconds after eye reflexes appear if an electrically stunned animal is not bled.

The American Meat Institute guidelines require that ALL of the signs of return to sensibility MUST be absent to pass an audit. Even thought an animal is probably insensible if it shows a weak corneal reflex or tongue movement, it is starting the process of return to sensibility. Weak indicators of return to sensibility can be abolished by improved stunning practices. Slaughter plants are not research laboratories where conditions are carefully controlled. Therefore a much greater margin of safety is required to ensure that the animal remains insensible.

An animal showing any of the above signs must be immediately re-stunned before any slaughter procedures are started.

TITLE 7 CHAPTER 48

CHAPTER 48—HUMANE METHODS OF LIVESTOCK SLAUGHTER

Release date: 2004-03-25

§ 1901. Findings and declaration of policy

The Congress finds that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce. It is therefore declared to be the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods.

§ 1902. Humane methods

No method of slaughtering or handling in connection with slaughtering shall be deemed to comply with the public policy of the United States unless it is humane. Either of the following two methods of slaughtering and handling are hereby found to be humane:
(a) in the case of cattle, calves, horses, mules, sheep, swine, and other livestock, all animals are 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; or
(b) by slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby 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 and handling in connection with such slaughtering.

§ 1903. Repealed. Pub. L. 95–445, § 5(b), Oct. 10, 1978, 92 Stat. 1069

Section, Pub. L. 85–765, § 3, Aug. 27, 1958, 72 Stat. 862, related to limitations on Government procurement and price support, modifications during national emergency, and statements of eligibility.

§ 1904. Methods research; designation of methods

In furtherance of the policy expressed herein the Secretary is authorized and directed—
(a) to conduct, assist, and foster research, investigation, and experimentation to develop and determine methods of slaughter and the handling of livestock in connection with slaughter which are practicable with reference to the speed and scope of slaughtering operations and humane with reference to other existing methods and then current scientific knowledge; and
(b) on or before March 1, 1959, and at such times thereafter as he deems advisable, to designate methods of slaughter and of handling in connection with slaughter which, with respect to each species of livestock, conform to the policy stated in this chapter. If he

deems it more effective, the Secretary may make any such designation by designating methods which are not in conformity with such policy. Designations by the Secretary subsequent to March 1, 1959, shall become effective 180 days after their publication in the Federal Register.

§ 1905. Repealed. Pub. L. 95–445, § 5(b), Oct. 10, 1978, 92 Stat. 1069

Section, Pub. L. 85–765, § 5, Aug. 27, 1958, 72 Stat. 863, related to establishment, composition, functions, compensation, meetings, and reports of advisory committees.

§ 1906. Exemption of ritual slaughter

Nothing in this chapter shall be construed to prohibit, abridge, or in any way hinder the religious freedom of any person or group. Notwithstanding any other provision of this chapter, in order to protect freedom of religion, ritual slaughter and the handling or other preparation of livestock for ritual slaughter are exempted from the terms of this chapter. For the purposes of this section the term "ritual slaughter" means slaughter in accordance with section 1902 (b) of this title.

§ 1907. Practices involving nonambulatory livestock

(a) Report

The Secretary of Agriculture shall investigate and submit to Congress a report on—

(1) the scope of nonambulatory livestock;

(2) the causes that render livestock nonambulatory;

(3) the humane treatment of nonambulatory livestock; and

(4) the extent to which nonambulatory livestock may present handling and disposition problems for stockyards, market agencies, and dealers.

(b) Authority

Based on the findings of the report, if the Secretary determines it necessary, the Secretary shall promulgate regulations to provide for the humane treatment, handling, and disposition of nonambulatory livestock by stockyards, market agencies, and dealers.

(c) Administration and enforcement

For the purpose of administering and enforcing any regulations promulgated under subsection (b) of this section, the authorities provided under sections 10414 [7 U.S.C. 8313] and 10415 [7 U.S.C. 8314] shall apply to the regulations in a similar manner as those sections apply to the Animal Health Protection Act [7 U.S.C. 8301 et seq.]. Any person that violates regulations promulgated under subsection (b) of this section shall be subject to penalties provided in section 10414.

BACKGROUND INFO ONLY - NO LONGER PRESENTED
Animal and Egg Production Food Safety

OBJECTIVES

To demonstrate mastery of Animal and Egg Production Food Safety the trainee will:

1. Describe and explain why certain classes of livestock presented for slaughter are historically the highest risk for violative residues.

2. Be familiar with the dairy, pork, egg and beef producer HACCP-compatible, Quality Assurance or Good Production Practices Programs. Be able to describe the newest trends in verifiable, third party audited programs and the advantages to industry these programs bring.

3. Be able to describe the role of the in-plant Public Health Veterinarian when interacting with animal and egg production food safety partners.

4. Be familiar with promising research in pre-harvest food safety and why multiple interventions are believed to be more likely to succeed from farm to slaughter in reducing, controlling and/or eliminating public health hazards reasonably likely to occur in and on animals, poultry and eggs presented to processing.

REFERENCES

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4. Federal Register, Nov. 28, 2000, Residue Control in a HACCP Environment. 5 (229): 70809-70815 http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=54385985008+2+0+0&WAISaction=retrieve

INTRODUCTION

FSIS has a firm commitment to a farm-to-table public health strategy in pursuit of its broad public health mission. The Agency has committed to developing the role of its veterinarians to include a number of non-regulatory responsibilities. These responsibilities and roles include delivering food safety and public health messages by interacting with colleagues in animal and public health agencies and organizations outside the establishment environment.

Since FSIS has no regulatory authority on farm or during the transportation of food animals and poultry to slaughter, it is apparent that the regulatory model used in the slaughter and processing establishments does not apply for enhancing food safety

during the animal production link of the food chain. A different approach must be taken to identify and promote programs that encourage food animal producers, veterinarians and information multipliers who communicate with them to adopt production practices that support HACCP and reduce food safety hazards in animals presented for slaughter. There is a need for all of FSIS to help carry the food safety message to those who can help implement practices that will result in a safer animal being presented for slaughter. In short, the knowledge and experience of FSIS veterinarians is necessary to put the "farm" in "farm to table food safety" but you must be knowledgeable about production practices.

The animal production segment of the food chain in includes breeding, raising and transporting to the next stage of production or to markets, feedlots or slaughter establishments.
Because there are so many different production practices for poultry and livestock, as well as exotic species, it is important to be familiar with them. Resources will be provided to you in this module to get you started.

Here are the subject areas we will review in this module.

- Foodborne hazards carried in and on food animals and poultry to processing, and high risk classes of livestock for hazards
- Producer Quality Assurance and Certification Programs
- Your role in collaboration, information sharing and scientific assessments
- Promising areas of research

Food animal producers are impacted by public media events. For example, the U. S. News story "Outbreak," was about a farmer's family that contracted multi-drug resistant *Salmonella* from their dairy cattle and calves. An investigation included the state animal and public health authorities, USDA APHIS, FSIS and the CDC. The family was devastated emotionally and economically by the event that they felt they had no control over. So, it is important that when dealing with the animal production stakeholders that you speak from a frame of reference of science and not emotion.

The 2003 finding of one "mad cow" in Canada resulted in a significant negative economic impact on the cattle industry there. You are probably also familiar with the impact of the finding of BSE in the U.S. in December 2003.

Foodborne hazards

Foodborne hazards can be carried internally and externally on the hide, hair, saliva and feathers. Some examples of chemical hazards include animal drugs, pesticides, and antimicrobials. Examples of physical hazards include injection needles and lead shot. Some microbial hazards that are found in food animals include *Salmonella* and *E. coli* O157:H7. Chemical and physical hazards may be introduced via improper injection of drugs into muscle tissue. A study by the National Cattleman's Beef Association (NCBA) found that almost 14% of dairy cattle in feedlot pens going to slaughter had visible abscesses. From a public health standpoint, these injection site abscesses are a clinical sign of potential violative drug residues. There are sufficient historical data that show the following classes of animals are more likely to have violative residues and may be

prone to animal and public health pathogens: Bob veal (3 weeks, 150 pounds), culled cows and bulls, culled boars and sows, roaster pigs (approximately 35 pounds), hospital pen "clean-outs." These are the primary classes of animals which need a greater focus for residue testing efforts to protect the public's health.

Good management practices

One helpful way to communicate the message about food safety to the production community is to explain how good management practices will result in more value, better food safety results, and improved animal health.

Examples of good management practices are:

- Quality assurance programs (see below).
- Animal identification to permit trace back for critical foreign animal diseases, such as BSE, and residue violations. Good animal ID practices will help producers to contain an animal or public health problem from spreading, such as Food and Mouth Disease, and therefore will aid biosecurity efforts.
- Proper treatment records of drugs, pesticides and antimicrobials.
- Proper drug use; use only as directed by the label.
- Practicing feed quality and safety to prevent chemical and microbial contamination that can spread throughout the herd.
- Good culling practices which means removing animals from the herd before they become so ill that they end up in the 4-D category of down, diseased, disabled or dead on arrival to slaughter establishments (thus less valuable and resulting in more food safety and quality problems).
- Good sanitation and waste management practices.
- Good external and internal biosecurity.

Good management practices can improve the health of the animals. Food animal veterinarians recognize that very thin or sick animals will often be condemned and that livestock with better body condition scores bring higher prices. Cattle not too fat or too thin have a higher percentage of good carcass quality. These findings indicate that good production practices also result in an economic benefit at slaughter. Other research shows more profitability on farms where producers cull (remove) animals from production before they become emaciated and diseased, disabled and/or non-ambulatory.

Livestock in general with poor condition have a higher incidence of disability and have poor red meat yield. If the animal is emaciated, it has a greater susceptibility to bruising and injury at slaughter. Approximately 3% of slaughtered dairy cattle are too fat. Increased carcass quality means increased profit.

Since FSIS implemented the HACCP rule in slaughter and processing establishments, beginning in 1996, there has been a ripple effect on the animal production or "pre-harvest" section of the food chain. FSIS recommends that there are basic production practices that are HACCP compatible - meaning that when practiced they reduce the relative public health risks of incoming animals for their HACCP plan. These HACCP compatible animal production practices include:

- Animal or premises identification.
- Management and health records.
- Proper and documented use of antibiotics, biologics, and pesticides.
- Feed and water quality/safety.
- Good sanitation practices.
- Animal waste management.
- Biosecurity
- Quality assurance programs.
- Third party certification.

One of the best starting places for food safety in the pre-harvest (pre-slaughter) segment of the food chain, and the best option for progress in this area lies in the industry-developed, voluntary quality assurance programs that are driven by processors, food businesses, and consumers. Third party certification will be described in more detail later. It is the "wave of the future," as more and more purchasers of food products and live animals require specific reasonable guarantees that certain practices have or have not been in place.

Here are some questions to consider for reducing, controlling or eliminating hazards reasonably likely to occur in the animal production process that are likely to result in better protecting animal and public health and be HACCP-compatible.

- What are the possible problems?
- Where's the best place to prevent the problems?
- At what point in the process do we recognize the problem?
- How do we detect the problem?
- What to do if we go over the critical limit?
- How can we keep track of the results of testing programs?
- What kind of reports and records are needed of our processes?

You may recognize these as representing producer language for the seven HACCP principles. For example, McDonalds Corporation requires a phase-out of growth promoting antibiotic use on farms and uses a third party certification to verify that the growers are complying. They also have their own third party audit of humane slaughter and handling practices at slaughter establishments, and have their own buyers evaluate records and information about production practices of animals purchased for slaughter.

More and more retailers and wholesalers are setting up purchasing criteria based on the practices and records of livestock and poultry producers, feedlots and marketers.

The livestock production industry has long-established Quality Assurance Programs (QAP). For example, the Milk and Dairy Beef Quality Assurance Program requires that a practicing veterinarian have a valid working relationship with the producer for dispensing veterinary drugs. There are strict guidelines for storing and administering veterinary drugs and antibiotics and for conducting milk drug screening tests. State milk inspectors conduct on-farm certification of drug use. Working with the Food and Drug Administration, the State will enforce violative levels of drugs in milk- resulting in dumping of entire tanks if violations are found. The details of the program can be found at Milk and Dairy Beef Quality Assurance Center, 801 Shakesphere, Box 497, Statford,

IA 50249; Phone (515) 838-2793; FAX (515) 838-2788; website: www.dqacenter.org; email: dqa@netins.net.

Another well known QAP is the Pork QAP. The first two levels of the Pork QAP involve education and self-test for the producer. For Level 3, required by many packing establishments before they purchase swine, a veterinarian must go over each good production practice to verify that the producer is performing it. Every two years the veterinarian recertifies the producer at Level 3. The PQAP also includes environmental and humane handling recommendations as the program evolves.

The Beef Quality Assurance Program has yielded major improvements in beef quality and value by raising the awareness of the need for proper injection of vaccines and medications and for proper handling of cattle to reduce the level of injuries and bruises. It has a number of elements that encourage food safety at the live animal level.

One successful pre-harvest program in this country has significantly reduced on-farm human pathogens and was linked to a decrease in human foodborne infections. The USDA began the pre-harvest program to control *Salmonella* serotype Enteritidis (SE) in the early 1990s. The flock-based intervention program became the Pennsylvania Egg Quality Assurance Program. The Center for Disease Control stated that, "the decrease in SE infections in the Northeast may reflect the collaborative prevention efforts in that region." As part of its farm-to-table strategy, in FY 1996 FSIS worked with constituent groups to encourage and coordinate voluntary efforts to address public health issues associated with food animal production. It is the first egg quality assurance program to demonstrate effectiveness in reducing SE infections in poultry houses. The percentage of flocks testing positive for the presence of SE decreased from about 40 percent to less than 15 percent. The program continues as a successful example of industry, academia, and government cooperation in a voluntary, on-farm intervention program to reduce foodborne pathogens. Currently egg safety programs are overseen by the Food and Drug Administration, which has regulatory authority for shell eggs in interstate commerce. Prevention programs use on-farm microbiologic testing and control procedures developed to reduce SE contamination of eggs. Further control of SE will require limiting the spread of SE on farms.

Let's take a closer look at this successful program that is a model for others in encouraging good animal production practices that benefit the producer and result in increased food safety. The Pennsylvania Egg Quality Assurance Program (PEQAP) is a voluntary industry program intended to minimize SE contamination of chicken eggs. Although the program does not guarantee shell eggs to be free of SE contamination, the program does assure consumers of the commitment producers and processors are making to prevent SE contamination. The Pennsylvania Department of Health provides technical advice regarding public health implications. PEQAP participants are assuring the public that they are taking every reasonable precaution to assure the safety of their eggs.

The details of the program can be found at the web site
http://poultryextension.psu.edu/PEQAP.html#PEQAP

Following is a summary of the program.

Wholesale Pennsylvania Egg Quality Assurance Program Program Requirements

Pullets

- Purchase chicks from U.S. Sanitation Monitored SE *negative* breeder flocks.
- Obtain samples of chick dropping papers at time of delivery. Sample every 10th chick paper and submit to laboratory for SE.
- Sample and culture the manure at 10 to 15 weeks of age. A culture will consist of two samples taken from the manure beneath each row of cages.
- Maintain a defined rodent control and monitoring program.
- Houses with positive manure or chick samples must be cleaned and disinfected before new chicks can be placed

Layers

- Purchase and place pullets from an SE monitored flock.
- Houses with positive manure samples must be thoroughly cleaned and disinfected between flocks.

Eggs

- Houses with negative manure samples will not be required to test eggs.
- Houses with positive manure samples must test 480 nest run eggs or a combination of all available blood spot eggs plus additional nest run eggs to total 480 eggs every 2 weeks for 4 lots of samples. If any egg pools are positive, then all eggs must be diverted for pasteurization or hard cooking. Egg testing will eliminate the need for further environmental testing.

Force Molted Flocks

- Test manure at five to seven weeks following return to feed and follow egg testing procedures if positive.

Rodent Control

- A defined rodent control and record monitoring program must be maintained at all times.

Biosecurity

- All participants must maintain an acceptable biosecurity program.

Refrigeration

- Eggs must be kept under refrigeration as specified in the Pennsylvania law.

Processing Plant·

Processing plants packing eggs bearing the PEQAP "Tested Quality" seal must meet all applicable USDA, Pennsylvania Department of Agriculture, and PEQAP program requirements. These address plant and employee sanitation, refrigeration, egg washing and sanitation, water testing, packing materials, carton coding and records.

Participating producers and processors are:·

- Demonstrating their concern about food safety.

- Producing a quality egg which helps to assure consumer confidence in eggs.
- Addressing the demands of buyers for eggs produced in a food safety program.
- Reducing potential foodborne illness liability claims.
- May have insurance premiums reduced.

The importance of quality assurance certification is that it:

- Promotes animal health and food safety.
- Ensures proper drug and antibiotic use.
- Provides records to assure purchasers of good production practices.

In summary, the basic requirements of a verifiable animal production certification program that could improve animal and public health include:

- Knowledge of risk factors for transmission of pathogens among food animals.
- Management interventions which reduce or eliminate risk for hazard exposure.
- An objective audit and other records sufficient to document risk-reduction management practices.
- Tools for monitoring absence of infection or residues in a certified population.
- Administrative, record-keeping and reporting systems to support certification.

To successfully implement a verified food safety system, producers on farm, in livestock markets and at feedlots will need to:

- Know food-safe production practices.
- Carry out those practices.
- Document practices.

The rule of thumb is, “If it is not documented, then it did not happen.”

As more and more of these systems are established, processing establishments will need to evaluate the records. Suppliers and FSIS veterinarians will play a role in making sure they are based on science if they are included in the establishment’s HACCP plans.

<u>The Trichinae Certification model</u>

Let’s review a “food safe” verified certification program that currently exists. It is a pathogen reduction model established by the USDA, the National Pork Board, practicing veterinarians, and producers. This is truly a collaborative effort. It is the Trichinae Certification model and it’s based on the use of management practices which minimize the risk of exposure of pigs to *Trichinella*. It relies on written records and third party auditing to document that good production practices are being followed. It is supported by regular testing of animals from certified premises to verify the absence of infection. Although trichinosis in market pigs is at a very low level (0.01%), it is still a significant concern of both domestic and foreign consumers (customers). Millions of dollars a year are spent on testing and holding meat for *Trichinella spiralis* cysts. USDA’s Agriculture Research Service developed an on-farm ELISA blood test that is used in the U.S program. USDA, APHIS developed a certification program with the pork producers, and USDA FSIS veterinarians collaborated with sampling in establishments to verify the new certification model.

The components of the certification process are:

- USDA accredited veterinarians, trained in trichinae Good Production Practices (GPP), work with producers to assure that trichinae infection risks are minimized on their farms.
- Periodic audits, performed by trained herd veterinarians, document the absence of trichinae infection risks.
- USDA-APHIS makes the certification decision and notifies the producer.
- Routinely, statistical samples are tested (ELISA) at slaughter and to verify absence of infection and verify program integrity
- USDA-APHIS-VS: Veterinarians conduct random spot-audits of certifications to ensure completeness and to build credibility among trade partners regarding the certification process.
- Verification of Certification: It is the responsibility of the slaughter facility receiving swine originating from certified production sites to verify that certification is current. This is done by:
    - verifying the producer's certification status by accessing the APHIS trichinae certification web site, or
    - maintaining certification documentation on file

Your role

FSIS veterinarians need to use all of their knowledge, skills and abilities when addressing public health issues at production/ pre-harvest areas. Here are some things to consider.

Credibility: YOU represent FSIS and your expertise is valued by others.

Voluntary: There is no regulatory authority in out-of-establishment initiatives. Our key role is to encourage others to adopt practices that will reduce chemical (antibiotic and drug residues, pesticides, etc.), physical (broken needles, buckshot), and microbial pathogens in animals presented for slaughter and to encourage HACCP-compatible production practices

FSIS State Partnerships

In order to promote food safety at the animal production level, FSIS has funded state partnerships. The intent of such cooperative agreements has been to promote collaboration among all food safety stakeholders. There have been as many as 10-20 partnerships funded each year, each one receiving from $10,000 to $50,000 to support activities that bring people together. Should one ever be funded in your State, you can provide expertise to these groups regarding food safety hazards at slaughter and processing. Be sure to coordinate all such activities with your supervisor and the FSIS Strategic Initiatives, Partnerships, and Outreach (SIPO) staff. Information on previously funded cooperative agreements can be found on the FSIS website at About FSIS / Cooperative Agreements.

FSIS funding of state partnerships began in 1998. Funded projects have focused on preventive measures and include producer education, biosecurity, quality assurance programs, *Salmonella* serotype Enteritidis, residue prevention and identifying practices associated with *Salmonella* and *E. coli* O157:H7 at dairies.

Some examples of the results from partnership activities include the following:

- Promoting quality assurance programs and Good production practices that may help reduce pathogens.
- Creating producer handbooks on residues, quality assurance programs, biosecurity, and animal production food safety.
- Conducting educational meetings and seminars on food safety for producers.

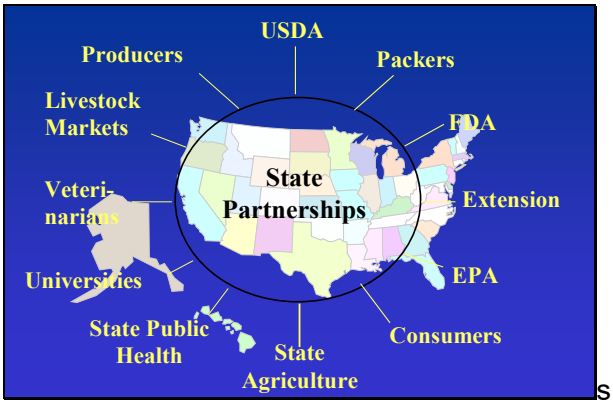
Quality assurance programs and state partnerships help build infrastructure for communicating with producers about animal production food safety. They also increase awareness of the need for production practices which reduce food safety risks.

Your roles in working with the animal production stakeholders include:

- Collaboration: look for opportunities to advance state-of-art food safety practices from farm to table.
- Education: help others change behaviors that may negatively impact public health.
- Information: keep everyone informed about preventive practices to reduce, eliminate and control hazards before, during and after processing.

Use your skills to build relationships among all food safety, public health, and animal health partners. Recruit others in food animal production to seek a career in FSIS. It is important to build bridges whenever possible among animal and human health experts regarding food safety. We all need to look for the best and brightest veterinarians to join our agency and to encourage students to pursue a rewarding career in public health practice in FSIS.

Educators are critical contacts because they can effectively spread your message to their audiences. Providing new information about FSIS is always welcome. Your role is to serve as the FSIS spokesperson to raise awareness that food safety is a shared responsibility among all parties from farm to table. In order to do this you must stay current on the latest interventions and preventive practices that offer the most promise for reducing chemical, physical, and microbiological hazards. Be sure to clear these activities with your supervisor and to use materials that have been cleared by the Agency for this purpose.



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This graphic illustrates the partnerships among the important stakeholders in public health. FSIS encourages local partnerships to bring these key partners “to the table” to

play collaborative roles in protecting public health and food security. Make a list of animal and public health educators and communicators in your area such as:

- local colleges and universities, veterinary, veterinary technician, and medical schools;
- Minority institutions (Native American, historically Black, etc.);
- extension service agents;
- Future Farmers of America, 4-H Clubs; and
- Consumer organizations

As a FSIS Public Health Veterinarian, you are the local Agency spoke person for farm-to-table food safety. Collaboration activities include:

- stay informed of current animal and public health issues;
- make presentations (always clear presentations with supervisor): use Agency materials available on the web and AEPFSS;
- articulate concurrent benefits of GPP to animal, health, food safety, and productivity;

Good Production Practices or Quality Assurance Programs are specific guidelines developed by industry to address food safety as well as animal health, welfare, and productivity.

Scientific Information on Best Practices for Animal Production

The public health model for improving human health dramatically in the past century includes a multiple hurdle approach: water treatment, attention to food safety and proper sewage disposal. Human enteric illnesses continue to be a major problem in developing countries due to poor water sanitation, food protection practices and sewage disposal. FSIS works with the animal and egg production researchers and partners to develop the scientific evidence that good public health practices can be successfully applied from farm to slaughter.

There is a complex interaction including animals, birds, the environment, retail, restaurant and consumer practices, fruits and vegetables and human outbreaks of foodborne disease Current research considers multiple interventions to reduce foodborne hazards at many different steps. Since *E. coli* O157:H7 is the agency's priority foodborne pathogen and it's reservoir is in animals, we will focus on research on that organism but research on others will be mentioned.

The current research on sodium chlorate shows that trials indicate a reduction in *Salmonella* spp. and *E. coli* O157:H7. It targets enteric pathogens. This compound is added to feed prior to slaughter and it works in multiple species. FDA has indicated that it will evaluate sodium chlorate as a feed additive. Tissue residue studies are required by the FDA's Center for Veterinary Medicine. The USDA Agriculture Research Service is feeding radio-labeled sodium chlorate to cattle in Fargo, ND, to provide the required information.

Some researchers have stated that if they fed only hay or other forages prior to slaughter they could reduce *E. coli* O157:H7. However there are conflicting results in the literature. Some findings showed that altered rations or schedules resulted in increased shedding of pathogens. Others have shown that it decreases the shedding. There are economic and meat quality concerns. Further research is needed in this area.

Recently a promising *E. coli* O157:H7 vaccine has had good results when combined with concurrent interventions at feedlots, such as antimicrobials and *Lactobacillus* cultures added to feeds. In March, 2009, a one-year conditional license for an *E. coli* O157:H7 vaccine was granted by the USDA. The vaccine will be used in feedlot cattle to decrease pathogen shedding. It works by preventing uptake of iron, thus decreasing bacterial enumeration in the intestines. Other vaccines are being evaluated that may prevent attachment and colonization. Some are designed to target intimin which is necessary for pathogen attachment in the intestine. Other bacterial species are under investigation.

Research is also being conducted using bacteriophages to reduce bacterial pathogens. These are viruses which attack bacteria. There has been some success in killing *Salmonella* spp. on poultry carcasses with bacteriophages. There may be pathogen reduction potential when the bacteriophages are used internally. Collaborative work with Russian scientists is under way. However, no product is currently approved.

Research with antibiotic treatment has shown that some antibiotics (tilmicosin) increase shedding while others decrease shedding (ceftiofur, bicozamycin, and neomycin). Repeat successful trials are needed. These treatments are currently not approved for pathogen reduction.

Tasco® is an extract from the seaweed *Ascophyllum nodosum* and is a source of cytokinins with increased antioxidant activity believed to reduce *E. coli* O157:H7 Currently it can be fed in commercial feedlots. Trials on reduced pathogen shedding are pending and have not been published in refereed journals.

CONCLUSIONS

Carriage of food borne pathogenic bacteria is a complex and sensitive issue. There is no “magic bullet.” Integrated multiple hurdle schemes using several complementary intervention strategies is most likely to be successful. Further pre-harvest intervention strategies need to be researched and developed. With continued progress, animal producers will lead the way to significant positive changes in animal and public health.

WORKSHOP

1. The pork, beef and dairy Quality Assurance Programs primarily address production practices that:

    a. Help prevent violative residues in high risk livestock (cull sows, boars, cows, bulls, calves and roaster pigs)
    b. Help prevent *E. coli* O157:H7 from contaminating livestock
    c. Uses veterinary practitioners to certify and guarantee livestock are safe for food
    d. Are required by all slaughter establishments before a producer can sell to them

2. Verifiable producer certification programs:

    a. Guarantee that the animals and eggs are safe
    b. Are the wave of the future as purchasers require objective audits and other records sufficient to document risk-reduction management practices
    c. Require a third party audit of records and/or practices
    d. Promote public health by ensuring chain of custody

3. Multiple hurdle hazard reduction interventions are a key public health tool:

    a. Because Typhoid Mary had to wash her hands to prevent spread of typhoid to others
    b. Because human outbreaks from food are caused by direct contact
    c. Because water treatment, food handling practices and proper disposal of feces reduced human illness and current animal production research is also looking into how similar approaches can apply to reducing *E. coli* O157:H7
    d. Because a magic bullet will probably be found that will be able to reduce fecal contamination, improve water sanitation and reduce pathogens on meat products

Small Business Regulatory Enforcement Fairness Act (SBREFA)

Objectives

Upon completion of this module the trainee will be able to:

1. Describe what SBREFA is and the purpose it serves.

2. Identify the two areas of emphasis under SBREFA.

3. Describe the goal of small and very small establishment outreach.

4. List the challenges and common issues faced by small and very small establishments.

5. Locate available outreach materials.

6. Describe the role of the EIAO in outreach and in providing compliance guidance.

7. Describe the Agency's role in enforcement fairness.

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.

SBREFA (Public Law 104-121) contains a variety of provisions, some affecting Federal Agency regulations. For example, SBREFA provides for Congressional review of Federal regulations, including those promulgated by FSIS, before the regulations can take effect.

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. FSIS Notice 18-01 describes the regulatory requirements that FSIS must meet under SBREFA, and what FSIS is doing to meet the goals of SBREFA.

SBREFA also provides a number of protections for small businesses against what they may regard as unfair actions by Federal regulatory agencies. Thus, SBREFA gives small businesses expanded authority to go to court and seek awards for attorneys' fees and costs when an Agency has been found excessive in its enforcement of regulations. Also, each Federal Agency is required to establish a policy to provide for the reduction, and in some circumstances, the waiver of civil penalties for violations of a regulation. There are two major areas you should be aware of: advocacy, and enforcement fairness.

Definitions

SBA: Small Business Association

Small Establishment: 10-499 employees.

Very Small Establishment: Less than 10 employees or less than $2.5 million in annual sales.

National Ombudsman and Fairness Boards are a forum for small businesses to report compliance or enforcement experiences with Federal regulatory agencies.

Ombudsman: A person who has a proxy to represent someone. In government, an Ombudsman represents persons who complain about alleged wrongdoings of the public administration. In the Small Business Administration, the National Ombudsman represents small businesses in their dealings with Federal regulatory agencies.

What qualifies an establishment to be a small business? The definitions FSIS used for the phased in implementation of HACCP were modeled after SBA's definitions. These are listed above. FSIS allows establishments to "self identify," meaning that we require no proof that they fall into one category or another.

Key Areas of Emphasis

We will talk about SBREFA and your role as an EIAO in terms of two key areas. These areas of emphasis are advocacy and enforcement fairness.

Advocacy (Compliance Assistance or Outreach)

Agencies must assist small businesses in understanding and complying with the regulations. The goal of small and very small establishment outreach is to provide technical guidance and assistance to small and very small meat and poultry establishments in the United States. Approximately 300 of the establishments we regulate meet the definition of a "large" establishment. The remainder, approximately 5700 establishments, are small and very small establishments. These establishments usually need technical guidance and assistance with the HACCP and food safety regulatory requirements.

The Challenge

Small and very small establishments may:

- Lack resources.
- Lack knowledge.
- Have language barriers.
- Not belong to associations that provide resources.
- Hold the belief that old methods result in safe products.

This is why we devote so much time and attention to compliance assistance efforts, including the outreach conducted by EIAO trained employees.

Common Issues

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.

Small/Very Small Establishment Outreach

On May 31, 2006, FSIS announced the Small/Very Small Establishment (SVSP) Outreach Program to assist the owners and operators of these establishments in understanding and complying with regulatory requirements. EIAO's have been designated as the key position within OFO for conducting outreach to small and very small establishment owners. The majority of the issues small businesses face when meeting FSIS regulatory requirements deal with the food safety system design and this makes the EIAO a natural choice to reach out to these businesses.

In 2006 10 outreach sessions were held around the country. Five sessions have been held in 2007, with 6 more scheduled for this year.

EIAO's Role in Outreach

The EIAO plays a vital role in helping FSIS meet its obligations to small businesses under SBREFA. With the implementation of the new outreach effort, EIAO's have been conducting outreach visits in which they meet with establishment owners specifically for the purpose of providing outreach assistance. For example, an EIAO may be doing an assessment at one establishment and, while in the area, visit some small establishments for the purpose of providing outreach assistance to them. This provides an excellent opportunity to meet with establishment owners and open the door for communication without being in the "regulatory" assessment mode.

EIAO's reach out to help small/very small establishment owners better understand regulatory requirements, explaining what is expected should a establishment undergo a scheduled food safety assessment (FSA), and identifying materials and resources that are available.

PHV's Role in Outreach/Advocacy

It is important to note that questions may arise during these outreach visits that the EIAO will not be able to answer on the spot. If that is the case, the EIAO will take notes, tell the establishment owner that they will get them the answer, and follow up with the frontline supervisor (FLS) that oversees the establishment. This is a good opportunity for the FLS to work with the PHV/IIC to get the answer to the establishment owner. Again, this is improving communication between not only the industry and FSIS, but within FSIS itself.

As a PHV 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, the EIAO and the PHV must walk a fine line in terms of the assistance you can provide a establishment owner. 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; 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.

Resources

FSIS' Outreach and Partnership Staff and State Outreach and Technical Assistance Staff were established because FSIS recognized the unique needs of the small and very small establishments with HACCP implementation. They prepare compliance materials like those listed in the "Food Safety Resources" brochure. These divisions of the Office of Outreach, Employee Education and Training (OOEET) merged into a single division, called the Outreach and Partnership Division (OPD) and service FSIS employees, especially EIAOs in their outreach efforts, small establishment owners and operators, State and local governments, and American Indian/Alaska natives.

To help address some of the challenges and issues, there is an extensive library of free outreach materials. Some have been translated into Spanish, Chinese, Korean, and Vietnamese and include materials such as:

- Guidebook for Preparation of HACCP Plans
- 13 Generic HACCP Models
- Booklets, videos, CDs on virtually every aspect of HACCP and Food Safety
- Developing a Recall Plan

To get materials you can call (202) 690-6520, or go to the FSIS Webpage at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-plant-outreach

OOEET also works with Contacts and Coordinators, associations, and other groups to promote outreach to small and very small establishments.

These offices /representatives work closely on SBREFA issues and on reporting requirements.

To be Announced, OFO
Rachel Edelstein, OPPD (202) 205-0495
Victoria Levine, OPPD (202) 720-5627
Scott Safian, OPEER (202) 418-8872
Keith Payne, OOEET (202) 690-6522

Enforcement Fairness

Through the provisions of SBREFA, the Small Business Administration (SBA) appoints a National Ombudsman and creates ten Regulatory Fairness Boards, made up of small businesspersons.

National Ombudsman and Regional Regulatory Fairness Boards

In the SBA, a National Ombudsman is appointed to represent small businesses in their dealings with Federal regulatory agencies. In addition, there are ten Regulatory Fairness Boards located throughout the US. 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; however, the public rarely attends. Attendance is generally made up of small businesses who want to air their concerns, and Federal agency representatives. The boards offer an additional avenue of appeal for small business entities. However, the board does not replace our FSIS appeal processes. EIAO's regularly 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/ONO 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.

Some things to keep in mind regarding the National Ombudsman and the Fairness Boards are that they 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.

More information on enforcement fairness, such as a Calendar of Events, Fairness Board members, and how to file comments can be obtained at the following website: http://www.sba.gov/ombudsman

Be aware that FSIS gets "graded" by the Small Business Administration in regard to these efforts. The SBA reports to Congress on how well agencies are doing to meet the goals of SBREFA. In FY 2011, FSIS received the following grades from the SBA:

- A – Timeliness
- A – Quality of follow-up responses
- A – Non retaliation policy
- A – Compliance Assistance
- C – Informs about SBREFA

- A – Overall grade

Comments from small business entities flow through the SBA Contact to FSIS. FSIS reports to the SBA on SBREFA activities through OBPA (Office of Budget and Program Analysis).

Agency Role

The Agency'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 (SBA/ONO).

Workshop

1. S_____ B_____ R_____ E_____ F_____ A_____

2. The two areas of emphasis under SBREFA are:

    a. _____
    b. _____ _____

3. Which area of emphasis does outreach fall under?

4. What is the goal of small and very small establishment outreach?

5. List four challenges and common issues faced by small and very small establishments.

6. Where can the PHV get outreach materials?

7. Describe the role of the Agency in enforcement fairness.

Professionalism and Government Ethics Essentials

OBJECTIVES

To demonstrate mastery of Professionalism and Government Ethics Essentials the trainee will:

1. Define “professionalism”- what does it look like.
2. Define how professionalism relates to, and impacts, food safety and biosecurity.
3. Identify appropriate and inappropriate behavior and explain how they affect employees, industry officials, consumers and others.
4. Define the Agency’s expectations and the role each employee has in supporting the Agency in achieving its public health mission.
5. Identify the Principles of Ethical Conduct in public service and your annual responsibility to complete the ethics training.

REFERENCES

1. FSIS Directive 4735.3, Employee Responsibilities and Conduct
2. FSIS Directive 4735.9, Ethics and Conflicts of Interest
3. USDA Workplace Ethics website

INTRODUCTION

We’ll be talking about professionalism at all levels of our workforce, which is critical to support FSIS in achieving our vision of becoming the premier public health agency and improving our working environments.

To achieve our public health mission:

- Professionalism and a culture change must take place within FSIS.
- Food safety, bio-security, morale and workplace safety must be enhanced.
- We must become a world-class public health agency.
- Have management and accountability systems in place.

In FSRE you will learn “What are the Best Tools for Making the Right Decisions?” (acts, due process, professionalism) – Like all professionals, we have a set of tools that we use in our work – the acts, due process, and professionalism.

Conduct and behavior affects 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 bio-security, because it detracts from:

- Inspection responsibilities
- Authority to enforce food safety standards
- Effectiveness.

Professionalism Characteristics

Describe that person:

What do you notice about him or her?

How do they act?

Five Characteristics of Professionalism

List the 5 Characteristics that distinguish Professionals:

1. _____

2. _____

3. _____

4. _____

5. _____

Definition of Professionalism
We said in the beginning that we need to be able to define Professionalism.
If we look at the dictionary definition of professionalism, we will see it says:
"skillful virtue". Virtue is another one of those words that we have an intuitive feeling for, but we find it difficult to describe in words. When we look up the dictionary definition of Virtue, we will see it says: "moral excellence". We now have our definition of Professionalism, the art of moral excellence! Since it is a skill/art, it is something that we learn and can improve upon

CASE STUDIES EXERCISE

Please read your group's case study and answer the questions that pertain to your case study.

1. Romantic Relationships

An FSIS employee has been dating a plant employee and this has evolved into a romantic relationship. They become deeply involved.

Is this professional behavior? Why or why not?

How does this behavior compare to the definition of Professionalism?

What is the potential impact for food safety/bio-security?

What impact does it have on the Agency's credibility?

What might be the outcome of this situation?

How could this behavior be prevented or avoided (by supervisor or employees)?

How would you demonstrate your professionalism in this situation?

2. Attitude, Initiative, and Communications

The FSIS line inspector is on the poultry line and the plant foreperson walks up to the line inspector. The plant foreperson starts asking questions in a harsh manner. The FSIS inspector slams the red button and stops the line, steps off the line, and an argument results. At this point, the FSIS floor inspector comes upon the situation, approaches the two and asks, "What is the problem?" After hearing their explanation, the FSIS floor inspector says, "I will take care of the problem" and asks the line inspector to, "Please go back to the line." The FSIS floor inspector tells the plant foreperson to take the problem up with the IIC and requests that the foreperson leave the immediate area. The FSIS floor inspector promptly reports the incident to the IIC.

Which one of the FSIS inspectors exhibited professionalism? Why?

How does this behavior compare to the definition of Professionalism?

What is potential impact for food safety/bio-security?

What impact does it have on the Agency's credibility?

What might be the outcome if the floor inspector had not taken action?

How could this behavior be prevented or avoided?

How would you demonstrate your professionalism in this situation [line inspector]?

3. Relationships, Touching or Hitting

There are two FSIS employees with an attraction to the same plant employee. Each is involved in a dating relationship with the plant employee. While on the line they are distracted from their duties and carcasses are not being inspected. Instead, they take every opportunity to get a glimpse of the plant employee or to show-off. The competition for attention leads to an exchange of negative comments between them. Their animosity builds until they are in each other's face. One places a finger on the other and the other knocks it off. They exchange blows.

Is this professional behavior? Why or why not?

How does this behavior compare to the definition of Professionalism?

What is potential impact for food safety/bio-security?

What impact does it have on the Agency's credibility?

What might be the outcome of this incident?

How could this behavior be prevented or avoided (by supervisor or employees)?

How would you demonstrate your professionalism in this situation?

4. Horseplay

The FSIS employee is hit by a spleen / lymph node / piece of fat thrown by someone. The FSIS employee saw that it was another FSIS employee that threw the object.

Is this professional behavior? Why or why not?

How would a professional respond?

How does this behavior compare to the definition of Professionalism?

What is potential impact for employee safety / food safety / bio-security?

What impact does it have on the Agency's credibility?

What might be the outcome of this incident?

How should this be handled if a plant employee threw the object?

How could this behavior be prevented or avoided (by supervisor or employees)?

How would you demonstrate your professionalism in this situation?

5. Dress/Appearance/Sanitation

The FSIS employee comes to work wearing apparel that has dirt and grease spots on them, and pet hair clinging to their clothing.

Is this professional behavior? Why or why not?

How does this behavior compare to the definition of Professionalism?

What is the potential impact for food safety/bio-security?

What impact does it have on the Agency's credibility?

What might be the outcome of this incident?

How could this situation be prevented or avoided (by supervisor or employees)?

How would you demonstrate your professionalism in this situation?

Exercise on Personal Action Plan:

Please take about 5 minutes to complete your Personal Action Plan. In a brief sentence or phrase, list three things you plan to do differently, or that you will do more conscientiously, that will signify your commitment to professionalism, personal excellence, and being part of the team along with Mr. Almanza, Dr. Ken Peterson, and FSIS. This is your personal goal setting.

Three things that I plan to do differently, or more conscientiously, are:

1.
2.
3.

Three things that I have learned from this training that will help me focus on professionalism, personal excellence, and teamwork are:

1.
2.
3.

Key Points from "Professionalism and You: The FSIS Employee"

- The Agency values each and every one of you.
- You represent FSIS and that means being a person of integrity, honesty, respecting others, pride in your work, and a commitment to excellence.
- Ensuring that the food that reaches the consumer is the safest possible, and that if something does go wrong we will act quickly, investigating and taking action to prevent further distribution of adulterated products, because, after all, our public health mission is to ensure food safety and prevent foodborne illness.

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.

WORKSHOP

1. An employee may sell products to co-workers during breaks when it does not disturb others.

   a. TRUE
   b. FALSE

2. When can an employee use an establishment's copying machine to make copies of official documents?

   a. When the plant requests a copy of the document
   b. When there is no other resource available
   c. When it is only one copy so the cost is minimal
   d. When the employee pays for the copy

3. You may collect contributions to fund political activities.

   a. TRUE
   b. FALSE

4. You do not need approval for outside employment or activity when it has nothing to do with your government job.

   a. TRUE
   b. FALSE

5. You just found out the plant will be working overtime tonight. Since you will not be able to get to your emergency small animal veterinary clinic job because of the overtime, you can use the government phone to call them and let them know.

   a. TRUE
   b. FALSE

6. You can sell personal items such as a car, washer, VCR, etc. to plant employees and coworkers as long as you first put up a notice on the plant's bulletin board.

   a. TRUE
   b. FALSE

7. When you have a work-related ethics question, you should:
   a. Ask the plant manager
   b. Flip a coin
   c. Ask your subordinates
   d. Ask the USDA Ethics Advisor

APPENDIX

FSIS Directive 4735.3, Employee Responsibilities and Conduct
FSIS Directive 4735.9, Ethics and Conflicts of Interest

The FSIS Directives on employee responsibilities, conduct, ethics, and conflicts of interest cover all of the incidents/situations that we have discussed today as well as many others you may encounter at some time in your employment. FSIS Directive 4735.3 contains Agency policy regarding conduct standards of Agency employees. Part One, Basic Provisions, Section VI, Policy, states:

> *"It is FSIS policy that employees maintain high standards of honesty, integrity, impartiality, and conduct. It is essential that employees carry out their 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 on the part of Government employees through informed judgment is indispensable to the maintenance of these standards.."*

PRINCIPLES OF ETHICAL CONDUCT

1. Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws and ethical principles above private gain.

2. Employees shall not hold financial interests that conflict with the conscientious performance of duty.

3. Employees shall not engage in financial transactions using nonpublic Government information or allow the improper use of such information to further any private interest.

4. An employee shall not, except pursuant to such reasonable exceptions as are provided by regulation, solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interest may be substantially affected by the performance of the employee's duties.

5. Employees shall put forth honest effort in the performance of their duties.

6. Employees shall make no unauthorized commitments or promises of any kind purporting to bind the Government.

7. Employees shall not use public office for private gain.

8. Employees shall act impartially and not give preferential treatment to any private organization or individual.

9. Employees shall protect and conserve Federal property and shall not use it for other than authorized activities.

10. Employees shall not engage in outside employment or activities, including seeking or negotiating for employment that conflict with official Government duties and responsibilities.

11. Employees shall disclose waste, fraud, abuse and corruption to appropriate authorities.

12. Employees shall satisfy in good faith their obligations as citizens, including all just financial obligations, especially those such as Federal, State or local taxes that are imposed by law.

13. .

14. Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards promulgated pursuant to this order.

CONFLICT OF INTEREST

In accordance with 5 C.F.R. 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.

The Agency will continue to ensure that all employees are trained on conflict of interest matters for which employees are to be knowledgeable and accountable, in conjunction with providing a copy of the Standards of Ethical Conduct for Employees of the Executive Branch.

Conflict of Interest

In accordance with the Standards of Ethical Conduct for Employees of the Executive Branch, 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. The employee shall state any suggestions as to how the situation may be remedied. Employees who fail to make such situations known within fifteen (15) days may be subject to disciplinary action. In accordance with 5 C.F.R. 2635.102(b)(14), whether particular circumstances create an appearance that the law or applicable standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts. Employees shall disclose fraud, waste, abuse, and corruption to appropriate authorities.

Employment of Relatives

Employees shall not be assigned to any establishment where a member of his/her immediate family (father, mother, spouse, child, brother, sister) is employed. Employees shall not be assigned to any establishment where other family members (father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, mother-in-law, son-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half-brother, half-sister, aunt, uncle, niece, nephew, grandparents, grandchildren), who are residents of the employee's household are employed. Employees shall not be assigned to any establishment where other family members, who are not a resident of the employee's household but who are in supervisory, managerial, or policymaking capacity at the establishment.

Outside Employment

An employee shall not engage in outside employment or other outside activity that conflicts with his/her official duties. An activity conflicts with an employee's official duties: if it is prohibited by Statute or by an Agency supplemental regulation; or, if under the standards set forth in government-wide regulation, it would require the employee's disqualification from matters so central or critical to perform the duties of his/her position would be materially impaired. Employees must obtain prior approval for all outside employment or activities whether paid or unpaid. Requests must be made through supervisory channels to the approving official on FSIS Form 4735-3 "Request For

Approval Of Outside Employment or Activity" prior to the beginning of the employment or activity.

Reports of Misconduct

Employees who have reason to believe that misconduct has been committed shall report it promptly to their supervisors. If the circumstances of the case are such that the employee feels his/her report should not be routed through his/her supervisor, it shall be reported to the next higher or appropriate level of supervision. Employees are covered by the Whistleblower Act. Nothing herein shall affect the right of employees to petition Congress or other officials.

Ethics Official

Employees will be notified of the identity and phone number of the Agency's Designated Ethics Official. Employees who have questions about the application of ethics requirements or any particular situations should seek advice from the Agency Ethics Official. Disciplinary action for violating such requirements or any supplemental Agency regulations will not be taken against an employee who has engaged in conduct in good faith reliance upon the advice of an Agency Ethics Official, provided that the employee, in seeking such advice, has made full disclosure of all relevant circumstances.

Bribery or Attempted Bribery

Any employee who is offered a bribe has the responsibility for immediately reporting the facts of the case to the Office of Investigation (OI) by the most expeditious means available.

The employee shall not disclose the information reported or that it was reported without the prior approval of OI or the Federal Bureau of Investigation (FBI). The Agency shall maintain a listing of appropriate OI reporting points, which shall be readily available to employees in field locations.

If an employee has reasonable cause to believe that he/she is the personal subject of a bribery investigation, he/she has the right to contact a representative of his/her choice.

Farm/Ranch

Any outside employment or financial interest in land used for commercial production of any commodities inspected, graded, regulated, or otherwise controlled by FSIS must be reported through supervisory channels for appropriate conflict of interest review and approval.

Applicability of Employment Restrictions

Employment restrictions will apply when there is an appearance of a conflict of interest or a conflict of interest between one's off-duty activities and performance of inspection duties.

Purchase of Product

Employees may not purchase, without prior approval from an immediate supervisor, products, personally or through another individual, from a plant or establishment regulated, inspected, or otherwise controlled by FSIS if employee performs a function related to the commodity or commodities dealt with or processed by the plant or establishment.

Political Activity

Employees will not be subject to additional limitations on political activity beyond those provided by law.

Member of Family Conduct

Although FSIS employees will not be held responsible for the conduct of their adult family members, they will be held responsible to acknowledge and report all situations in which any adult family member's employment, duties, or financial interests may create or give the appearance of a conflict of interest in relation to the FSIS employees' employment and/or assignment.

FSIS "ETHICS AT A GLANCE"

The following highlights of the ethics regulations published by the Office of Government Ethics (OGE) are not meant to be a summary of the ethics regulations. They are for guidance for use by FSIS employees only. If you have any specific questions, feel free to ask your supervisor or an employee relations specialist. Remember: any time you are in doubt when confronted with an ethical problem--ASK!

Gifts from Outside Sources
(Subpart B - 5 CFR 2635.201-205)

The rule: As a Federal employee, you may not accept gifts from a prohibited source. You may never solicit a gift. While the OGE regulations allow for some exceptions for the acceptance of gifts, as FSIS employees operating under the Federal Meat Inspection Act, you may not take advantage of any of the exceptions, as you are prohibited from accepting anything of value, no matter for what purpose it is offered.

Prohibited Source: A prohibited source is any person, company or organization which does business with FSIS, or is seeking to do business with FSIS, or conducts activities regulated by FSIS, or has interests that may be substantially affected by the performance or nonperformance of your duties, or is an organization a majority of whose members fit any of the above categories.

Gifts Between Employees
(Subpart C - 5 CFR 2635.301-304)

The rule: You may not (1) give a gift to your supervisor or anyone higher up the chain, or (2) accept a gift from any lesser-paid employee.

Exceptions: It is okay to give or receive a gift if it is one of the following: (1) a gift from a lesser-paid employee who is not your subordinate; (2) a gift for a traditional occasion such as a birthday if it is worth less than $10; (3) food or refreshment shared among FSIS employees; (4) a small contribution for a gift for a special occasion like a wedding or an employee leaving the job; (5) a gift in connection with personal hospitality, like a bottle of wine on being invited to someone's home. Remember, these exceptions apply to gifts between FSIS employees, not between you and plant employees.

Conflicting Financial Interests
(Subpart D - 5 CFR 2635.401-403)

The rule: You may 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, or outside employer.

Impartiality in Performing Official Duties
(Subpart E - 5 CFR 2635.501-502)

The rule: If you are in a situation where your official duties could affect your own financial interests, or those of your business partner in an outside employment, or those of someone like your spouse or child, or one where a reasonable person might questions your impartiality, you may not work on that matter until your have informed your

supervisor and the Agency's ethics official about it. The Agency ethics official will let you know whether you may proceed or not.

Seeking Other Employment
(Subpart F - 5 CFR 2635.601-606)

The rule: 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.

Misuse of Position
(Subpart G - 5 CFR 2635.701-705)

The rule: 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. 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, typewriters, computers, computer software, office equipment, supplies, copiers, fax machines, government vehicles, etc.

Exceptions: There are a few exceptions to these rules, such as brief use of the government telephone to check on children with a babysitter, or the use of a copier machine on behalf of recognized employee organizations or professional associations.

Outside Activities
(Subpart H - 5 CFR 2635.801-809)

The rule: An FSIS employee may not engage in any outside employment or activity, whether you are compensated for it or not, if it conflicts with your official duties, or creates the appearance of a conflict of interest with your official duties.

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE
DEPARTMENT OF AGRICULTURE

PART 416-- SANITATION--Table of Contents

(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

[64 FR 56417, Oct. 20, 1999]

Points of Contact

Questions on ethics:

- Mary Royster, Branch Head, USDA Office of Ethics, (202) 720-0020
  http://www.da.usda.gov/ethics.htm
  http://www.usda-ethics.net/advisor/index.htm

Questions concerning Labor Relations, Employee Relations, or Workplace Violence Prevention:

- Labor and Employee Relations Division, (202) 720-5657

To report incidents of Workplace Violence, call: 1-877-987-3747
http://www.fsis.usda.gov/FSIS_Employees/Workplace_Violence_Prevention/index.asp

Post-mortem Inspection

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 procedures.
5. Identify the establishment responsibilities with regard to conducting post-mortem inspection.
6. Describe the process of conducting post-mortem inspection procedures.
7. Define how the establishment must dispose of condemned product.
8. Describe how to complete post-mortem reports.

INTRODUCTION

Post-mortem inspection covers the inspection of the carcasses and parts of meat and poultry used for human food. It takes place after ante-mortem inspection and after the animal or poultry has been slaughtered thus the term “post-mortem,” meaning “after death” in Latin. Post-mortem inspection covers the steps in the slaughter process that begin at stunning and ends at the step where the carcass is placed in the cooler.

The purpose of post-mortem inspection is to protect the public health by ensuring that the carcasses and parts that enter commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. This means that any carcasses or parts that are unwholesome or adulterated, and thereby unfit for human food, do not enter commerce. In performing inspection methods, making regulatory decisions, documenting findings, and taking enforcement actions when appropriate, in relation to post-mortem inspection we are guided by the following statutes, regulations, directives, and notices.

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.

<u>Statutes covering post mortem inspection</u>

The statutory authority for post-mortem inspection is as follows.

Livestock:

FMIA Section 604. *“Post-mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection. For the purposes hereinbefore set*

forth 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 cattle, sheep, swine, goats, horses, mules, and other equines to be prepared at any slaughtering, meat canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce 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 said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection, shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof."

Poultry:

PPIA Section 455(b). *"Post-mortem inspection: quarantine, segregation, and reinspection. The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors, post-mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation, and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this chapter."*

<u>Regulations covering post-mortem inspection</u>

The regulations that cover post-mortem inspection for livestock are as follows.

- 9 CFR 310.2 – States that the establishment must have a system that is used to identify livestock carcasses and parts to be used in the preparation of meat food products or in medical products (e.g., head, tail, tongue, thymus, viscera, blood, and other parts) as being derived from the particular animal involved until the post-mortem inspection of the carcass and parts is completed.

- 9 CFR 310.3 – States that any carcasses, organs, or parts in which any lesion or other condition is found that might render the meat or any part unfit for human food, or otherwise adulterated must be retained for veterinary disposition. The identity of the carcass, organs, and parts must be maintained until final disposition has been completed. Retained carcasses shall not be washed or trimmed unless authorized by FSIS.

- 9 CFR 310.4 – Identifies that U.S. Retained tags will be used to temporarily identify any carcasses, organs, or parts retained for veterinary disposition. These tags can only be removed by an FSIS employee.

- 9 CFR 310.5 – States that any carcass or part found upon final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated shall be conspicuously marked as U.S. Condemned. These carcasses or parts must remain in the custody of FSIS and disposed of according to the regulations before the close of the day upon which they are condemned.

- 9 CFR 310.6 – States that carcasses and parts that are passed for cooking only shall be marked U.S. Passed for Cooking, and must remain in the custody of FSIS until they are cooked according to 9 CFR 315.

- 9 CFR 310.8 – Describes passing and marking carcasses and parts. Those that are found to be sound, healthful, wholesome and otherwise not adulterated are marked U.S. Inspected and Passed. Those that show localized lesions are passed for food or for cooking, and the U.S. Retained tag is attached until the affected tissue is removed and condemned.

- 9 CFR 310.18(a) — States that *"carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however if contamination occurs it shall be promptly removed in a manner satisfactory to the inspector".*

- 9 CFR 310.21 – Covers residues in post-mortem inspection. We will address this in a separate section of the training.

- 9 CFR 310.25 – Covers contamination of livestock carcasses and parts with microorganisms; process control verification criteria and testing; and pathogen reduction standards. You will learn about this is more detail when you attend the Inspection Methods class.

- 9 CFR 311 – Covers diseased and otherwise adulterated carcasses and parts. You will learn more details about the specific diseases and disposition principles in the module called Multi-Species Dispositions.

- 9 CFR 314 – Covers how establishments must handle condemned and inedible carcasses and parts.

- 9 CFR 315 – Covers rendering or other disposal of carcasses and parts, and product that has been passed for cooking during post-mortem inspection.

The regulations that cover post-mortem inspection for poultry are as follows.

- 9 CFR 381.76 – Covers post-mortem inspection procedures for five systems: traditional systems, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System, the New Turkey Inspection (NTI) System, and the Ratite Inspection System. Section 381.76(a) states that *"a post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in an official establishment."* Section 381.76(b) outlines the inspection procedures for each of these four inspection systems. It includes responsibilities of the establishment helper and trimmers, and requirements of establishment facilities. It also defines the maximum inspection rate, which is the line speed that is

allowed for each inspection system. Inspection procedures and actions are outlined, as well as reinspection duties.

- 9 CFR 381.77 – Covers carcasses held for further examination. It indicates that each carcass or any parts in which there is a lesion of disease or other condition which might render it adulterated and with respect to which a final decision cannot be made upon first examination by the inspector shall be held for further examination. The identity of the carcass and all parts must be maintained until a final examination has been completed.

- 9 CFR 381.78 – Covers condemnation of carcasses and parts; and separation of poultry suspected of containing biological residues. Section 381.78(a) states that at any time during inspection a carcass or part is found to be adulterated, it shall be condemned, except any articles that may be made not adulterated by reprocessing if reprocessed under the supervision of an inspector and then found to be not adulterated. Section 381.78(b) states that *"when a lot of poultry suspected of containing biological residues is inspected in an official establishment, all carcasses and any parts of the carcasses in such lot which are condemned shall be kept separate from all other condemned carcasses or parts."*

- 9 CFR 381.79 – States that *"each carcass and all organs and other parts of carcasses which are found to be not adulterated shall be passed for human food."*

- 9 CFR 381.80 – Addresses biological residues. Section 381.80(a) states that the carcasses or parts found during post- mortem inspection or at any subsequent inspection to be affected with any diseases or conditions named in other sections of this subpart shall be disposed of in accordance to the section that pertains to the disease or condition. It states that because it is impractical to formulate rules for all diseases or conditions, the decision as to the disposal of all carcasses, organs, or other parts will be left to the inspector in charge, and if the inspector in charge is in doubt of the disposition to be made, he or she shall forward specimens from the carcasses to the laboratory for diagnosis. Section 381.80(b) states that all carcasses, organs, and parts shall be condemned if it is determined on the basis of a sound statistical sample that they are adulterated because of the presence of any biological residue.

- 9 CFR 381.81 – States that *"carcasses of poultry affected with tuberculosis shall be condemned."*

- 9 CFR 381.83 – States that *"carcasses of poultry showing evidence of any septicemic or toxemic disease, or showing evidence of an abnormal physiologic state, shall be condemned."*

- 9 CFR 381.84 – States that *"carcasses of poultry with evidence of extensive involvement of the air sacs with airsacculitis or those showing airsacculitis along with systemic changes shall be condemned. Less affected carcasses may be passed for human food after complete removal and condemnation of all affected tissues including the exudate."*

- 9 CFR 381.85 – States that *"carcasses of poultry showing evidence of any disease which is characterized by the presence, in the meat or other edible parts of the carcass, or organisms or toxins dangerous to the consumer, shall be condemned."*

- 9 CFR 381.86 – States that *"any organ or other 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."*

- 9 CFR 381.87 – States that *"any organ or other part of a carcass which is affected by a tumor shall be condemned when there is evidence of metastasis or that the general condition of the bird is found to have been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned."*

- 9 CFR 381.88 – States that *"organs or other parts of carcasses which are found to be infested with parasites, or which show lesions of such infestation shall be condemned and, if the whole carcass is affected, the whole carcass shall be condemned."*

- 9 CFR 381.89 – States that *"any part of a carcass which is badly bruised shall be condemned and, if the whole carcass is affected as a result of the bruise, the whole carcass shall be condemned. Parts which show only a slight reddening from a bruise may be passed for food."*

- 9 CFR 381.90 – States that *"carcasses of poultry showing evidence of having died from causes other than slaughter shall be condemned."*

- 9 CFR 381.91 – 381.91(a) states *"that carcasses of poultry contaminated by volatile oils, paints, poisons, gasses, scald vat water in the air sac system, or other substances which render the carcasses adulterated shall be condemned."* Section 381.91(b)(1) states that any carcass accidentally contaminated during slaughter with the contents of the digestive tract shall not be condemned if promptly reprocessed under the supervision of an inspector and subsequently found not to be adulterated. Contaminated surfaces that are cut shall be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming, or at an approved reprocessing station away from the main processing line may be cleaned by a method that will removed the contamination, such as vacuuming, washing, and trimming. All visible specks of contamination must be removed and if the inner surface is reprocessed by a method other than trimming alone, all surfaces of the carcasses shall be treated with chlorinated water. Section 381.91(b)(2) states the conditions under which FSIS will approve a reprocessing station.

- 9 CFR 381.92 – States that *"carcasses of poultry that have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned."*

- 381.93 – Section 381.93(a) states that putrefied or stinking carcasses shall be condemned. Section 381.93(b) states that any part of a carcass which is green struck shall be condemned, and if the whole carcass is affected it shall be condemned. Section 381.93(c) states that carcasses affected by post-mortem

changes that are superficial can be passed for human food after removal and condemnation of affected parts.

- 9 CFR 381.94 – Covers contamination with microorganisms; process control verification criteria and testing; and pathogen reduction standards. You will learn more about these requirements and the procedures that you perform to verify compliance when you attend the Inspection Methods class.

- 9 CFR 381.95 – Covers the disposal of condemned poultry products.

Directives and Notices related to post-mortem inspection

The Directives that cover the procedures for post mortem inspection are found in the 6000 series. Following are some examples of these directives.

- FSIS Directive 6100.1, Rev. 1 Post-mortem Livestock Inspection
- 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 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 Grant of Inspection
- FSIS Directive 6240.1, Inspection, Sampling, and Disposition of Animals for Tuberculosis
- FSIS Directive 6500.1, New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirement
- FSIS Directive 7320.1, Rev. 1, Prevention and Control of Trichinella in Pork Products
- FSIS Notice 17-16, Verification of Carcasses that an Establishment Further Processes Without an Official Inspection Legend
- FSIS Notice 67-14 Unsplit Sternum of Livestock Carcasses in Slaughter Establishments
- FSIS Notice 48-14 Pathology Sample Reports Delivered Only Electronically

The regulations and directives provide the instructions for performing inspection procedures, making regulatory determinations, documenting noncompliance when appropriate, and taking regulatory actions.

ESTABLISHMENT RESPONSIBILITIES

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

- sanitary practices in preparing the carcass for post-mortem inspection,
- presenting carcasses and parts for inspection in a specified manner (called presentation), and

- facility requirements at the inspection stations

In general, the establishment's procedures to prepare livestock or poultry for inspection must take place in sanitary conditions and must use sanitary procedures to prevent contamination of the carcasses and parts (9 CFR 310.18, 381.91, and 416). For example, during livestock slaughter, the establishment must use sanitary dressing procedures to remove and skin the head, dehide 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 removing 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 (307, 381.76). For example, they must be hung on the line in a specified manner and spaced appropriately. The organs of livestock must be displayed in a specified order so that the inspector does not have to spend time locating them before he or she performs 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. You will learn about these during the in-plant portion of your training.

The establishment is also responsible for providing appropriate inspection stations that meet regulatory requirements (307.2, 381.76). The requirements vary depending on the type of equipment used at the establishment. For example, in large livestock slaughter establishments, there may be separate inspection stations for heads, viscera, and carcasses. In large poultry slaughter establishments, there may be separate inspection stations for carcasses and for carcasses that are salvaged and reprocessed. However, if you are assigned to a very small establishment, inspection for all of the regulatory requirements may take place in one location. Regardless of the number or placement of the inspection stations, the following conditions must be provided by the establishment.

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

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

During this section of the training, we will cover the post-mortem inspection procedures. Just as was true in ante-mortem inspection, there are three possible outcomes of the inspection.

1. passed, and thus eligible to receive the marks of inspection (310.8, 381.79);

2. U. S. Suspect, which must be retained for veterinary disposition (310.3, 381.77); and
3. U. S. Condemned, which is not eligible to receive the marks of inspection and cannot enter commerce (310.5, 381.78)

As the public health veterinarian, you may be responsible for making dispositions on carcasses and parts that are suspect. We will introduce the diseases and conditions in this module, but we will cover the specific details of veterinary disposition in another module, "Multi Species Disposition." It is during this step that the final determination is made 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.

Sanitation

You and all other inspection personnel must always maintain proper employee hygiene when conducting inspection procedures. In most cases, the establishment will have a set of requirements, such as standard operating procedures, that are required for establishment employees. 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. 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. The establishment is required to have and to follow a set of procedures to maintain sanitary operations. We will cover the regulatory requirements and how they are verified for employee hygiene and sanitary operating procedures later when we cover the Sanitation Performance Standards and the Sanitation Standard Operating Procedures (Sanitation SOPs) that are in 9 CFR 416.

Safety

You must maintain safety with regard to the use 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. There is also a separate module on in-plant safety practices.

General methods of post-mortem inspection

The general methods you will use to detect diseases, abnormalities, and contamination will involve your senses. These include:

- Sight – observing a disease lesion (abscess, tumor).
- Feel – palpating (feeling an abnormal lump in tissues, feeling abnormal firmness in an organ).
- Smell – smelling the urine odor of uremia, smelling the contents of a broken abscess).
- Hearing – listening to a carcass fall off the line on to the floor.

The purpose of post-mortem inspection is to make a decision about the wholesomeness of each poultry carcass inspected. One of the following outcomes will result from post-mortem inspection.

- If the carcass is wholesome and normal without any localized disease condition, it is passed and allowed to continue down the line.
- If the carcass is wholesome except for a localized disease condition, it is retained. It is typically routed to an area where it can be trimmed so that the unwholesome or diseased portions are removed. These removed materials are considered to be inedible and are condemned. The remainder of the carcass which is now wholesome or free of disease is allowed to continue after removal of the affected areas to become passed product.
- If the carcass exhibits abnormal signs or conditions that indicate it is unwholesome or diseased, the entire carcass is condemned.

The final consideration for carcass disposition is questionable carcasses that require further examination. Borderline or questionable carcasses are retained for veterinary disposition (livestock) or placed on the hang back or retain rack pending further review (poultry). When the inspector is undecided about the proper disposition of a carcass, the carcass is tagged and railed out or the establishment helper is notified to place the carcass on the hang back or retain rack. The public health veterinarian reviews all such carcasses and makes a final disposition of whether to pass, trim, or condemn the carcass.

<u>The importance of lymph nodes in livestock post-mortem inspection</u>

In order 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 notes function as filters for disease microorganisms and abnormal or toxic chemicals in the tissue fluids of the body. An example you may have seen is “blood poisoning” in a hand or finger of a person. Red streaks that are not blood vessels become visible up the arm and a lump, with swelling and pain, develops in the armpit. The red streaks are inflamed lymph vessels. These are normally invisible to the eye. The lump is formed by the inflamed proper axillary lymph nodes. Under the skin you can see the redness and enlargement of the nodes. 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 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 or not 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 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.

Livestock post-mortem inspection

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

- head inspection,
- viscera inspection, and
- 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, equine – differ. However, there are similarities. We will walk through the general steps involved in swine post-mortem inspection as an example of post mortem inspection procedures. The post-mortem inspection procedures for other species are shown in the Appendix of this module. You will learn more about making veterinary dispositions when we cover the module Multi Species Dispositions.

In order to perform inspection procedures appropriately, you must be familiar with the anatomy of a livestock carcass and its parts. For example, for swine post mortem, the example we will be using, you will need to learn how to locate and identify the mandibular lymph nodes in the head; the mesenteric, hepatic, and tracheobrochial lymph nodes in the viscera; the lungs, heart, and the liver; and the kidneys of a carcass. The Appendix provides schematics outlining livestock anatomy.

Example: Swine head inspection

The head inspection procedures for swine are as follows:

1. Observe head and cut surfaces – the eyes, fat, cheek muscles, and other tissues for abnormalities.
2. Incise and observe the right and left mandibular lymph nodes – examine the closest tissues first.
3. When abnormal conditions are observed, retain the head for veterinary disposition.

Your veterinary mentor will show you how to perform these procedures in detail.

Here are some common abnormal conditions observed during head inspection.

- 311.2 - Tuberculosis may be detected during head inspection in varying degrees. The inspector must condemn the head if any amount of tuberculosis is found in the head during head inspection. The head is usually stamped at the viscera inspection station and the nodes in the jowls removed and condemned as required. Ensure that the carcass is also identified with a retain tag.

- Abscesses are another common finding during the inspection of the head. When slight, small, well-encapsulated abscesses are found on head inspection, the carcass should be tagged. When well-marked or extensive abscesses are seen, the carcass should be tagged by the head inspector. Ultimately, the disposition of the extensive or well-marked abscessed head will be condemnation (probably at the viscera inspection station) and the affected areas in the jowl will be removed and condemned.

- At the head inspection station you may see atrophic rhinitis. Swine with atrophic rhinitis may have a characteristic nose disfiguration, absence of nasal turbinate bones, and small amounts of pus or exudate in the nasal sinuses. The turbinate soft tissues may be present, but they are folded against the nasal cavity wall since the supporting bony structure has disappeared. Since this condition is usually localized, head tissues can be removed without contamination and saved for food.

In addition to observing abnormal conditions in heads, post-mortem inspectors also identify improper presentation by the establishment. Here are some examples of improper presentation of swine for inspection:

- Head missing — the head can't be inspected if it is missing. Remember, you must be able to determine at all times which parts belong to a carcass (310.23).

Therefore, the establishment must have a method of identifying the carcass and all its parts (e.g., tag).

- Mandibular lymph nodes left in the neck instead of on the head.
- Hog rings — these should have been removed as part of the cleaning operation prior to head inspection.
- Ear tags and rosin contamination.

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

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 has to 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.

Note: Examples for head inspection of different species (e.g., cattle) are shown in the Appendix.

Example: Swine viscera inspection

Viscera include the contents (organs) of the animal's abdominal cavity. You must be able to determine at all times which parts belong to a carcass. Therefore, the establishment must have a method of identifying the carcass and all its parts (e.g., tag).

Viscera inspection includes the following steps:

1. Observe the eviscerated carcass, viscera, and parietal l (top) surface of spleen.
2. Observe and palpate mesenteric lymph nodes.
3. Palpate portal lymph nodes.
4. Observe dorsal (curved) surface of lungs.
5. Palpate bronchial lymph nodes – right and left.
6. Observe mediastinal lymph nodes.
7. Turn lungs over and observe ventral (flat) surfaces.
8. Observe heart.
9. Observe dorsal (curved) surface of liver.
10. Turn the liver over and observe ventral (flat) surface.

Your veterinary mentor will show you how to perform these procedures in detail.

When abnormal conditions are observed, retain the viscera for veterinary disposition.

Here are common abnormal conditions that are observed during viscera inspection.

- 311.7 - Arthritis--joints with localized arthritis and corresponding lymph nodes shall be removed and condemned during dressing operations and before inspection is completed.

- 311.16(a)(1) - Pleuritis--localized, chronic pleuritis with adhesions may be "peeled out" with the remainder of the carcass passed for food. If pleuritis is acute, extensive, or other associated pathology is present, the carcass and its parts should be retained for veterinary examination.

- 311.16(a)(1) - Pneumonia--lungs that have been contaminated with scald vat water resemble lungs with pneumonia

- 311.16(a)(7) - Nephritis--one or both kidneys may be affected. Localized conditions require the affected kidney(s) to be removed and condemned. If there is doubt as to whether the condition is localized to the kidney or if other pathology exists, the carcass should be retained.

- 311.16(a)(7) - Embryonal nephroma--these are tumors of the kidney. Generally, they are benign and occur more commonly in young animals. These should be retained for veterinary disposition.

- 311. 16(a)(7) - Hydronephrosis--one of both kidneys literally become a "bag of water". Normal kidney tissue is replaced by fluid. There is generally no effect upon the carcass. Affected kidneys are removed and condemned.

- 311.20 - Sexual odor--each boar hog that is slaughtered should be screened for the pungent sexual odor that is characteristic in some boar hogs. If sexual odor is detected by the viscera inspector, the carcass and viscera should be retained for veterinary disposition.

- 311.16(a) - Pericarditis--if acute, extensive, or other pathology is detected, retain for veterinary disposition. If pericarditis is localized and chronic (adhesions of the pericardial sac to the wall of the heart), the heart and pericardium is condemned, but the carcass may be passed for food.

- 311.24 - Cysticercosis (pork measles)--a parasitic condition caused by a tapeworm cyst (Taenia solium cysticercus). Similar to beef measles, it can affect any muscle tissue in the carcass. In pork, the heart seems to be the most common site. The carcass and parts must be retained for the veterinarian to examine.

- 311.19 - Icterus--the carcass has a lemon-yellow appearance. Icterus particularly affects connective tissues (tendons, ligaments, sclera of the eye, etc.). Carcasses affected with any degree of icterus are retained for veterinary disposition.

- 311.3 - Hog cholera--identified by such findings as hemorrhagic lymph nodes and red spots on belly and legs, and possibly a "turkey egg" kidney. If abnormal hemorrhages are observed, the carcass should be retained for veterinary disposition.

- 311.17 - Septicemia--a generalized inflammatory conditions caused by pathogenic bacteria and associated toxins in the blood. Most, or all, of the body lymph nodes may be enlarged, hemorrhagic, and edematous. Kidneys may have petechiae (small pinpoint hemorrhages). Other pathology may be present. Retain the carcass for veterinary disposition.

- 311.24 - Ascarids--the larva of these roundworms frequently migrate through the liver and cause scarring on the livers surface. "Slight" scarring may be trimmed (spotting the liver). More than slight evidence of ascarids requires the liver to be condemned.

- 311.14 - Abscesses--If the carcass has been tagged by the head inspector for a slight cervical abscess and the viscera inspector finds tuberculosis (TB) in the viscera, the carcass and viscera must be retained for veterinary disposition. If no lesions are found in the viscera, the viscera inspector will permit the head to be used for food after complete removal and condemnation of the mandibular and adjacent lymph nodes in the jowls. However, if the establishment does not choose to trim as described, the head and jowls will be condemned.

- 311.12 - Tuberculosis (TB)--the primary seats of TB are defined as the mandibular, the mesenteric, and the mediastinal lymph nodes in swine. These sites are regarded as the primary seats for disposition purposes only and do not necessarily have any correlation with the frequency at which tuberculosis is found in any location. Probably the most common sites at which tuberculosis lesions would be found would be the mandibular and mesenteric nodes and the liver. The food inspector is authorized to make a limited disposition for tuberculosis on a swine carcass with TB lesions in only one primary seat. For example, if tuberculosis is found in the mesenteric lymph nodes only, it is not necessary to tag the carcass and retain it. However, if there is TB in more than one primary seat or in any site other than a primary seat, then that carcass and viscera must be retained for veterinary disposition.

- 311.30 – Suffocation (Asphyxia) - a scarlet red appearance of the carcass and organs that are engorged with blood; must be retained for veterinary disposition.

As in head inspection, there are various forms of improper presentation that occur at the viscera inspection station. Contamination with feces or ingesta is one of the most common defects. Hair, toenails, pus, bile, and parts of viscera missing are other common examples of improper presentation. When improper presentation occurs, take the same actions as when it occurs at head inspection, which includes the following.

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 has to 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.

Note: Examples for viscera inspection of different species (e.g., cattle) are shown in the Appendix.

Example: Swine carcass inspection

There are four steps to carcass inspection.

1. Observe the back of the carcass. This may involve observing it in a mirror, or turning the carcass manually
2. Observe the front parts and the inside of the carcass.
    a. Observe all cut surfaces.
    b. Observe all body cavities (pelvic, abdominal, and thoracic).
    c. Observe the lumbar region.
    d. Observe the neck region.

3. Grasp, turn, and observe the kidneys (both sides).

Your veterinary mentor will show you how to perform these procedures in detail.

If abnormal conditions seen on carcass inspection do not require veterinary disposition, the inspector can have the establishment employee properly trim the carcass. However, some abnormal conditions require retention for veterinary disposition. Here are some examples of abnormal conditions that may be seen during carcass inspection.

- 311.7 - Arthritis--arthritis in a joint may be indicated by the appearance of the lymph nodes associated with that joint

- 311.14 - Abscesses--abscesses may be found anywhere in the carcass or its parts.

- 311.6 - Diamond skin disease--these carcasses should be retained for veterinary disposition.

- 311.16(a)(7) - Nephritis

- 311.24 - Cysticercosis--cysticercosis (measles), or cysts, can be found in any muscle tissue. Retain for veterinary disposition.

- 311.13 - Melanoma--these are tumors that contain black pigment (melanin). Retain these for veterinary disposition.

- 311.11 - Neoplasm (malignant lymphoma)--these tumors are commonly found in and around lymph nodes, but may be detected anywhere. Anytime you detect an abnormal mass (tumor), you should retain the carcass for veterinary disposition.

- 311.16(a)(7) - Cystic kidney--clear, fluid filled cysts of varying sizes. Condemn the kidneys (unless the condition is slight) and pass the carcass for food.

- 311.16(a)(7) - Embryonal nephroma--retain for veterinary disposition.

- 311.24 - Kidney worms--this condition can also be seen in the soft tissue of the carcass and abdominal viscera.

- Adhesions--these fibrous bands form as a chronic response to inflammation and are an attempt by the body to heal. Condemn affected parts and pass the carcass if no other pathology is noted.

- 311.14 - Abscess in the backbone--always check carefully along the backbone of the split carcass. It is possible to see abscesses, neoplasms (tumors), or evidence of trauma (fractures and bruising).

- 311.14 - Bruises--bruised tissue should be trimmed and condemned. If evidence of infection exists, retain the carcass for veterinary disposition.

- 311.2 - Cervical tuberculosis – retain the carcass for veterinary disposition.

- 311.14 - Slight cervical abscess, or well-marked or extensive abscess – retain the carcass for veterinary disposition.

- 311.30 – Suffocation (Asphyxia) - a scarlet red appearance of the carcass and organs that are engorged with blood; must be retained for veterinary disposition.

- 310.18(a) - Contamination (Overscald) – carcasses that have been overscalded will have a cooked appearance and will usually have varying degrees of mutilation and contamination of tissues with scald vat water.

Once again, when improper presentation occurs, take the same actions as when it occurs at head or viscera inspection, which includes the following.

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 has to 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.

Note: Examples for carcass inspection of different species (e.g., cattle) are shown in the Appendix.

<u>Poultry post-mortem inspection</u>

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, SIS, NELS, NTIS, NPIS, or Ratite – is being used at the establishment. You will learn the specifics of the inspection procedures in-plant with your mentor. However, following is a general overview of the procedures that must be performed. If you are working at a very small or a small establishment, you may perform all of the inspection

procedures yourself. If you work at a large establishment, there will be inspection stations where different inspection procedures are performed.

The conditions are listed on FSIS Form 6000-16 (Lot Tally Sheet), and the criteria for condemnation in each category is as follows.

FSIS Directive 6100.3 covers post-mortem disposition of poultry products.

Let's review the disease conditions and inspection determinations that you must make.

- 381.81 – Tuberculosis One definitive lesion is all that is required to condemn a poultry carcass for tuberculosis.

- 381.83 - Septicemia/toxemia The Agency considers both conditions under the general category of septicemia/toxemia, commonly referred to as sep/tox. If a carcass shows systemic change, it is condemned for sep/tox.

- 381.86 – Synovitis/Tendonitis Synovitis is caused by a number of organisms, most often members of the genus *Mycoplasma*. Injury and nutritional deficiencies also lead to synovitis. A carcass with synovitis is not condemned *unless* it also shows systemic or sep/tox changes.

- 381.87 – Tumors This category refers to tumors, including those of the leukosis complex. Some of the more common tumors include squamous cell carcinomas, adenocarcinomas, leiomyomas, and fibromas. Condemn a carcass for tumors if there is gross evidence of metastasis. Policy specific to keratoacanthomas in FSIS Directive 6100.3.

- 381.89 – Bruises If bruises cause systemic change in a carcass, or 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.

- 381.90 – Cadaver Poultry that die from causes other than slaughter are condemned under the cadaver category.

- 381.91 – Contamination This category is for carcasses that are so contaminated they cannot be inspected or made wholesome by reprocessing.

- 381.92 – Overscald The muscle must be cooked through the level of the *deep pectoral* muscle in order to be classified as an overscald.

- 381.84 – Airsacculitis Numerous microorganisms cause airsacculitis, which is inflammation o*f air sacs*. Carcasses are condemned if airsacculitis is extensive, or if carcass exhibits airsacculitis along with systemic changes.

- 381.86 Inflammatory Process (IP) - When the condition is generalized, condemn the carcass.

- 381.88 Parasites - Organs or parts of carcasses found to be infested with parasites shall be condemned. If the entire carcass is affected, the bird will be condemned.

Veterinary supervisors may check the accuracy of inspector dispositions by observing birds upstream or downstream from the inspector or by checking birds and parts in the condemn barrel.

Salvage of Carcasses Away From the Post-mortem Inspection Station (381.76)

The term salvage refers to the actions the establishment takes to trim away any unwholesome or diseased portion of a carcass that is localized (381.76). The establishment is not required to have a written procedure for each type of salvage; however the procedure must be verifiable. The procedures must be conducted under sanitary conditions, with adequate facilities, and personnel must be available to conduct the procedures. There should be a continuous product flow without pileup or delay.

Facilities at salvage stations should include:

- adequate space located in the eviscerating area
- a retain rack designed to prevent cross-contamination
- a trough or table sloped and properly drained
- a singer, if there is not one in the picking room
- 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

Contamination Knife Salvage

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

- remove the viscera
- hang the carcass in a designated area on the retain rack
- transfer the carcass to the salvage station and hang 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 external 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

All knife salvage must be done in a sanitary manner and must not produce contaminated or adulterated product.

Airsacculitis Knife 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. All exudates must be removed. The kidneys must be removed 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 airsaccultitis 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.

All knife salvage must be done in a sanitary manner and must not produce contaminated or adulterated product.

Airsacculitis 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 memebranes making the kidneys an affected tissue, and the posterior part of the carcass is salvaged for airsaccultitis 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.

Reprocessing of Carcasses due to Contamination

Contamination Reprocessing

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

381.91(b)(1) Online Reprocessing: Poultry accidentally contaminated with digestive tract contents may be cleaned by applying an online reprocessing 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 online reprocessing intervention system into their HACCP plans, SSOPs or other prerequisite programs.

Establishments may also elect to utilize offline reprocessing, 381.91(b)(2), where carcasses are removed from the line due to contamination and directed to another station for a combination of trimming and antimicrobial treatments. Offline reprocessing must have adequate facilities, trained personnel, and the procedure must be accomplished in a sanitary manner while maintaining product flow.

Facilities typically seen at the offline reprocessing station are:

- adequate space in the eviscerating room or a suitable adjacent area
- a retain 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 (CFR 381.91(b)(2))

When a carcass is designated for reprocessing because of body-cavity (inner surface) contamination, the establishment is required to:

- remove the viscera and hang the carcass in a designated area on the retain rack
- transfer the carcass to the reprocessing station and suspend it to prevent contamination during reprocessing
- remove the crop
- wash the external surface thoroughly
- 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 (CFR 381.91(b)(1)), or other approved antimicrobial treatment
- measure and record the chlorine concentration at least once a day
- monitor reprocessed birds
- make birds available for reinspection by the FSIS inspector

If retain 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 (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 will 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 product. 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 the transfer of disease or pathogen from the product to the consumer.

Control of any restricted product begins at the time the veterinarian 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 (311.23). Then, the carcass is retained. If any additional lesions are discovered at a later time (while the carcass is being boned for example), the veterinarian 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 needed facilities (316.18). 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 product 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 non-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.

Records must be kept on boneless restricted product, as well as other restricted product. The records should be kept on file in the government office. The records should contain the following information:

1. U.S. Retain tag numbers(s).
2. Quantity of restricted product (e.g., number of carcasses, pounds boned, or pounds boxed).
3. Quantity of condemned material (i.e., trimmed visible lesions).
4. Destination of product (if shipped under seal).
5. Inspector's name
6. Date

Let's review each of the four categories involving restricted product.

Passed for refrigeration

Only carcasses that are moderately affected with beef cysticercosis (beef measles) may be passed with a refrigeration restriction (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 boxed boned meat affected with beef measles that have been designated "Passed for Refrigeration" by the veterinarian. The carcass may be branded with a "U.S. Inspected and Passed" brand prior to placing it in the freezer because it is very 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. The establishment is allowed to do this to avoid considerable unnecessary work in transferring unmarked frozen meat to boxes bearing the mark of inspection.

Passed for heating

There are two conditions that may be "Passed for Heating" by the veterinarian. One is cysticercosis of sheep (sheep measles), the other cysticercosis of beef (beef measles) (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 "US Passed for Cooking" stamp by the veterinarian when he or she makes 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 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 veterinarian. The first is certain carcasses affected with eosinophilic myositis (EM) (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 retain 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. However, if the boned, boxed meat from these carcasses is properly packaged and labeled "Boar Meat for Use in Comminuted Cooked Product Only," shipping under seal is not necessary. Restricted boar meat properly packaged and labeled this way is the only exception to the rule that restricted products must be shipped from one establishment to another under seal.

For review purposes, the following chart lists those conditions that the veterinarian may pass with a restriction, the regulation reference and the specific restrictions.

CONDITION	REG.	FREEZING (15°F) Days: 10-carcass 20-boxed	COOKING 170°F/ 30 min.	HEATING 140°F	COMM. 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

Trichinosis

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 fr, om the United States 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 product for export. Additionally, IPP should follow the guidance in FSIS Directive 7320.1, Revision 1, Prevention and Control of Trichinella in Pork Products, Chapter II-Certifying Fresh/Frozen Raw Pork Products for Export when Produced under Pork Quality Assurance Plus (PQAPlus) Programs for Trichinella Mitigation, if applicable.

On May 31, 2018, the Food Safety and Inspection Service (FSIS) published the final rule “Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations” (83 FR 25302). The final rule eliminated the prescriptive requirements in 9 CFR 318.10 for pork products to be treated to destroy

Trichinae (*Trichinella*). FSIS removed 9 CFR 318.10 because the regulations were inconsistent with the HACCP regulations (9 CFR part 417). The HACCP regulations require establishments to consider food safety hazards in their hazard analysis (including *Trichinella*). The final rule became effective July 30, 2018.

The final rule requires establishments producing RTE and NRTE pork products to 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. All of these products were previously listed in 9 CFR 318.10(a).

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 prerequisite program 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 Compliance Guideline titled FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other parasitic Hazards in Pork Products (*Trichinella* Compliance Guideline). The following Table summarizes the options recommended in that 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, Revision 1.

As a safety factor, inspection personnel should consider all pork to be potentially contaminated with trichinae. This is why pork products must be kept separate from meat products of all other species. If pork and beef are both boned in the same establishment, a complete separation of the two products must be maintained at all times. This must either be a physical separation of the products or the two products must be worked at different times. For example, if pork is boned on a table in the morning, and beef is to be boned on the same table later in the day, a thorough cleanup of the area and all equipment must be done before the beef is processed in order to prevent cross-contamination. An alternative to this would be for the establishment to process pork at the end of the day after all other product has been removed and there is no possibility that non-pork products could come in contact with pork products. The same rule applies to grinding product. A small amount of pork tissue left in the grinder could potentially contaminate beef if there was not a thorough cleaning and sanitizing of the grinder between the two products. If pork products were ground after all other product had been ground and removed from the area, a cleanup of the grinder would not be required. One final example: Some establishments may be allowed to reuse shipping containers if the containers are in good condition. You would not allow this practice if the containers had previously been used to package pork products and the establishment wished to use them again for beef, lamb, or some other species. Always be alert for potential cross-contamination and its possible deleterious effects on public health.

ESTABLISHMENT RESPONSIBILITY FOR DEALING WITH CONDEMNED AND INEDIBLE PRODUCT

Condemned product is product that has been determined through inspection to be diseased or condition that renders it unfit for human consumption. It is prohibited from entering commerce for use as human food (314, 318.95).

Inedible product is any product that is adulterated, uninspected, or not intended for use as human food. The term inedible refers to product that by its nature is not handled as

human food (301.2). Examples include bones, uncleaned intestines, lungs, reproductive organs, feet, etc. If inedible product is diseased or has the appearance of edible product, it must be handled as condemned.

Both condemned and inedible products are not fit for human consumption. Due to the edible appearance of condemned product, its control is most crucial and the requirements found in the regulations are very specific. Edible product may have a similar appearance to condemned product and some inedible product.

Principles of control

FSIS control of condemned and inedible product involves five principles:

- -Identification
- -Custody
- -Separation
- -Destruction
- -Documentation

FSIS personnel must monitor the establishment's handling procedures of condemned and inedible product to assure that it is properly identified, maintained in custody, kept separate from edible product, and properly destroyed. Additionally, all actions taken must be appropriately documented.

Identification

As has been discussed, condemned products may look edible. For this reason they must be properly identified. The regulations require that each condemned carcass, part, or visceral organ be marked with the "U.S. Inspected and Condemned" brand (312.6(a)(5), 381.101). If the condemned product cannot be branded because of its size or texture, it must be placed in a container identified with the words "U.S. Condemned." Condemned product is to be disposed of by tanking.

An exception in the regulations allows the salvage of certain classes of condemned product for the production of pet animal food (314.11). One example is beef livers condemned for human consumption but allowed for use in pet food. The system used to identify product that is condemned versus product that is allowed for animal food must be consistent.

Custody

The FMIA requires that the inspector be able to certify that all condemned product is properly destroyed. To assure this, security of condemned product is essential. The regulations state that all condemned product must be kept in custody (security) of inspection personnel until it is destroyed for human purposes on or before the close of the day on which it was condemned. Destruction can be accomplished by incineration, rendering (tanking), or denaturing (314.1, 314.3). Custody involves direct supervision or security. This means that the condemned product must either be within sight of an inspector at all times or be placed in a secure container or room equipped with an official lock or seal. Therefore it is not permissible for inspection personnel to allow

establishment personnel to leave indentured condemned or inedible product on the kill floor during lunch or other break periods. Once condemned and inedible product is destroyed, or properly denatured, custody is no longer required.

Organs and parts (e.g., stomachs, intestines, bones, and feet) may be saved for edible (human) food at some establishments. Others may save these organs and parts as inedible product for animal food production. This is permitted provided that the establishment properly identifies the organs and parts. If the organs and parts are not used for either purpose, the product doesn't require any special security if kept separate from edible product. If it is shipped off premises for rendering, the product doesn't require denaturing as long as the establishment's handling of the product results in an inedible appearance (e.g., denaturing). Hair, hide, horns, and hooves of any animal are products considered naturally inedible. It is not necessary to require special identification or denaturing, but they must be kept separate from edible product.

Separation

Condemned and inedible products 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 materials from inedible and condemned product has potentially grave public health consequences. Inedible containers brought into edible departments must be watertight, acceptably clean, and properly identified. There are two types of inedible product containers. Containers for product condemned to tankage are marked "U.S. Inspected and Condemned." Those for product condemned for human use (inedible) but eligible for pet animal food are identified as "Inedible."

Carcasses of animals found dead or animals condemned on ante mortem inspection are not to be brought into or through an edible product area (314.8). Dead animals, except those that die en-route and are received with other livestock to be slaughtered, may not be brought onto the premises (314.7). 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 postmortem inspection.

Bile historically has been regarded as inedible and when contamination of edible product occurs it must be removed before completion of inspection by FSIS personnel. There are provisions allowing that inedible bile can be saved for manufacturing uses and stored in edible product areas. Where it is allowed, bile must be segregated, handled, and labeled as an edible product.

Destruction

There are three basic methods approved for making condemned and inedible meat products incapable of being used as human food. They are:

-Rendering (314.1)
-Incineration (314.3)

-Application of approved denaturants (314.4)

Inedible rendering is a process by which materials are heated sufficiently to destroy them for human food. When the establishment has its own facilities to perform the rendering process this is termed "on-premises" rendering. Many establishments do not have such facilities. Instead, they may ship condemned and inedible materials to an outside rendering facility. This is referred to as "off-premise" rendering.

Tanking is when condemned product is placed in a rendering tank under the supervision of an inspector who would then seal the tank. Once the contents are heated adequately to destroy them for human purposes, the inspector will then remove the seal, thereby releasing it from his/her custody. This method is rarely, if ever, used today. Establishments that perform their own "on-premises" rendering today generally utilize hashers and/or pre-breakers as a pre-tanking preparation of condemned product. This gives an inedible character and appearance to the product. For this reason, custody is not necessary once the material has been hashed. In addition, there is no requirement to use denaturant on this product to be rendered on-premises. However, prior to hashing, custody of the product must be maintained. This includes all equipment prior to the hasher. For example, if an auger is used to convey condemned material to the hasher, it must be covered and sealed or be located in a secured room.

Whenever condemned materials are to be shipped to another site, they must be properly denatured. This is true whether the material has been hashed or not.

If the establishment doesn't have inedible tanking facilities and it does not send condemned product for off premises rendering, all condemned product must be destroyed (under inspector custody) by incineration or by the application of an approved denaturant. A listing of acceptable denaturing agents may be found in two sources: the Regulations and the "List of Proprietary substances and Nonfood Compounds." Before an approved denaturing agent is applied, the product must be freely slashed so that pieces are less than 4" in diameter. This allows the denaturant to contact all parts of the product. Denaturants change the color and/or odor of products sufficiently to destroy them for food purposes.

In addition to any approved denaturant compounds found in the "List of Proprietary substances and Nonfood Compounds," there are three types of denaturants approved for use on product condemned to tankage. They are:

-Crude carbolic acid
-Cresylic disinfectants
-A formula consisting of FD&C green color No. 3, oil of citronella, detergent, and water

A different group of denaturants are used on inedible product condemned for human food but salvaged for animal food. This is because the above agents would make the product unfit for even animal food. Animal food denaturants include:

-FD&C green color No. 3
-FD&C blue color No. 1
-FD&C blue color No. 2
-Powdered Charcoal
-Any compound approved for such use in the "List of Proprietary substances and Nonfood Compounds" book

Documentation

Inspection actions regarding the control of condemned products must be properly documented. On ante mortem, actions might be recorded on FSIS Form 6150-1 (Identification Tag-Antemortem) or FSIS Form 6502-1 (MP 35) (US Reject/Retain Tag). FSIS Form 6750-1 (Daily Tanking Report) is a report (used at the option of the frontline supervisor) to document the control of condemned products in slaughter establishments. All establishments that ship condemned of inedible product 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 (MP 403-10) (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.

This form is also the permit to ship undenatured lungs for pharmaceutical or animal food use. Undenatured lungs for pharmaceutical purposes must be labeled "Inedible [Species] Lungs - For Pharmaceutical Use Only." If an establishment wishes to ship undenatured lungs for animal food, several requirements must be met. Permission must be obtained in writing from the district manager. The lungs must be shipped directly to an animal food manufacturer, zoo, mink farm, or storage warehouse. Shipping containers must be labeled "[Species Lungs - Not Intended for Human Food" and return copies of the shipping certificate must indicate to the inspector that the shipment reached its destination.

Shipment of undenatured condemned carcasses eligible for use as animal food may be approved. This requires a special permit issued by the District Manager. This product must be shipped directly to a manufacturer of inedible products. Additionally, there are special labeling and container sealing requirements.

Poultry

The regulations related to the handling and disposal of condemned or other inedible poultry products are similar to the meat regulations. They are found in 9 CFR 381.95. Here's a brief summary of this regulation. FSIS inspectors must verify that the establishment disposes of condemned and inedible products using one of the appropriate methods outlined in the regulation.

Condemned and inedible poultry products may be disposed of by one of the following methods.

- Steam (381.95(a))
- Burying (381.95(e))
- Incineration (burning) (381.95(b))
- Chemical denaturing (381.95(c))
- Dye denaturing (381.95(c)(3))

Only burying and burning may be used for products condemned for biological residues.

LINE SPEEDS

Maximum line speeds established by FSIS are permitted on the slaughter or eviscerating line when optimum conditions exist (381.65(a), 381.67, 381.68, 381.76 and 310.1(b) (1)). When there are less than optimum conditions, line speed adjustment is required to ensure that IPP can perform a 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. When the IIC is satisfied that the situation that necessitated the line speed reduction has been corrected, he or she will permit increase in the line speed.

FSIS may require the establishment to adjust line speed to a slower rate than the maximum when process control of line speeds is not maintained because of inconsistencies in size, weight, class of animal or bird, health, pathology, contamination, sanitary dressing or presentation.

Poultry

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 sanitarily with a minimum of contamination
- establishment facilities

FSIS does *not* require line speed adjustments for excessive feathers on carcasses at post mortem inspection.

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;
- document the reduction of line speed on a non-compliance 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 Verification Task in PHIS.

Livestock

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 IPP's 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;
- use the Livestock Sanitary Dressing task in PHIS to document noncompliance in accordance with FSIS Directive 6410.1 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 Other Verification Task in PHIS to document noncompliance only when the maximum line speed has been exceeded or when particular deficiencies in carcass preparation and presentation has 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 his or her 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. Skimmings from such washing cannot be used for edible purposes.

For livestock carcasses, the marks of inspection are applied just prior to the carcass entering the cooler. Each carcass must contain 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. 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 381.98. FSIS Directive 6810.2 covers marking meat carcasses and products.

STORAGE AND SHIPPING

Inspection procedures related to the regulatory requirements regarding sanitation and documentation must be performed in relation to product storage and shipping.

Condensation in coolers is a common problem. It is caused by hot air contacting a cold surface and causing moisture to form. It is the establishment's responsibility to prevent product contamination from condensation. If contamination from condensation does occur, the inspector should retain contaminated product and reject the area until the condition is corrected. Any condensation on product is considered to be contamination.

Wooden pallets may be used for temporary in-plant storage of packages or properly protected product provided they are structurally acceptable, clean, and do not contribute to unsanitary conditions or product contamination.

The inspector assigned to coolers, shipping, and receiving 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.

Unmarked inspected and passed product intended for further processing may be shipped under official seal from one official establishment to another (316.8). For unmarked product to be shipped under seal, *at least* 25% of the product in the vehicle must be unmarked. This is to prevent the establishment from purposely placing a small amount of unmarked product into each vehicle and having them sealed with an official government seal and warning tag for the purpose of discouraging theft. If the shipment does not meet this requirement for sealing, then all products must be properly marked or labeled. The 25% requirement *does not apply when restricted product is being shipped.*

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 1/2 inch rubber brand. A U.S Retained tag must be affixed to each container and an FSIS Form 7350-1 used for each shipment.

In many establishments, it is common for product to be returned from unofficial establishments, such as retail stores. In order that the inspection program can control returned product, it must be delivered to this area as soon as practical. The establishment should not sort, remove, or otherwise handle the returned product until it

has been reinspected (318.2). After sorting by the establishment, inspect the product the establishment has elected to save. Any product found to be wholesome and bearing the official mark of federal inspection is released for use to the establishment. Any product found to be unwholesome or unidentifiable is condemned. The product must be accompanied by inspection personnel to be either tanked or denatured.

When unclean or unsound product is received from another establishment the inspector will complete an FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product.* This form is executed only when the conditions reflect negligent procedures on the part of the originating establishment, such as kill floor dressing, contamination, rail dust, etc. The form should not be used for conditions that cannot be controlled by the originating establishment. An example of an uncontrollable condition would be off-condition product resulting from failure of the refrigeration unit during transit. The form is intended for internal use of the inspection program and is not to be issued to the establishment. For the FSIS Form 8140-1 to be effective, information entered on it must be specific - the type of contamination, where it was located on the carcasses or parts, and the number or amount of product affected.

Establishments are permitted to ship properly marked or labeled product without an inspector on duty if they have a good history of shipping clean acceptable product in acceptable vehicles. If an establishment continuously receives FSIS Form 8140-1, Notice of Receipt of Adulterated or Misbranded Product, the privilege of shipping without an inspector on duty may be revoked by the Frontline Supervisor
.

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. The types of reports required are described in FSIS Directive 6100.2, “Post-Mortem Livestock Inspection” and FSIS Directive 6100.3, “Ante-Mortem and Post-Mortem Poultry Inspection”. 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.

Example: Poultry Post-mortem Reports

Inspection personnel are required to keep track of the number of poultry carcasses condemned on post-mortem inspection for each condemnation category. This information is collected on the lot tally sheet, FSIS Form 6000-16, at the inspection station. The food inspectors are responsible for the maintenance of the Lot Tally Sheet. During the shift, the “inspector’s helper” records condemnations on the Lot Tally Sheet.

Completing the Documentation on FSIS Form 6000-16 (Lot Tally Sheet) for Poultry Post-Mortem inspection

The PHV or designee (off-line IPP) is to complete the appropriate sections of the Lot Tally Sheet including the:

a. inspection date
b. shift of inspection
c. establishment number
d. specific production (lot number)

e. class of poultry

f. number of condemnations for each category

The Food Inspector gives the Lot Tally Sheet to the “inspector’s helper” at the beginning of each shift. The ”inspector’s helper” records the condemnations throughout the shift. The Food inspector ensures the CSI or designee receives the Lot Tally Sheet at the end of the shift.

At the end of the shift, the lot tally sheets from all on-line inspectors are collected by the CSI or their designee. The CSI will total the condemnations for each condemnation category from the Lot Tally Sheets of the on-line inspectors. They will also record on the Lot Tally Sheet the number of establishment rejects. Establishment rejects are carcasses rejected by the establishment before inspection or re-inspection. These totals are acquired from establishment personnel during the shift.

Enter the information from each Lot Tally Sheet into the Animal Disposition Reporting (ADR) section of PHIS.

Establishment management is responsible for collecting and supplying information to inspection personnel on the total number of live birds and their live weight per lot, and the total pounds condemned at ante mortem inspection. This will include the dead on arrival carcasses (DOAs). Establishment management must also supply inspection with the total weight in pounds of carcasses and of parts condemned on postmortem, and with the total weight in pounds of chilled and frozen product from that lot. Establishment management supplies inspection with these data on FSIS Form 6510-7, the Poultry Lot Information sheet.

All of the above information is to be recorded by the inspector into the ADR section of PHIS. The ADR data is collected and reported on a lot basis for each shift. This means that there may be multiple sets of numbers reported for each shift.

A condemnation certificate must be completed for each lot of poultry slaughtered. The condemnation certificate, FSIS Form 9061-2, is completed and signed by the inspector in charge. The condemnation certificate contains both ante mortem and post mortem condemnation information. The condemnation certificate is generated by PHIS, using the information entered in the ADR section.

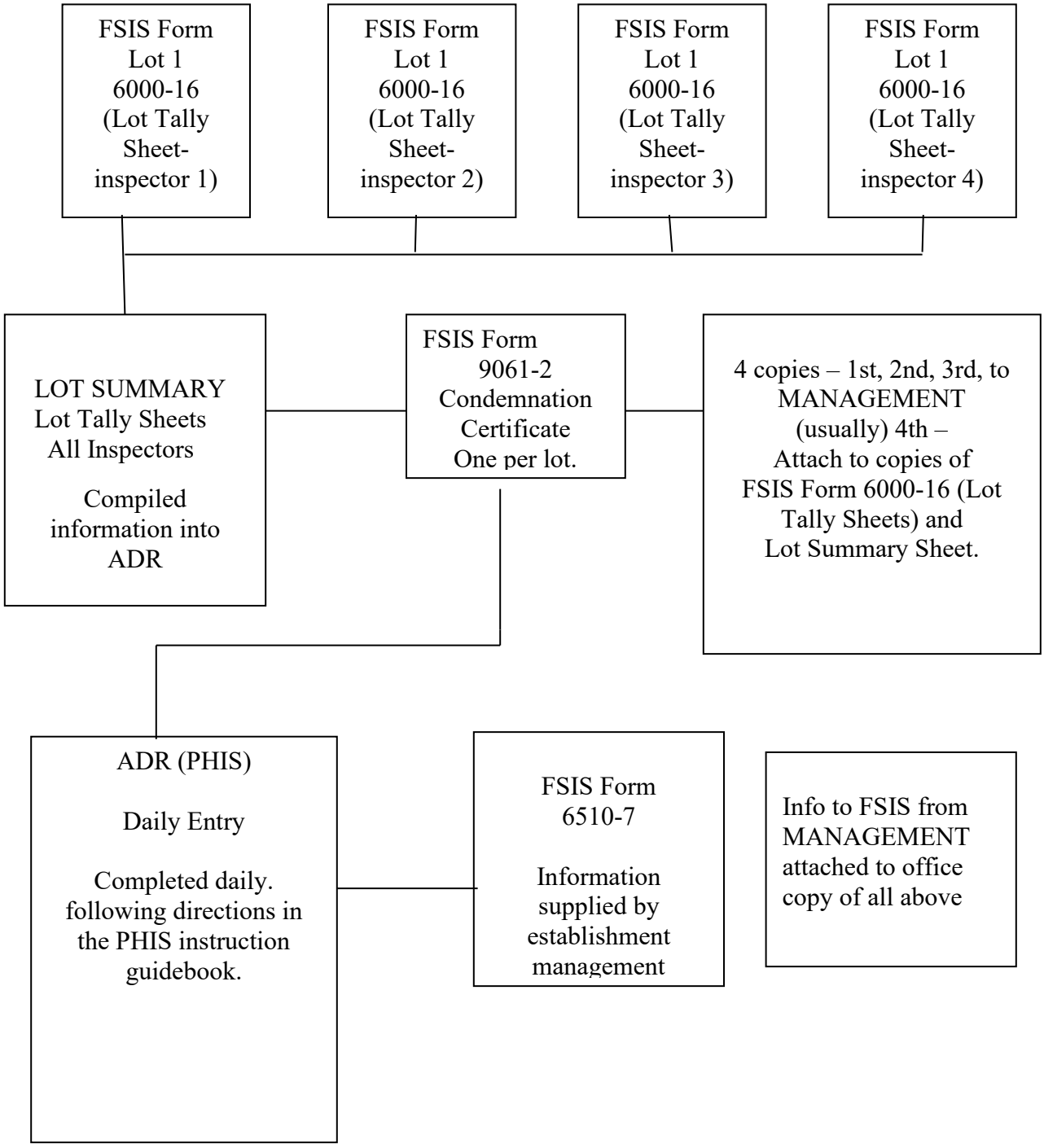
Once all of the required forms have been completed and information gathered, they must be properly filed, entered, and/or distributed, as follows:

1. FSIS Form 6000-16, the lot tally sheets, are kept in the government office attached to the summary for each lot;
2. FSIS Form 6510-7, the Poultry Lot Information sheet from establishment management, is filed in the government office with the other records for each lot;
3. The ADR data is collected and reported on a per-lot, per-shift basis.
4. FSIS Form 9061-2, the condemnation certificate, is distributed as follows: after establishment management signs the form, the first 3 copies are given to establishment management, and the fourth copy is filed in the government office with the other records from each lot.

The following page contains a flow chart of the distribution of all FSIS forms related to postmortem reports.

FLOW CHART FOR POST-MORTEM REPORTS

Example for a Establishment with 4 line Inspectors



APPENDIX

Post-Mortem Inspection Procedures

CATTLE

Head inspection

There are four steps in head inspection.

1. Step one is to observe the outer surface of the head and eyes.

There are some specific conditions that may be identified during head inspection. For example, when inspecting cattle heads, during step one, the observation of the head's surface and eyes, the diseases and conditions that may be detected include contamination (e.g., hide, hair, dirt, rust, and grease), epithelioma, actinomycosis, actinobacillosis, and abscesses.

2. Step two is to incise and observe the four pairs of lymph nodes – mandibular, parotid, lateral retropharyngeal (atlantal), and medial retropharyngeal (suprapharyngeal).

The type of diseases and conditions that may be detected when performing step two (incising and observing lymph nodes of the head in cattle) include tuberculosis, actinobacillosis, epithelioma, and abscesses.

3. Step three is to incise and observe the masticatory or cheek muscles.

The diseases and conditions that may be detected during the performance of step three, incising and observing the masticatory muscles during cattle head inspection include cysticercosis, eosinophilic myositis, bruises, steatosis, and xanthosis.

4. Step four is to observe and palpate the tongue.

The diseases and conditions that may be detected when performing step four (observing and palpating the tongue while performing cattle head inspection) include actinobacillosis, and foreign bodies such as thorns.

You will learn more about what to do when these diseases or conditions are observed when we cover the Multi Species Dispositions module.

Carcass Inspection

Almost all establishments handle the carcass the same way until the time the head is removed. Once the head is removed however, any one of several methods may be used to complete the carcass dressing. Almost all the different methods being used today are variations of two basic operations. One of those basic methods is called a "bed" dress operation. The other is called an "on-the-rail" method was dressing operation. The bed dress method is by far the oldest method and probably date back to the time when animals were "field dressed." This method is still widely used; however, it

is most often used in the low-volume establishments. After the head has been removed, the carcass is lowered to the skinning bed. The skinning bed may be cradle or it may be the floor. The “on-the-rail" method was designed with volume in mind. The animal is moved around the slaughter floor by means of a rail and instead of one employee dressing the entire animal several specialists will perform their jobs as the carcass moves past them.

In either dressing method there are several sanitary dressing requirements you need to be alert to. First, *all* grubs, contamination, bruises, etc., *must* be trimmed from the back of the carcass in the path the saw is to proceed, before splitting.

Secondly, even though it is not required that the saw be sanitized after each use, on normal carcasses, it *must* be sanitized when used on a retained carcass or when a hidden abscess or other pathology is contacted.

The two halves are moved to the carcass (rail) inspection station. The establishment is responsible for assigning an employee prior to the inspection station to trim and remove all bruises, blood clots, grubs, and the like. The establishment employee must *not* remove any abnormality that could affect the disposition of the carcass.

Frequently on the bed dress operation, the carcass will be trimmed and rail inspection accomplished by the viscera inspector while the split carcass is in the same area where it was eviscerated.

After the rail inspection is completed the carcass will be moved, or proceed on the chain, to the final wash area.

Any carcasses located on the "final" rail must be physically separated from other carcasses. This will prevent cross-contamination from one carcass to another. In no case will a retained carcass be washed or trimmed unless authorized by a program employee.

The following steps are those to follow when inspecting the carcasses.

Hindquarter inspection

1. Observe back of skinned carcass while eviscerated.
2. Palpate scrotal (superficial inguinal), or mammary (supramammary), and medial iliac (internal iliac) lymph nodes.
3. Observe body cavities.

Forequarter inspection

1. Observe cut surfaces of muscles and bones, diaphragm's pillars and peritoneum.
2. Observe and palpate kidneys and diaphragm.
3. Observe pleura, neck and carcass exterior.

Carcass inspection

1. Palpate superficial inguinal, or supramammary, and internal iliac lymph nodes. Observe lumbar region.

2. Observe and palpate kidneys.
3. Observe diaphragm's pillars and peritoneum.
4. Observe and palpate diaphragm.
5. Observe pleura, cut surfaces of muscles and bones, neck, and carcass exterior.

You are usually doing two dexterity actions during each step. For example, you may be required to *observe* and *palpate*, or *incise* and *observe*.

If you observe a disease or condition that requires you to retain a carcass, tag each half-carcass, request that the viscera and head be retrieved, and apply one tag to each.

Products, parts, etc., that are removed and condemned for various reasons are usually placed in a container near the rail inspector and the viscera inspector. These containers must be properly identified for their intended purpose. The inspector who is responsible for the area where the containers are located must also be responsible for seeing that the containers are either locked, sealed with an official seal, or under visual security at all times. You would not leave the area before the container was locked or sealed. We will cover this in more detail later during this module.

In most operations, a final inspection rail or final disposition room is located immediately following the rail inspection station. The rail inspector must be alert to require that *all* carcasses that need a final inspection by the veterinarian or further trimming to insure they are wholesome, are removed to this area.

Viscera Inspection

Viscera separation is the dividing of the internal organs of the body such as the heart, lungs, liver, kidneys, intestines, etc., into various offal products. Offal parts are animal parts other than the carcass (body).

The following steps are performed in viscera inspection.

1. Observe cranial and caudal mesenteric (mesenteric) lymph nodes, and abdominal viscera.
2. Observe and palpate rumino-reticular junction.
3. Observe esophagus and spleen.
4. Incise and observe lungs lymph nodes - mediastinal [caudal (posterior), middle, cranial (anterior)], and tracheobronchial (bronchial) right and left.
5. Observe and palpate costal (curved) surfaces of lungs.
6. Incise heart, from base to apex or vice versa, through the interventricular septum, and observe cut and inner surfaces.
7. Turn lungs over; observe ventral (flat) surfaces and heart's outer surface.
8. Incise and observe hepatic (portal) lymph nodes.
9. Open the bile duct (both directions) and observe its contents.
10. Observe and palpate liver's ventral surface.
11. Turn liver over, palpate renal impression, observe and palpate parietal (dorsal) surface.

Here are some further details about viscera inspection.

Inspection of the Abdominal Viscera

Abscesses are frequently detected during the palpation and observation of the rumino-reticular junction. These abscesses are usually localized and required only that the viscera be condemned. You should be alert though, to the overall condition of the carcass, and thoracic viscera. If abscesses are found in other locations, in addition to the abdominal viscera, it could be an indication of a generalized condition, in which case you would retain the carcass and all parts for the veterinarian to make a final disposition.

The mesenteric lymph nodes may show evidence of tuberculosis, neoplasms, and in some cases pigmentary color changes.

You must retain the carcass and all parts when you detect tuberculosis and tumors.

Most pigmentary color changes in the lymph nodes may be due to the animal's age or the environment in which the animal has been maintained and is usually of little concern. As with all abnormal conditions, though, if you were unsure of the cause or involvement of a condition, you would retain the carcass and parts for the final disposition by the veterinarian.

The small intestines may appear dark red to purple; this would indicate a condition called enteritis. The determination whether the condition is acute or chronic must be made.

There are several other conditions detectable at the time you observe the abdominal viscera. These may vary from a slight redness or odor in the uterus or pyometra (metritis), to a retained placenta or fetus. In these instances, you should evaluate the degree of involvement, the remaining viscera condition, the condition.

Evidence of adhesions may be seen. Again, if the condition appears localized, or chronic, and no further carcass or viscera involvement is observed, the abdominal viscera would be condemned and the carcass retained for trimming.

Inspection of the Spleen

The inspection of the spleen is done by observation. If tuberculosis is suspected, the carcass and all parts will be retained for veterinary disposition. You will see physical differences between normal and abnormal. There may be a definite swelling or size difference, or a color difference. When an abnormal spleen is detected, retain it as well as the carcass and all parts. The spleen may be helpful in making a final disposition on any carcass. Ensure that the spleen is included with the viscera whenever a carcass is retained for a disease condition.

Inspection of the Esophagus

Observe the esophagus for *Cysticercus* (measles); eosinophilic myositis (EM); and evidence of grub infestation. *Cysticercus* and EM conditions require retention. Grub infestation is usually a localized condition requiring affected organs and areas be trimmed or condemned, but the carcass will usually be passed without retention

Inspection of the Pluck (Lungs and Heart)

Pneumonia and pleuritis are the most common abnormalities observed. Acute pneumonia is characterized by enlarged, edematous lymph nodes and/or dark red to purple sections or spots in the lung tissue. Retain this carcass and all parts for disposition.

A chronic pneumonia may be characterized by a localized abscess within the lungs, or many times evidence that the lung has become adhered to the pleura (lining of the thoracic cavity), frequently called pleuritis. Observe the rest of the viscera and carcass to look for evidence that the condition is generalized. For example, you may detect other sections of the carcass with swollen lymph nodes, or other adhesions. The carcass may appear degenerated. There may be water tissue, fat sloughing, etc. Any of these would indicate a generalized condition. You will retain the carcass and all parts upon detecting a generalized condition. When the condition is strictly localized, the lungs would be condemned, as well as any contaminated organs, and the carcass retained for removal of the adhesions.

Tuberculosis may also be detected during incision of the lung's lymph nodes. When TB lesions are detected, the carcass and all parts must be retained.

Another condition you may detect while incising the mediastinal lymph nodes is the thoracic granuloma. A granuloma may appear as an abscess or pus pocket in the lymph node. Retain the viscera, especially the pluck, for disposition. You may collect and submit samples of the granuloma lesion. The granuloma could be TB related. We will cover this in more detail during the module on Multi Species Dispositions.

Neoplasms (tumors) may be detected during palpation of the lungs. These tumors would appear as nodules or lumps in or on the lung tissue. The carcass and all parts would be retained.

Inspection of the Heart

The inspection of the heart involves opening it by an incision form the base to the apex, or vice-versa. The usual procedure is to position the heart in a manner that will allow you to safely cut away from your body, and incise the left ventricle about an inch and one-half posterior to the lefts of large vessels leading into the chamber. Then grasp the opened edge of the ventricle and incise the septum. By rotating the knife 180 degrees with the cutting edge pointing up, complete opening the ventricles and great vessels with two incisions, causing the heart to lay flat or open.

In some establishments, the heart may be inspected without being opened. If this is the case, a company employee must invert the heart for you to complete your inspection, and you would normally make a slight incision in the septum walls in addition to observing the inner heart surfaces. This procedure is difficult except on older animals, where the heart muscle is thinner and more pliable. The company employee will also re-invert the heart for you to observe the heart's outer surface.

Some of the conditions you may detect while inspecting the heart include:

Cystircercus (tapeworm cysts, measles, etc.)
Eosinophilic myositis (EM)

Neoplasms (tumors)

Pericarditis is an inflammation of the pericardium or heart sac. When an inflammation of the inner lining of the heart occurs, the condition is referred to as endocarditis.

Inspection of the Liver

Liver Abscess

An abscess is a circumscribed area of pus with related swelling and/or inflammation caused by a variety of factors. Abscesses may be associated with specific diseases, but are usually seen as localized conditions. Many feedlot cattle (fat) have localized abscesses and the cause seems to be related to high-energy cereal diets, with unsanitary feedlot conditions also a factor. An abscess may appear on the surface and be quite obvious, or it may be located under the surface, and only detected when you palpate properly. (You must remember to palpate deeply to detect hidden or invisible conditions.) You may make as many incisions as you feel necessary to search for abnormal conditions, but remember you should not mutilate product unnecessarily. In *all* cases, a liver containing an abscess is condemned as not fit for human consumption. Benign abscesses (non-malignant, and judged *not* to be affecting surrounding tissue) may be salvaged for animal food *after* removal of the abscess itself.

"Sawdust" and Telangiectasis (Telang)

The condition in which a liver has pinkish-white to yellow-gray necrotic (dead) spots that make the liver appear as if sawdust had been sprinkled or scattered through it is called "Sawdust." The area around the spots appears normal and the liver's surface over the spots is usually smooth. The condition in which a liver has purple-red to bluish-black spots present both on the surface as well as throughout the organ is called telangiectasis and is referred to as "Telang." Usually the surface of the liver is slightly depressed when affected with Telang.

To determine the disposition of sawdust and Telang conditions, *three* degrees of involvement are used.

1. Slight: Where the lesions are small in size and slight in number. A liver meeting the slight criteria is passed for food without restriction.
2. More severe than slight but involves *less* than one-half of the organ: The portion of the liver that is *not* affected or only slightly involved may be passed for food without restriction, while the remainder of the liver is condemned.
3. More severe than slight and involves *more* than one-half of the organ: The entire organ is condemned. (It may be salvaged for animal food.)

Liver Flukes (Distoma)

The appearance of a fluke infested liver depends a great deal on the amount of fluke infestation. A slight infestation will probably not affect the liver tissue as such. A heavy infestation may cause a cirrhotic effect on the organ, with the surface becoming scarred. Many times there are bumpy, raise and/or depressed areas, and sometimes a discoloration showing dark blue to black sections on and within the tissue. The liver may take on a "hobnail appearance."

The primary purpose in opening the bile duct during liver inspection is to detect flukes. When there is a fluke infestation the bile duct may be thickened and sometimes swollen; frequently you will observe live flukes. The three liver flukes most often seen in domestic cattle today are: *Fascioloides magna; Fasciola hepatica; Dicrocoelium dentricum* (Lancet).

In all cases of liver fluke infestation the liver is condemned and not eligible for human consumption. The liver *may* be salvaged and used for animal food.

Carotenosis

A liver with carotenosis is characterized by a highly colored yellow-orange color or pigmentation. This condition is quite common in cattle livers and may cause the liver to become enlarged, soft, and friable (easily crumbled). Here's a practical test to assure the correct recognition of carotenosis. The test is made be placing a white paper towel or napkin on the cut surface of a liver suspected of being affected with carotene discoloration. An orange-bronze stain would be indicative of carotenosis. The liver is condemned and not eligible for use a human food but *may* be salvaged for animal food uses. The pale-colored liver found in near-term cows may resemble carotenosis. For this reason you must be sure of your diagnosis. The pale liver may vary from tan to yellow to gray in color and may be enlarged. Usually the cut surface feels greasy. The cause of this pale liver is thought to be the result of a change in fat metabolism of the near-term cow. Livers from cattle that are normal except for the pale color are passed without restriction.

Hydatid Tapeworm Cyst

Hydatid cysts may occasionally affect livestock. Most domestic food animals are the intermediate host for this tapeworm cyst, which usually is a result of the tapeworm (*Enchinococcus granulosus*) of dogs. While the animal eats or grazes, it consumes the eggs, probably deposited by the dog, and the eggs in turn change to larvae in the food animal's system. The larvae then end up in various organs via the blood stream.

The cyst will vary in size but may be as large as two to four inches in diameter. The fluid inside the cyst is usually clear and colorless. You must be careful not to confuse the hydatid cyst with an accessory gall bladder.

The organ or part affected with a hydatid cyst is condemned and is *not* suitable for use in animal food.

Control of Condemned Livers

Those livers that *are* condemned, but which the company has indicated it wishes to salvage for animal food, must be handled properly before they may be shipped from the establishment as animal food livers. Here is a summary of the steps to take.

1. The livers must be marked "U.S. Condemned."
2. The condemned livers may be held in containers on the slaughter floor, or may be worked as inedible product during the slaughter procedure.

a. When the condemned livers are placed in a container, the container must be plainly marked "inedible." Ensure that the product in these containers is maintained under security at *all* times. This means under you direct supervision, or locked or sealed in a container with an official device until such a time that the product *is* properly denatured.
b. When the establishment requests an opportunity to slash and denature the condemned livers during the slaughter operation, it *may* be done, provided it doesn't create problems of control, security, or contamination.

Liver Disposition Chart

Disease or Condition	Degree	Disposition
Telangiectasis Sawdust Spotted	Slight	Pass for human food
	The affected portion trimmed when less than 1/2 of liver is more than slight	Condemn/Use for animal food
	Balance of this liver is slight or less	Pass for human food
	More than slight involving 1/2 or more of liver	Condemn/Use for animal food
Contamination	Excessive	Condemn/Tank
Cirrhosis	Any amount	Condemn/Use for animal food
Nonmalignant change	Any amount	Condemn/Use for animal food
Abscesses-benign (trim)	Localized - Affected area	Condemn/Tank
	Localized - Non-affected area	Condemn/Use for animal food
Flukes	Any evidence of infestation	Condemn/Use for animal food
Hydatid Cyst	Any amount	Condemn/Tank
Abscesses (Not benign)	More than localized	Condemn/Tank
Carotenosis (yellow)	Any amount	Condemn/Use for animal food
Other Parasites	Numerous lesions and cannot be removed	Condemn/Use for animal food
	Localized: Affected area trimmed	Condemn/Use for animal food
	Localized: Non-affected area	Pass for human food

References: Regulation 311.25; 311.31, and 314.10

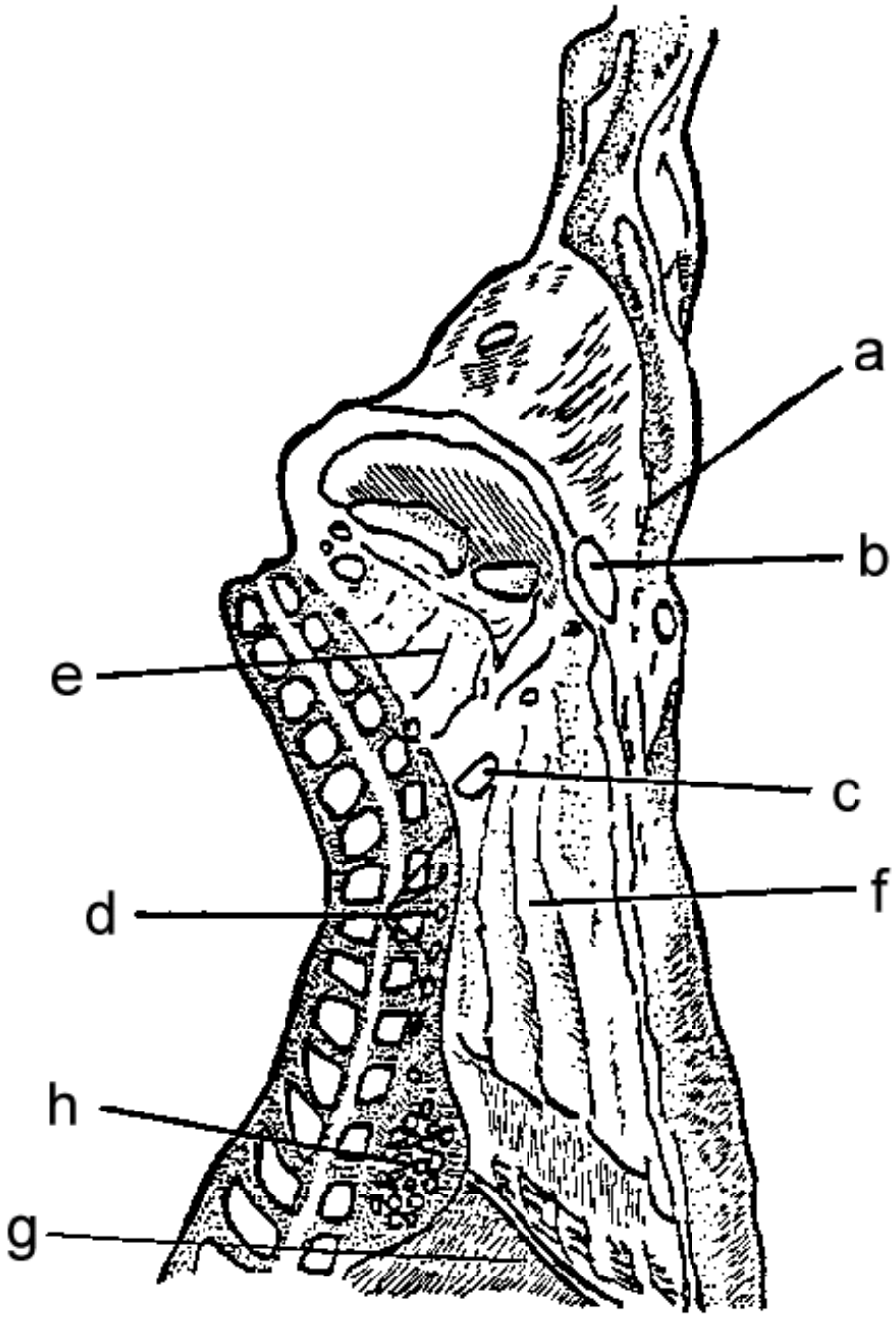
<u>Presentation</u>
During the evisceration procedure several improper presentations may occur. The following are examples:

- The liver may be placed with the parietal surface up.
- The hepatic (portal) lymph nodes may be missing from the liver.
- The bladder may be leaking urine onto exposed surfaces of the carcass or viscera.
- The paunch or intestines may be cut or broken, causing contamination.
- The pluck may be placed upside down, i.e., the ventral surfaces of the lungs pointing up.
- The liver, pluck, and viscera, or any one of these organs, may be pushed to or deposited on the opposite side of the table from your station, or literally missing.

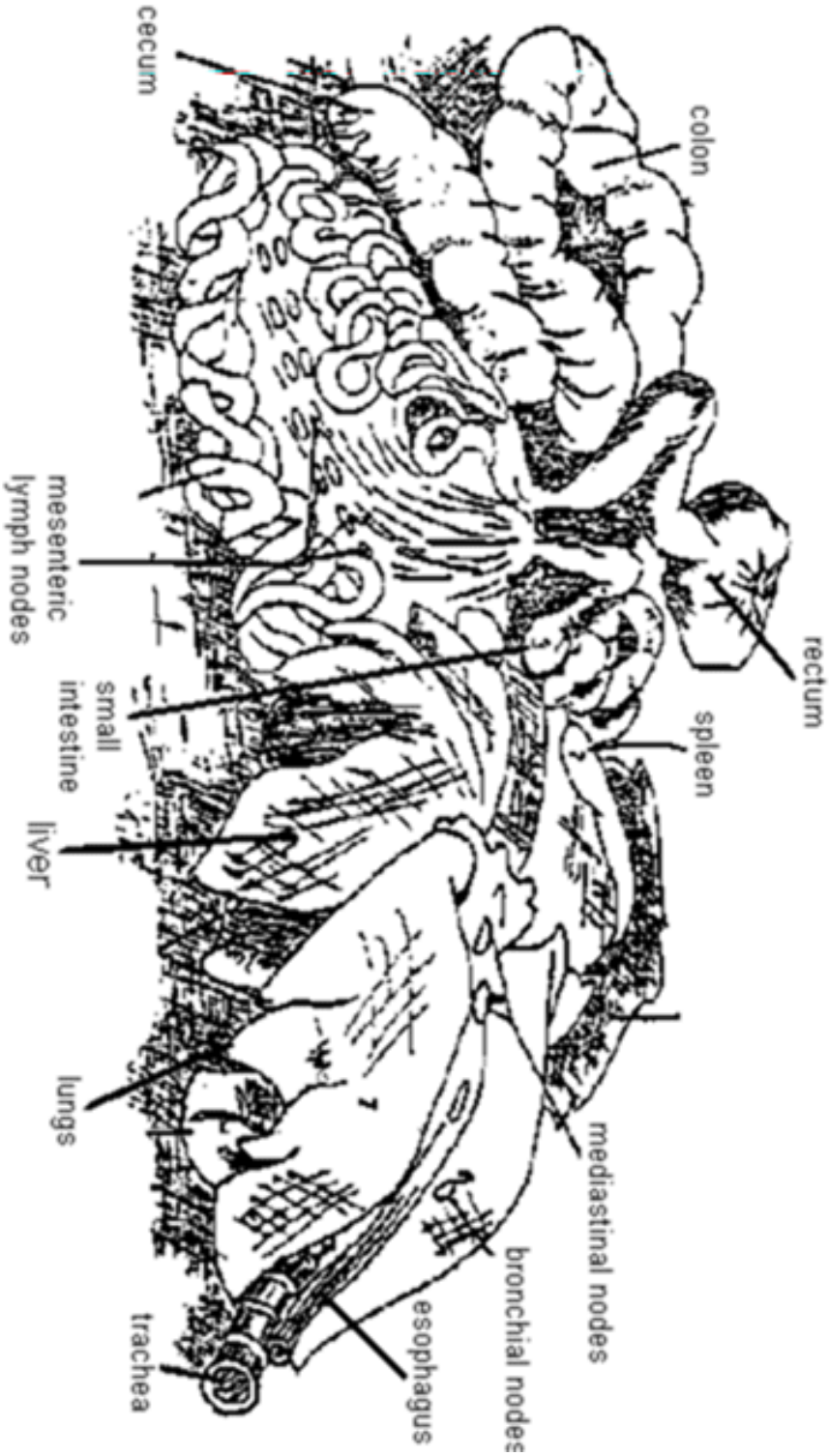
There are many other examples of improper presentation. Generally, if an improper presentation occurs infrequently, delay inspection long enough to complete inspection duties. Also require that any contamination be removed. *A very important consideration*

is that your attention to the actual inspection procedures must not be distracted. You may miss something you need to see.

If any improper presentations occur frequently, delay inspection, and meet with establishment management in an effort to get the problem(s) under control. *Your attention must not be distracted during the inspection procedure.*



LIVESTOCK ANATOMY SCHEMATICS



CALF INSPECTION

Calves of all sizes and ages are slaughtered. Some establishments slaughter "bob veal" calves. These calves are defined as, “under 150 pounds and less than three weeks of age”. Although it is beyond the scope of this module to cover bob veal slaughter in detail, there are some aspects of these operations of which you should be aware. Historically, these very young calves have been a serious source of residue violations, particularly sulfa residues. Because of this, much of the work in establishments that slaughter bob veal calves involves the use of rapid in-plant tests to detect sulfas and antibiotics. The FAST test is used to detect residue violations. Should you be assigned to a bob veal operation in the future, become familiar with the statistical sampling plans and tests used.

Beyond three weeks of age, definite guidelines or definitions for what size constitutes a calf are not in FSIS publications. Some regions have established policies for size limitations on calves. This is important because inspection procedures for calves are not nearly as complete as those for mature cattle. It is important to note that large calves require an expanded inspection procedure that is identical to that for cattle inspection. This is because some abnormal conditions, such as measles (Cysticercosis), require a certain amount of time to develop. If in doubt about whether to use calf or cattle inspection procedures, it is essential to check with your supervisor to assure you perform the appropriate procedures.

Calves are dressed by one of two methods. Calves may be hot skinned. This method is essentially the same used for other livestock. The hide is removed on the kill floor at the time of slaughter. Alternatively, calves may be cold skinned. This is also referred to as dressed "hide-on." In this method the hides are not removed on the kill floor but rather in the cooler after the carcasses have chilled.

It is said that cold-skinned calves maintain their "bloom" (the bright red appearance of freshly dressed, properly chilled carcasses and meat) and shrink less than hot-skinned calves. This is because the hide prevents loss of moisture from the carcass during the chilling process, resulting in less weight loss.

<u>Hot skinning</u>

The same basic sanitary dressing requirements that apply to cattle are applicable to hot-skinned calves. They include:

- Daily cleaning of the knocking box.
- Keeping the animals as dry as possible.
- Not bleeding in the dry landing area if possible.
- Clean head skinning and removal (head with carcass identification).
- Sanitary hide and feet removal.
- Bung and bladder tying as necessary.
- Sanitizing brisket opening device between each use

Establishment management is responsible for handling all carcasses and parts in a sanitary manner regardless of the dressing method used.

Cold skinning or Hide on

The carcass (hide) must be completely clean of dandruff, dirt, and fecal material before heading or opening of the carcass. Cleaning is sometimes facilitated with "curry combs" or other scraping instruments, and always with potable water. There needs to be sufficient water pressure, volume, and a competent washer to accomplish complete cleaning. There is one exception to the rule that cleaning of the hide must precede heading or opening of the carcass. Should you ever be assigned to an establishment where Kosher slaughter is performed, you will note that the head may be removed before the hide is washed.

Monitoring the spacing of carcasses is a very critical point. After removal from the carcass, the head is thoroughly washed and the cavities flushed in the same manner as cattle heads (this is true of hot-skinned calves also). The head is then placed on a rack or hook for inspection. As in other species, when the head is removed from the carcass a method of identification acceptable to the IIC is necessary to assure that the identity of the head and its corresponding carcass is maintained until inspection is complete.

Some establishments may wish to save calf tongues but do not want the rest of the head and therefore do not want to expend the effort to skin the head. This is acceptable provided:

- the head is washed,
- medial retropharyngeal (suprapharyngeal) lymph nodes are exposed for inspection, and,
- tongues are washed individually

The hide is then opened and skinned back on the hock just far enough to allow insertion of the gambrel. The lower leg with the hide attached can then be removed. The front side of the hock should not be skinned until the hide is completely removed. *The hock is not to be exposed until final skinning.*

Next, the front feet are removed. Note that all procedures to this point have been performed prior to any opening being made in the carcass.

Brisket splitting, bung dropping, belly opening, and evisceration must be consistently done in a sanitary manner. Splitting the brisket may be done with a knife, saw, or other acceptable instrument. Whatever device is used, it must be sanitized following each use. The person opening the belly must take care to prevent unnecessary contamination of the carcass.

Bung tying in large calves is done as in cattle, i.e., the bung and bladder must be tied before evisceration unless the urinary bladder is removed and the bung does not cause contamination. The procedure in small calves is similar to that in sheep. The bung and bladder are grasped and the large intestine preceding the bung is stripped. The bung is severed and the bung and bladder are removed.

Now the carcass is ready to be eviscerated. Following evisceration, the viscera (abdominal viscera and pluck) are placed into a tray or truck for inspection.

Hot skinned calves

A. Head Inspection

1. Observe head's surfaces.
2. Incise and observe medial retropharyngeal (suprapharyngeal) lymph nodes - left and right.

B. Viscera Inspection

1. Observe and palpate lungs' lymph nodes [tracheobronchial (bronchial) and mediastinal], costal (curved) surfaces of the lungs, and the heart.
2. Turn lungs over and observe ventral (flat) surfaces.
3. Observe spleen.
4. Observe and palpate dorsal surface of liver.
5. Turn liver over, observe ventral surface, and palpate hepatic (portal) lymph nodes.
6. Observe stomach and intestine.

C. Carcass Inspection

1. Observe outer and cut surfaces.
2. Lift forelegs and observe neck and shoulders.
3. Observe body cavities.
4. Observe and palpate medial (internal) iliac lymph nodes and kidneys.

Cold skinned hide-on calves

In addition to the above inspection procedures, inspection procedures of "hide-on" carcasses must include observation of the hid for contamination, parasitic conditions and other abnormalities, and palpation of the back for grubs. The skins of bruised calves and those affected with grubs, lice, warts, ringworm, and other skin conditions, as well as those found unclean, must be removed as part of the dressing operations at the time of slaughter. In all cases, skinning of calves must be done in a sanitary manner and un-skinned carcasses must be adequately spaced.

Large calves

Recall that large calves require the same inspection procedure described for cattle. This expanded procedure is necessary on large calves because their age may have permitted abnormal conditions such as measles (*Cysticercosis*) to develop. Improper presentation of carcasses or viscera (such as dirt, hair, hide, ingesta, grease, pus, etc.) may occur as in other species. When this occurs, action must be taken by the inspector to correct the problem. Actions taken will depend on the nature and frequency of dressing errors. If in doubt about what actions need be taken, review the cattle and swine inspection modules for assistance.

Calf Post-mortem Pathology

When abnormal conditions are encountered on calf inspection, the proper reaction is to retain the carcass and parts for veterinary disposition, or retain just the carcass if only hide removal and/or extra trimming is necessary for the carcass to pass inspection. A two-section retain tag is usually used by placing one section on the carcass and one on the viscera if the carcass, head, and viscera are retained. The corresponding head is retained by use of the head-carcass house identification tag. If only the carcass is retained, both retain tags should be placed on the carcass. The large retain tag (US Retain/Reject tag) may be used to retain carcasses for dirty hides. Should you be assigned to a calf slaughter establishment you must become familiar with whatever means are utilized to identify retained carcasses and parts.

Calves are subject to disease and abnormalities as in other species, while some are unique to calves. A few examples of abnormal conditions that might be encountered include:

- Abscesses
- Pneumonia
- Nephritis
- Ringworm - This condition should be detected on ante mortem inspection. It is significant in hide-on calves and would require removal of the hide at the time of slaughter.
- Warts - See Ringworm.
- Grubs - Another hide condition that requires skinning the carcass. Grubs are the larvae of the heel fly, which infects cattle. The primary reason for palpating the backs of calves at postmortem inspection is to check for the presence of these parasites.
- Arthritis
- Icterus - The carcass and parts have a yellow appearance. In true icterus, normally white tissues (such as the tendons and sclera of the eye) are affected.

After carcasses are cold-skinned in the cooler, they must be examined for injection lesions, foreign bodies, parasites, bruises, or other pathology not detectable with the hide still on.

SHEEP AND GOAT INSPECTION

Viscera Inspection

1. Observe abdominal viscera, esophagus, mesenteric lymph nodes, and omental fat.
2. Observe bile duct and content and express gall bladder.
3. Observe and palpate liver (both sides) and costal surfaces of lungs.
4. Palpate bronchial and mediastinal lymph nodes.
5. Observe ventral surfaces of lungs.
6. Observe and palpate the heart.

When certain disease conditions are found, the viscera and carcass will be retained for the veterinarian's final disposition. The usual procedure for tagging is to use two small retain tags, each having identical serial numbers. One tag is attached to the viscera, and the other tag to the leading side of the carcass on the hind leg.

When an unacceptable or improper presentation occurs, you must evaluate the situation and require the establishment to take action you consider necessary. For example, a sheep pluck covered with paunch content is presented to you for inspection. You have been working the assignment all day and this is the first incident to occur today. You would delay your inspection of that pluck until it was cleaned up adequately for inspection. However, it the same situation was occurring frequently, you would have to stop the line and inform establishment management the problem had to be corrected.

Carcass and Head Inspection

1. Observe outer surfaces of carcass, body cavities (pelvic, abdominal, thoracic), and spleen.
2. Observe and palpate kidneys.
3. Palpate sub iliac, scrotal or mammary, and deep popliteal lymph nodes.
4. Palpate back and sides of carcass.
5. Palpate superficial cervical lymph nodes and shoulders and lift forelegs.
6. Observe neck, shoulders, and head.

Following are some of the more common disease conditions in sheep.

- Caseous lymphadenitis – a bacterial infection results in a disease that produces inflammation and resulting caseous (cheese-like) abscesses in lymph tissue. Retain for veterinary disposition.

- Tapeworm - a parasite found in the gall bladder and bile ducts (and occasionally pancreatic ducts). Livers affected with this parasite are condemned for human food; may be salvaged for pet food as an inedible product, provided they are properly handled.

- Nodular worms (*Oesophagostomum* species) – a parasite that produces pea-sized firm nodules on the surface of the small and large intestine, may be associated deterioration of the carcass (thinness, a poor carcass, or an otherwise run-down condition). Retain for veterinary disposition.

- Thin-necked bladder worm - large (3/4 inch or 2 cm), fluid-filled, clear cysts, usually attached to the surfaces of the liver, intestines, mesentery, and omentum. They are frequently also seen in the pelvic cavity. May take the form of an active (live) larva (clear soft cyst membrane and clear fluid contents) or may be degenerated (dead) and appear as firm nodules with a scar tissue or calcified consistency. Condemn organs affected with this parasite and have the pelvic cavity trimmed of any affected tissues, again after correlating with your supervisor.

- Sheep measles (*Cysticercus ovis*) – a parasite is similar to the measles found in cattle because it is found in muscle tissue such as the heart, diaphragm, esophagus, or carcass. The cysts are small (about 1/4 inch of 0.6 cm) and may appear as active, clear fluid-filled cysts or the degenerated firm nodules as described above for the bladder worm. Retain for veterinary disposition.

- Hydatid cysts – cysts are approximately 2-4 inches (5-10 cm) in diameter and may be multi-compartmented, with a white, thick-walled cyst membrane that contains an amber clear fluid that may contain sand-like granules. Occasionally, this thick white membrane will have a very slight clearing of the cyst wall, making it almost transparent. The cysts are most often seen in the lungs and/or the liver. The affected tissues must be condemned to tankage and never allowed for use in pet foods as is allowed with other parasitized product (9 CFR 314.10(a)).

- "Sarco" (*Sarcosporidiosis* sp.) - flat, white parasitic cysts are imbedded in muscle tissue (esophagus, heart, carcass, etc.), having a "rice grain" appearance and being "cigar-shaped bodies" about 1/4 inch (0.5 cm) long. Retain the carcass for veterinary disposition.

- Neoplasia, tumors - growths that can be bizarre or subtle changes of size and/or color of tissues and organs. Retain the carcass and parts for veterinary disposition.

- Pneumonia - an inflammatory disease in which the normal soft "foamy consistency" feel of the lungs and their normal "light-pinkish" color are changed. The color change may vary from a bright red, to reddish-brown, to brown, to gray, to white. The change in the consistency or feel of the lung may vary from the normal "foamy feeling" to firm (slightly or moderately or markedly). These changes may be accompanied by the occurrence of abscesses in the lung tissue itself or in the lung's lymph nodes. Retain the carcass for veterinary disposition.

- Nephritis - kidneys appear enlarged (swollen) or may be partially shrunken with a gristle-type scar tissue in the kidney tissue. Abscesses may be present. Petechiation, a hemorrhage from a small blood vessel, may be observed. The color change may vary from the kidney's normal color to pink, to blood red, to brick-red, to yellow or amber, to dark brown, to almost black. Various-colored radiating streaks can sometimes be seen on the kidney's surface in certain disease states. Retain for veterinary disposition.

- Abscesses - when this condition is localized, condemn the affected area and pass the reminder of the carcass. However, when it is not localized, retain the carcass and viscera for veterinary disposition. When an abscess has been cut into or

opened, there is a real possibility that other parts of the carcass have been contaminated by this pus. Carcasses so contaminated must be trimmed to your satisfaction before you allow it to pass. If the establishment can accomplish this with a minimum of interference to their operations and you find their solution acceptable, you can allow operations to proceed; however, if not, you must delay your inspection (or stop operations if necessary) until the problem is corrected.

- Arthritis - inflammation of the animal's joints. These are often infected and should not be opened (cut into) on the line. The affected joints will be enlarged and regional lymph nodes generally also are enlarged and may be discolored. Several joints may be involved (polyarthritis), particularly in lambs. Other disease conditions may complicate arthritis, such as septicemia, toxemia, or pyemia. Retain for veterinary disposition.

- Emaciation - fat tissue loses its normal white color and semi-firm consistency and becomes a darker color (almost brown), with a jelly-like to fluid-like consistency. Fat around the heart seems to be the first area of the body affected. Retain for veterinary disposition, but if only the fat around the heart is affected, don't retain the carcass and viscera.

- All localized conditions like bruises, contamination, adhesions, etc., are to be removed by a establishment employee before the carcass enters the cooler. An exception is made in the case of "wild oats," otherwise known as "needle grass or grass awns." These are slender barbed bristles that are a part of the cereal grasses, which become embedded in the subcutaneous tissues of sheep as they graze on pasture. They are black or brown wooden-like slender awns about one-half the size of a wooden toothpick when seen on the carcass. They often can be seen but usually are readily palpable. They are not noticeable on the live animal. They are found generally in the subcutaneous tissues over the abdomen (belly) and the thorax (chest) and occasionally on the back and legs. They are found only in certain parts of the country and therefore most lots are totally unaffected. When they are encountered on the production line the carcasses are trimmed, but when they are trimmed depends on how extensively the carcasses are affected and the proportion of carcasses in the lot affected and the establishments' history of cooperation in correcting the problem. If many of the carcasses (a high proportion) are affected and/or those affected carcasses have numerous grass awns in the tissues, FSIS will allow these carcasses to go into the cooler and be trimmed after cooling if the establishment will segregate or group all affected carcasses in one cluster. Further, if the establishment does not cooperate in this provision, then they must trim all affected carcasses in the presence of the FSIS inspector and before each carcass is passed. If there are just a few grass awns on affected carcasses and only a few (a low proportion) of these affected carcasses in the lot, the establishment should trim affected carcasses before they enter the cooler.

This module has not referred specifically to the slaughter and inspection of goats. Since the requirements and inspection procedures in goats are identical to those of sheep, the information on sheep contained herein can be extrapolated to goats.

RATITE INSPECTION

General Information

Ratites are flightless birds with small wings and flat breastbones. The name “ratite” is derived from the Latin word “ratis”, meaning “raft”, describing the shape of the sternum. The sternum of ratites has no keel, is convex to the outside, concave to the inside, and has a somewhat “raft-like” shape. Ostrich, emu, and rhea are members of this family. Ostrich is native to Africa. Emu is native to Australia. Rhea is native to South America. When fully grown, ostriches, which are the largest birds in the world, stand about seven to eight feet tall and can weigh 300 to 400 pounds. Emu are 6 feet tall and weigh 125 to 140 pounds. Adult rheas are 5 feet tall and weigh 60 to 100 pounds. Ratites are long lived. Ostriches can live to seventy years of age, with hens producing eggs for forty years. All ratites have acute hearing and keen eyesight. Their peripheral vision is almost 360°. Although they are unable to fly, they are excellent swimmers and are extremely agile. They have been around for 80 million years.

Ratite meat is available in innovative restaurants and some meat markets. They are the latest in meat products. The birds are 95% usable as meat, feathers, oil, and leather. It is lean and tastes like beef, but contains much less fat. Ratite meat is even lower in calories than chicken and turkey. Ratites are slaughtered at 10-13 months of age. Even though ratites are poultry, they are classified as “red” meat since the pH of their flesh is similar to beef. The raw meat is very dark cherry red. After cooking, the meat looks like beef and the flavor is similar, but a little sweeter. Ratite meat is sold as steaks, fillet, medallions, roasts and ground meat. The most tender meat comes from the thigh or “fan”. Meat also comes from the drum and forequarter. Emu, ostrich, and rhea meat are considered specialty items.

Post-Mortem Inspection

A careful post-mortem examination and inspection will be performed on the carcasses and parts of all ratites slaughtered at official establishments. The purpose of post-mortem inspection is to make a decision about the wholesomeness of each ratite carcass inspected. One of the following outcomes will result from post-mortem inspection, the wholesome is passed, the unwholesome is condemned, and anything questionable is retained for veterinary review. The PHV is responsible for uniform dispositions made on carcasses presented to food inspectors.

If the carcass is wholesome, except for some localized disease condition, it is allowed to continue unrestricted after removal of the affected areas. The diseased portion that is removed is handled the same as any other condemned material. If the carcass is considered unwholesome, the entire carcass is condemned.

The factors to be considered at post mortem exam include:

1. At the time of slaughter, is there evidence that the disease process is being resolved?
   **If it is being resolved it will show evidence of healing. This will be evidenced by connective tissue walling off lesions, minimal evidence of inflammation, and a return to functional activity of the tissues.*

2. Is there evidence that the disease process is remaining about the same?
   **In chronic conditions, there will be areas of active inflammation, areas of inactivity, or areas of connective tissue representing a granulomatous reaction. Function will still be present in the affected tissues*.

3. Is there evidence that the disease process has developed into an irreversible stage?
   **The lesions of the irreversible stage of an interrupted disease process represent extensive degeneration of parenchymatous organs. Classical signs of septicemia/toxemia (systemic change) are present. The bird would not have recovered from the disease if allowed to live.*

Localized lesions are restricted to a limited region or to one or more spots. The bird's immune system is able to keep the disease or condition confined.

Generalized lesions are systemic, affecting major organ systems. The physiologic functions of the interdependent organ systems are disrupted. The cells of the body are deprived of adequate maintenance to support normal function and they deteriorate. This deterioration may be very rapid when highly virulent microorganisms are the cause, or it can be more gradual if less virulent ones are involved.

Post-mortem Procedure

1. A careful post-mortem examination and inspection will be performed on the carcasses and parts of all ratites slaughtered at official establishments.

2. The heart is incised by establishment employees through the interventricular septum. The heart is observed and palpated by the inspector. The lungs are observed and palpated on all external surfaces. The abdominal and thoracic air sacs are observed.

3. The liver and spleen are observed and palpated.

4. The kidneys are observed with the carcass, then removed to an inspection tray and observed and palpated.

5. All other visceral organs are observed.

6. The neck, trachea, and esophagus are observed.

7. The head, eyes, and sinus openings are observed.

8. Internal and external carcass surfaces are observed.

9. Any carcass or viscera exhibiting abnormal physiological or pathological characteristics shall be tagged "U.S. Retained" and railed out for final inspection by a Public Health Veterinarian.

10. Each inspected carcass and all organs and other parts of carcasses which are not found to be adulterated will be passed for human food. The liver, heart, gizzard, and neck are considered edible byproducts if handled and processed in

a sanitary manner. Ratite kidneys are presumed to concentrate heavy metals and therefore are condemned.

11. Each individual carcass is properly washed immediately after being passed for wholesomeness. Following final washing, carcasses are promptly chilled.

12. Official marks and devices to identify inspected and passed products of ratites are found in 9 CFR 381.96.

Multi-species Disposition Basics with a Public Health Focus

Public Health Veterinarian Training
USDA FSIS Center for Learning

Contents

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Introduction – (agency mission, regulatory basis for dispositions, professionalism in performing dispositions)

Public Health Focus–

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Workshop I

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Workshop III

Multi-species Disposition Basics with a Public Health Focus

Objectives

At the conclusion of this module the trainee will be able to:

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 diseases 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

1. 9 CFR Part 309
2. 9 CFR Part 311
3. FSIS Directive 6000.1, Rev. 1, “Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions”
4. FSIS Directive 6020.1, Rev. 1, “Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak”
5. FSIS Directive 6100.1, Rev. 2, “Ante-Mortem Livestock Inspection”
6. FSIS Directive 6100.2, Rev. 1, “Post-Mortem Livestock Inspection”
7. FSIS Directive 6100.3, “Ante-Mortem and Post-Mortem Poultry Inspection”
8. FSIS Directive 6100.6, Rev. 1, “Post-Mortem Dispositions for Public Health Veterinarians”
9. FSIS Directive 6240.1, Rev. 2, “Inspection, Sampling, and Disposition of Animals for Tuberculosis (TB)”
10. FSIS Notice 05-19, “Instructions for Kidney Dispositions in Poultry Carcasses”

Introduction

The mission of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture is to assure the safety, wholesomeness, and proper labeling of meat and poultry for the consumer. 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 parts 309 and 311 of the Meat and Poultry Inspection Regulations and current written policies such as FSIS Directive 6100.2, Rev. 1, "Post-Mortem Livestock Inspection", FSIS Directive 6240.1, "Inspection, Sampling, and Disposition of Animals for Tuberculosis", and FSIS Directive 6100.3, "Ante-Mortem and Post-Mortem Poultry Inspection", FSIS Directive 6100.6, Rev. 1, "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 of the evidence.

Public Health Focus of Disposition Criteria

As a public health agency diseases and conditions that are of public health significance are a priority. The focus of this training will be on the diseases of public health significance. The outcome will be to identify animals on antemortem and postmortem 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 311 and 381 regulations are considered to be of public health significance. In this evaluation, diseases/conditions are deemed of public health significance if it is reasonably likely to present a meat- or poultry- borne (meat-borne) hazard or an occupational hazard to the public and/or FSIS inspection personnel. Food safety hazards of public health significance may contain infectious agents (bacteria, virus, rickettsial, fungus, protozoa or helminth organism) that may cause a 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 the 9 CFR 311 and 381 regulations 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 in this paper because of the probability that the underlying condition, not always determined organoleptically while conducting postmortem inspection, may be reasonably likely to pose a threat to public health.

Many conditions found in the regulations are not of public health significance. Conditions with consumer-protection implications were taken from HIMP (HACCP –based inspection models project) material and it has been used to categorize these conditions found in 9 CFR 311 and 381. HIMP is a pilot project designed to develop, in establishments, approaches based on the pathogen reduction and hazard analysis and critical control point (HACCP) regulations to slaughtering inspection of young, healthy and uniform animals and birds and to improve on the utilization of online slaughter inspectors. As part of the development of HIMP, animal diseases and conditions observable at postmortem inspection that pose food safety hazards or risks needed to be distinguished from diseases and conditions that present other consumer protection issues. Conditions under consumer-protection implications may adulterate product, but are not food safety hazards. In the consumer-protection implication (CPI) category, localized lesions are removed and the unaffected portion of the carcass is passed. Carcasses with generalized conditions would be condemned or treated to render 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 protect the public health by ensuring that meat and poultry are safe and wholesome. 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 the 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 - Any new and abnormal growth of tissue serving no physiological function; specifically, a growth of tissue in which 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 as a result of the transfer of cells via the general circulation, the lymphatic system, or within a body cavity (transcelomic).

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 description 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 in 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 of 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 such small lesions are occurring around an older focus.

Acute - In general, acute refers to a period of time 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 signs are seen on antemortem, systemic lesions on postmortem.

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 is a reflection of 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.

<u>Terms that apply to pathologic conditions affecting the carcass as a whole</u>

Bacteremia - The presence of bacteria in the blood. Not associated with systemic illness but may be associated with a focus of inflammation that provides a continuing supply of organisms.

Septicemia - A syndrome of septic bacteremia 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. Fever, chills, sweating, jaundice and abscesses in various parts of the body mark the condition.

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 by it throughout the living body.

Toxemia - A generalized intoxication due to the absorption and circulation in the blood of bacterial products (toxins) formed at a localized source of infection.

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 constitutional disorder, general ill health and malnutrition; a general physical wasting and malnutrition usually associated with chronic disease.

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 the 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 - Fat, muscle, tendons, and bone of the carcass, as opposed to the tissues of organs.

Organs - 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 can not be removed by trimming.

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.

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

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 data as ownership; geographical, herd, or lot origin; 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 history is available it is regarded as highly beneficial, though history is often unavailable.

Examination

Routine antemortem and postmortem 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 antemortem and all carcasses retained for veterinary disposition at postmortem inspection. The examination of all nonambulatory animals (excluding cattle- which are condemned by regulation) must include taking the temperature of the animal. Other animals that must have the temperature taken during the examination include TB Reactors and any animal which may be febrile.

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 in the examination process as possible, 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. 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 whether a tissue is:
1. Not adulterated, designated either as "residue not detected" or "positive but non-violative"; or
2. Adulterated, designated as "residue detected at a violative level." See FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program.

Diagnosis

A diagnosis is a definitive summary of all of the facts regarding a particular case. As such, a diagnosis may be made either after the PHV's examination at antemortem or postmortem.

As the examination is performed, the PHV should use a logical thought process to support a diagnosis. The following factors are important:

1. Correlate antemortem findings with postmortem 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 311.11 (b) to be condemned regardless of the extent. Another example would be temperatures at antemortem 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 the Meat and Poultry Inspection Regulations 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 a 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. Is the condition one that would 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.

Antemortem Disposition Choices

Livestock examined by a veterinarian on antemortem inspection will be either:

1. Passed for regular slaughter; or

2. Passed as a “U.S. Suspect”; or

3. Identified as “U. S. Condemned.”

Postmortem Disposition Choices

A carcass may be passed for food or condemned, but there are other possibilities that lie between these two extremes. The postmortem 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. Hold carcass and parts pending laboratory tests.

5. Pass the carcass and parts with restrictions as follows:

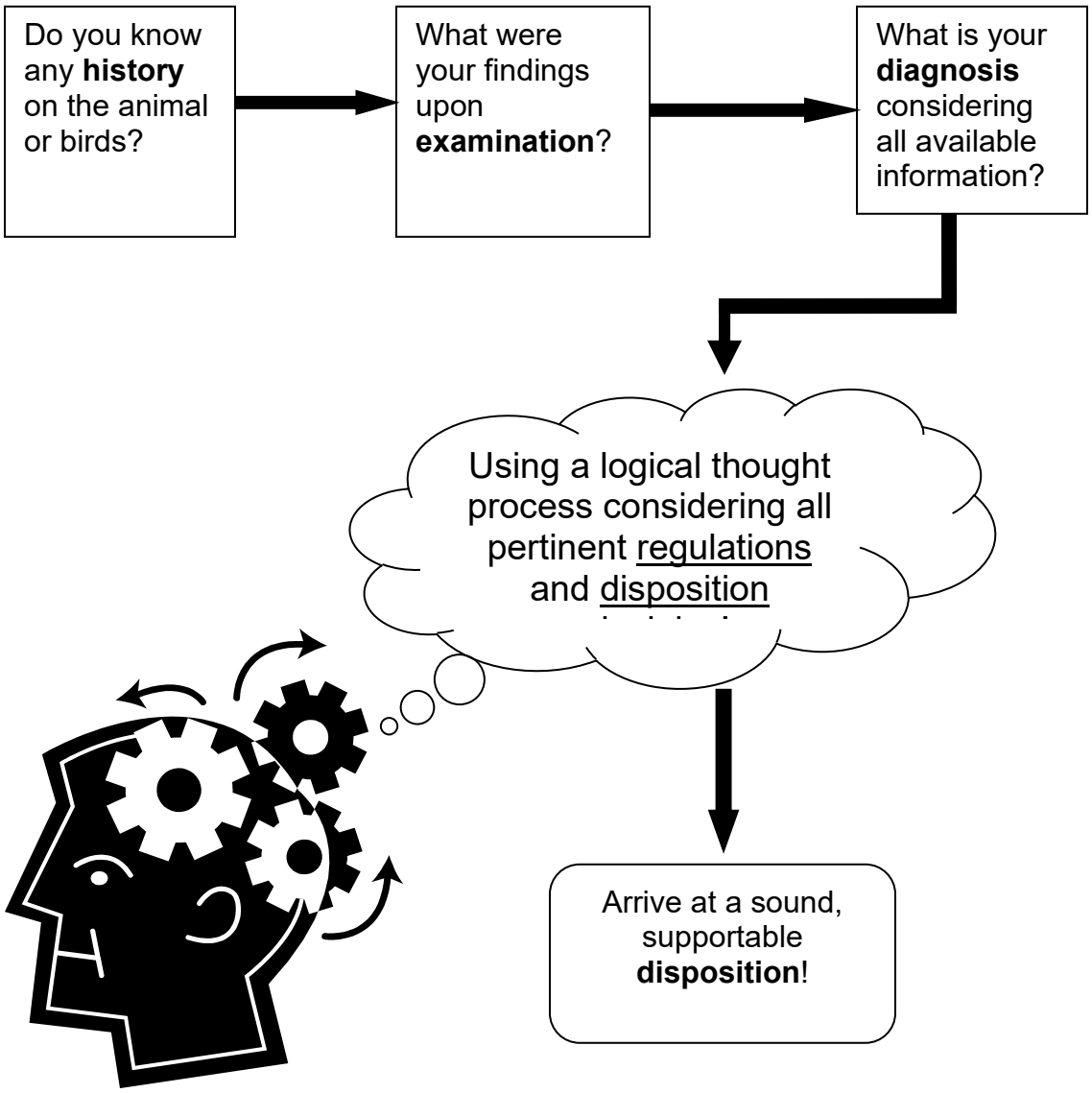
    a. Pass for heating: Heat thoroughly to an internal temperature of at least 140° F (e.g., certain cases of Cysticercus bovis or Cysticercus ovis).

    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!

Workshop I

1. What are the four basic components of the disposition thought process?

2. Which animals must be examined by a Public Health Veterinarian (PHV) at antemortem? Which carcasses at postmortem must be examined?

3. Which animals at antemortem should have their temperature taken as part of the examination by the PHV?

4. What are 6 questions you will consider as part of the thought process in arriving at a sound, supportable disposition?

5. What are the options for disposition at antemortem? At postmortem?

6. What is the difference between public health significance and regulatory disposition requirements?

Livestock Diseases and Conditions of Public Health Significance

Central Nervous System Conditions at Antemortem

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 antemortem 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 antemortem.

The Public Health Veterinarian (PHV) must keep in mind that condemning an animal on antemortem means either that the establishment shall kill the animal as stated in 9CFR 309.13(a); the livestock may be set apart and held for treatment as stated in □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 □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 antemortem 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 Veterinary Services. Because of the possible threat of adulterating our beef supply with a spongiform agent, it imperative that any cattle presented for antemortem inspection with signs of any central nervous system disorder be condemned and the appropriate APHIS (Veterinary Services) officials notified immediately.

The Food Safety and Inspection Service 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 antemortem and/or postmortem inspection(s).” FSIS 12-37-MU-334 A.5., page 2. Additionally, FSIS agrees, “When...reportable diseases or exotic diseases of foreign origin are suspected...during ante- or post-mortem inspection, the Area Veterinarian-in-Charge (AVIC) for Veterinary Services (VS) should immediately be notified.” FSIS 12-37-MU-334, Appendix 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 antemortem pens to keep them from overheating. If the water gets in the external ear canal, the affected pig will tilt its head.

The antemortem disposition thought process is similar in all cases with animals presenting with central nervous system disease.

Metabolic Disorders

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 month old calves fed exclusively milk.

Antemortem 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.

Antemortem disposition

Regulation §309.4(a) requires, “All livestock showing, on antemortem 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.” And §309.13(b) states, “Any livestock condemned on account of...ketosis,...or inflammatory condition 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 antemortem 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem findings may include the following:

Restlessness and incoordination are the early signs, followed by sternal recumbency, coma, and death.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Pregnancy Toxemia in Sheep (Ovine Ketosis)

A metabolic disorder (hyperketonemia with variable hypo/normo/hyperglycemia) of preparturient (usually undernourished) ewes.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

The regulations do not specifically address PSS but they do address transport tetany in §309.4(a) and §309.13(b). These regulations would apply to PSS.

Follow the same disposition process as discussed in hypomagnesemic tetany.

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.

Antemortem 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.

Antemortem disposition

Polioencephalomalacia is not specifically mentioned in §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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Regulation §309.4(a) requires, “All livestock showing, on antemortem 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 of 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.

Antemortem 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.

Cattle and smaller ruminants have a shorter clinical course and progress from excitement, trembling, and anxiety to incoordination, convulsion, coma, and death.

Pruritus is accompanied by extreme efforts to relieve itching.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Regulation §309.4(a) requires, “All livestock showing, on antemortem 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 of 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 prion 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, Cruetzfeldt-Jakob Disease [CJD], Gerstmann-Straussler-Scheinker syndrome, and fatal familial insomnia (humans). The TSEs have also been observed in a number of 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. As of December 2007, there is no antemortem test for BSE although much work is being done in this area.

Antemortem 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.

Antemortem disposition

Follow the same disposition thought process as previously discussed (i.e., condemn the animal and notify APHIS).

Scrapie

Scrapie is a progressive neurological disorder of sheep, possibly caused by an abnormally shaped protein called a prion. This is a transmissible (and possibly inherited) spongiform encephalopathy.
Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

§309.4(a) requires, “All livestock showing, on antemortem 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 of 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, §309.3(a), or condemned for comatose or semicomatose condition or...any condition...which would preclude release of the animal for slaughter of human food... □309.3(d), or

Condemned for toxic encephalomyelitis, □309.4(a), □311.10(a)(8)

Any cattle presented for antemortem 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.

Arsanilic Acid Poisoning

This poisoning occurs in pigs as a result of ingestion of excessive amounts of organic arsenical growth promoters. The CNS lesions are myelin and axonal degeneration in the optic and peripheral nerves.

Antemortem findings may include the following:

Affected pigs progress from hindlimb ataxia to tetraparesis.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Organochlorine (Chlorinated Hydrocarbons) Poisoning

Poisoning by organochlorines (aldrin, aphene, benzene hydrochloride, chlordane, dieldrin, endrin, heptachlor, lindane, and methoxychlor) causes stimulation of the central nervous system, manifested by colic or neurological signs.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Organophosphate (OP) Poisoning

Poisoning by organophosphates (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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Paspalum Staggers

Ingestion of paspalum grasses infested by the fungus Claviceps paspali. Cattle, sheep, and horses are all susceptible.

Antemortem findings may include the following:

Continuous trembling, jerky and incoordinated movements, falling, and paralysis.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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 heart beat, and brown mucous membranes.

Antemortem disposition

Follow the same disposition thought process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem findings may include the following:

Visual problems, excitability, incoordination, depression, head tremors, and shivering.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem findings may include the following:

Pigs show various CNS signs including deafness, blindness, aimless wandering, headpushing, circling, clonic-tonic seizures, opisthotonos, paddling, and coma.

Cattle CNS signs are blindness, seizures, and partial paralysis.

Antemortem disposition

Follow the same disposition process as discussed in 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.

Antemortem 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.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Senecio Poisoning

Senecio poisoning (seneciosis, ragwort toxicity, pyrrolizidine alkaloidosis) is caused by ingestion of a number of plants containing hepatotoxic alkaloids with a pyrolizidine base.

Antemortem findings may include the following:

The CNS signs are stumbling, headpushing, weakness, and aggressiveness.

Antemortem disposition

Follow the same disposition process as discussed in hypomagnesemic tetany.

Nonambulatory Animals

The regulations at 9 CFR 309.2(b) state 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, the regulation at 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 Significance

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, mycohemia, 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 postmortem, 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 of 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 but, if the disease progresses and overwhelms the animal’s immune system, pathogens may gain access to the carcass tissues and result in a septicemia and thus pose a food safety hazard.

Antemortem 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. Each case will have to be independently assessed by the PHV.

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

Antemortem disposition (Regulation 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 postmortem.

Suspect: All animals indicating signs and lesions of septicemia, but not conclusive evidence.

Postmortem 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 serous surfaces)

Sero-sanguinous fluid in abdominal and or thoracic cavities

Injection sites (recent)

Edema or other evidence of acute generalized inflammation

Postmortem disposition (Regulations 311.16, 311.17)

Condemn: In cases of generalized disease as a result of infected wounds or bruises, or when the primary pathology is masked and associated manifestations are present as outlined in the antemortem and postmortem 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 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.

Antemortem 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. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

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

Antemortem disposition (Regulations Part 309.2, 309.4)

Condemn: Animals showing conclusive signs of toxemia.

Suspect: Animals indicating signs and lesions, but not conclusive evidence, of toxemia.

Postmortem findings may include the following:

Petechial or ecchymotic hemorrhage (most noticeable in kidneys, epicardium, lungs, and serous surfaces)

Generalized, acute lymphadenitis

Degeneration of tissues or organs

Presence of areas of tissue necrosis

Postmortem disposition (Regulations 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 Note:

(1) Chronic lymphadenitis due to a previous infection or condition should not be confused with a toxemia.

(2) An enlarged pale liver from a pregnant animal nearing delivery should not be confused with a liver associated with a toxemia. Although a form of hepatic lipidosis may be seen in either, the postmortem array of lesions in one condition should not be confused with the tissue and organ changes in a periparturient carcass).

Special Note: The term toxemia should only be used for disposition purposes when a specific 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.

Antemortem findings may include the following:

Depression or lethargy

Variable temperature—depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

Swollen joints

Umbilical abscess

Subcutaneous abscesses

Cachexia

Scirrhous cord (funiculitis)

Antemortem Disposition (Regulations Part 309)

Condemn: Any combination of significant findings that would give evidence that the carcass would be condemned on postmortem, e. g., abscesses, as well as generalized (systemic) signs.

Suspect: Animals showing signs and lesions, but not conclusive evidence, of pyemia.

Postmortem 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 Note:

(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.

Postmortem disposition (Regulations 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 postmortem 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 (Sec. 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 postmortem inspection activities at establishments that slaughter livestock. The establishment must meet the slaughter food safety tolerance standard for visible contamination at the postmortem 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).

More information will be provided on "zero tolerance" during a later part of the 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.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem 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 live, dead, or degenerated.

The live cysts will appear as a vesicle or small bladder (balloon) filled with fluid. In most cases, the cyst will be dead, and 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 Note:

(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 procedure

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

Postmortem disposition (Regulations 311.23)

Special Note:

(1) When cysticercosis is detected during routine postmortem 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) Make one incision into each round, exposing the muscles in cross-section, and one transverse incision into each forelimb, commencing two or three inches above the point of the olecranon and extending to the humerus and expose the triceps brachii, totaling four incisions. Observe the cut surfaces for cysticercosis lesions.

Condemn: The carcass and its parts should be condemned when lesions of cysticercosis are present and:

The musculature is edematous or discolored, or

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).

Passed with Processing Restriction: 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.

Passed for Refrigeration

Carcasses—Hold 10 days at not higher than 15°F

Boned meat—Hold 20 days at not higher than 15°F

Passed for Heating

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 shall be 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 procedure: 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) Multiple incising of the interventricular septum and external and internal muscles of mastication. Close observation should also be made of 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 soleum.* It is of public health significance because it is transmissible to humans.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem findings may include the following:

Muscle is edematous or discolored

Cysts in muscle 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.

Postmortem disposition

Detailed Examination Procedure: When cysticercosis is detected during postmortem inspection, the following procedures is used by the PHV:

(1) Examine the cheeks, heart, and esophagus by sight and numerous incisions. Make several deep longitudinal incisions into the tongue.

(2) Remove the peritoneum from the diaphragm and examine the muscles of the diaphragm by numerous incisions.

(3) Carefully examine the cut surfaces of muscles exposed during regular dressing procedures (ventral muscles of the ham). 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).

(4) Make incisions parallel to 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 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: 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.

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 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 (Regulation 315.1, 315.2). Verify removal of U.S. Retained tags only after the product has met the processing restrictions in 9 CFR 311.24.

Poultry Diseases and Conditions of Public Health Significance

Septicemia/Toxemia 9 CFR 381.83 Carcasses of poultry showing evidence of any septicemic of toxemic disease, or showing evidence of an abnormal physiologic state, shall be condemned.

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.

In septicemia 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 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 (remove 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.

Toxemia, poisoning caused by the absorption of toxins produced by infective organisms, shows signs similar to septicemia. Both conditions often exist simultaneously.

Septicemia/toxemia is commonly referred to as sep/tox. If a carcass shows systemic change, it is condemned. Once a diagnosis of sep/tox has been made the carcass must be condemned.

Contamination 9 CFR 381.91
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 new regulations were 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 operations* 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 381.65(f), this is a review from the Inspection Methods 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 6420.2, Verification Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations, and FSIS Notice 64-14, Verifying an Establishment’s Procedures for Preventing Contamination by Enteric Pathogens and Fecal Material. During performance of the Poultry Zero Tolerance Verification task, how we verify inspection results will depend on how he establishment incorporates their written procedures into their food safety system.

If FSIS IPP find visible fecal contamination while conducting the Poultry Zero Tolerance Verification task and the establishment incorporates written procedures into the:
HACCP Plan: conduct a PHIS Slaughter HACCP Verification task and verify 417.3(a)
SSOP: conduct an Operational SSOP review and observation to verify 9 CFR 416.15
Prerequisite Program: conduct a PHIS HACCP slaughter verification task and verify 417.5(a)(1)
In either instance you will cite 9 CFR 381.65(f), for the establishments failure to prevent feces from entering the chiller.

9 CFR 381.91(a) Contamination: Carcasses of poultry contaminated by volatile oils, paints, poisons, gases, scald vat water in the air sac system, or other substances which render the carcass adulterated shall be condemned. Any 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 391.91(b) Any carcass accidentally contaminated during slaughter with digestive tract content need not be condemned if promptly reprocessed under the supervision of an inspector and therefore found not to be adulterated. Carcasses contaminated with fecal material must be reconditioned by either trimming or a combination of trimming and washing with hyperchlorinated water. 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. There is additional guidance on reprocessing in FSIS Notice 50-14: Verification of Online Reprocessing (OLR) and Offline Reprocessing (OFLR) Antimicrobial Intervention Systems. It explains that 9 CFR 381.91 was amended to permit poultry slaughter establishments 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.

Workshop II

1. Give as many examples as you can of signs that could indicate a Central Nervous System (CNS) disorder?

2. What is the disposition for an animal that is exhibiting signs of a CNS disorder?

3. What other action should be taken for cattle showing CNS signs?

4. What is the disposition for a nonambulatory cow?

5. What are some postmortem findings that could indicate septicemia in livestock?

6. What are some postmortem findings that could indicate pyemia in livestock?

7. What are the usual inspection sites for cysticercosis in cattle?

8. What are some findings that could indicate septicemia/toxemia in poultry?

9. What is the disposition for any livestock or poultry condition ending with the suffix “emia”? Why?

10. Why is contamination with feces considered to be a public health safety issue? What about septicemia – why is it a public health hazard?

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 (9 CFR 311.14) is a localized, “walled off” area of pus. Pus, according to Dorland’s Medical Dictionary, is “a liquid inflammation product made up of cells and a thin fluid called Liquor puris.”

Antemortem findings may include the following:

Swellings may be evident in various parts of the animal

Antemortem Disposition (Regulations Part 309)

Condemn: Any combination of significant findings that would give evidence that the carcass would be condemned on postmortem, e. g., abscesses, as well as generalized (systemic) signs.

Suspect: Animals showing signs and lesions, but not conclusive evidence, of pyemia.

Postmortem 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.

Postmortem disposition (Regulations 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 (9 CFR 311.14).

Arthritis

Arthritis is the inflammation of joint tissues that may be traumatic or infectious in origin.

Antemortem findings may include the following:

Enlargement of one or more joints

Abnormal locomotion

Variable temperature—depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

Painful or abnormal stance and movement

Reluctance to move or stand

Depression

Cachexia

Infected navel in young animals

Special Note: Transport injury (sore feet)—this also can result from pigs being raised on concrete and must be distinguished from arthritis.

Antemortem disposition (Regulations 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 postmortem examination the carcass may need to be condemned.

Postmortem 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 or not the condition is generalized (systemic) is of most public health importance.

Postmortem disposition (Regulations 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. (9CFR 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.

Antemortem 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

Antemortem disposition (Regulations 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.

Postmortem 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)

Edema of body tissues and fluid accumulations (ascites, pleural effusion)

Putrefactive odor of cut-surface of pericardial, abdominal, or thoracic lesion

Postmortem disposition (Regulations 311.16)

Condemn: When there is a 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.

Antemortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

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

Antemortem disposition (Regulations 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.

Postmortem 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

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

Postmortem dispositions (Regulations 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.) (Regulations 311.1)

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.

Antemortem findings – same as pneumonia

Antemortem disposition (Regulations 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.

Postmortem 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.

Postmortem dispositions (Regulations 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.) (Regulations 311.1)

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, or other irritants.

Antemortem 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; each case will have to be independently assessed by the PHV.

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

Antemortem disposition (Regulations 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.

Postmortem 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

Postmortem disposition (Regulations 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.

Antemortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

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

Antemortem disposition (Regulations 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.

Postmortem 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

Postmortem disposition (Regulations 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.

Antemortem findings may include the following:

Variable temperature—depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

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., grinding of teeth, kicking at abdomen, switching of tail).

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.

Antemortem disposition (Regulations Part 309)

Condemn: A specific diagnosis of nephritis is not really 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 postmortem inspection.

Postmortem 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: Certain conditions should not be confused with primary nephritis:

(1) Kidney worms in swine

(2) Urinary obstructions (uroliths)

(3) Infarcts

(4) Neoplasms

(5) Renal cysts or polycystic kidneys

(6) Hydronephrosis

(7) Traumatic injuries

(8) Depressed white areas—scars resulting from previous infarcts or nephritis

Postmortem dispositions (Regulations 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.

Antemortem 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. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV.

Purulent to sero-sanguinous exudate

Gangrenous blue-black discolored area may be sloughing

Antemortem disposition (Regulations Part 309)

Condemn: Any animal with mastitis exhibiting generalized signs.

Suspect: Animals with mastitis having sufficient clinical signs to indicate that the carcass will likely be condemned on postmortem 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.

Postmortem 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

Postmortem disposition (Regulations 311.16)

Condemn: 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.

Antemortem 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

Antemortem disposition (Regulations 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. Any animal treated for retained fetal membranes should meet withdrawal times for any medication used.

Postmortem 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.

Postmortem disposition (Regulations 311.16)

Condemn: 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.

Antemortem findings may include the following:

Foot rot

Cachexia

Dyspnea

Nasal discharge

Pyrexia

Antemortem disposition (Regulations 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 postmortem examination the carcass may need to be condemned.

Postmortem 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.

Postmortem disposition (Regulations 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*.

Antemortem 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 022A

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

Antemortem disposition (Regulations 309.2)

Condemn: If fever and signs of acute erysipelas are present, indicating the carcass would be condemned on postmortem

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.

Postmortem 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

Postmortem dispositions (Regulations 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 C*orynebacterium pseudotuberculosis*.

Antemortem 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

Antemortem 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.

Postmortem 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 (resembles 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 (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.

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 - 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. As applied to tuberculosis lesions in lymph nodes, extensive means that the lymph node is greatly enlarged, or nearly all of 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.

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

Postmortem disposition (Regulations 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

(1) 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.

(2) 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 of these conditions.

Certain conditions can be confused with "acti" on antemortem:

(1) Abscessed teeth

(2) Sinusitis

(3) Injuries

(4) Lymph node metastasis of squamous cell carcinoma

(5) Sialoadenitis, sialoliths, cysts

(6) Neoplasms

(7) Food impacted in the jaw (especially in old cows)

Antemortem 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

Antemortem disposition (Regulations Part 309)

Condemn: Livestock plainly showing, on antemortem inspection, actinobacillosis or actinomycosis to the extent that, under Meat and Poultry Inspection Regulation part 311, it would cause condemnation of the carcasses on postmortem inspection, shall be identified as U. S. Condemned and disposed of according with part 309.13.

Suspect: Any animal having actinobacillosis or actinomycosis to a lesser degree than that requiring condemnation

Postmortem 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 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 postmortem 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

Postmortem disposition [Regulations 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. (Regulations 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 Animal and Plant Health Inspection Service (or State or accredited veterinarian) are accompanied by APHIS Form V.S. 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 antemortem 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. (Also refer to 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 [referred to in (1) above], TB suspects, or TB-exposed animals and must identify them to the PHV before antemortem inspection is performed (FSIS Directive 6240.1).

(4) The FSIS PHV performs all of the antemortem and postmortem 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 antemortem.

(6) Special references for all species includes the Meat and Poultry Inspection Regulations (9 CFR 311.2) and FSIS Directives 6240.1, Revision 2, “Inspection, Sampling, and Disposition of Animals for Tuberculosis.”

(7) Bovine mycobacteriosis is defined as cattle having Mycobacterium bovis [FSIS Directive 6240.1, Inspection, Sampling, and Disposition of Animals for Tuberculosis,]. However many pathologists also refer to Johne’s Disease (M. paratuberculosis) in cattle as mycobacteriosis.

Antemortem findings may include the following:

Weakness

Weight loss

Cachexia.

Low-grade fever.

Intermittent, "hacking" cough

Superficial lymph nodes swollen and firm

Antemortem disposition (Regulations 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 postmortem examination that includes the expanded postmortem 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 has to be condemned on antemortem, it shall be given a thorough postmortem examination using the procedure described above (FSIS Directive 6240.1).

Suspect: All reactors are identified U.S. Suspects (using the USDA Reactor tag in lieu of Suspect tag)

Postmortem 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 of 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 postmortem 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 V.S. 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 postmortem 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 postmortem 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

- 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.
- 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 postmortem 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 postmortem inspection.

(6) When cattle without any special tuberculosis designation, as well as those identified as TB- exposed and TB suspects, are found on postmortem inspection to have thoracic granulomas or other lesions suspected of being tuberculous, the PHV shall perform the expanded postmortem 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 postmortem:

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

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.

Postmortem disposition (Regulations 311.2)

Special Notes:

(1) Laboratory assistance:

A. For cattle, TB-exposed and TB-suspect specimens, send V.S. Form 10-4 with the specimen to the USDA/APHIS National Veterinary Services Laboratory (NVSL), Ames, Iowa.

B. For cattle, a routine postmortem on nonreactors, send V.S. 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*.

C. For swine, the specimen should be sent with a completed FSIS Form 10,300-2 to the USDA/FSIS Eastern Laboratory, Athens, Georgia, unless lesions of generalized thoracic granulomas are found, in which case 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) [Reg. 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 antemortem.

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 [Reg. 311.2 (b)]:

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.

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 [Reg. 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 [Reg. 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 [Reg. 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. [Reg. 311.2(g)].

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 [Reg. 315.1].

1. Cattle [Reg. 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 [Reg. 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: Public Health Veterinarians should incise and observe all body lymph nodes of carcasses retained for tuberculosis with the following exceptions:

a. Incisions of body lymph nodes may be omitted when lesions are in the lymph nodes of head and mesentery only.

b. Incision of superficial cervical (prescapular) lymph nodes may be omitted when caudal deep cervical lymph nodes (prepectorals) and thoracic pleura have no lesions.

c. 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 [Regulations 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.

Antemortem findings and disposition - not detectable on antemortem.

Special Notes:

(1) Usually these granulomas are a sequelae 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 in 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.

Postmortem 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

Postmortem disposition (Regulations 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

Antemortem 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.

Antemortem 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 309.13.

Postmortem 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

Postmortem disposition

Condemn:

1. Carcasses showing extensive, generalized bruising that cannot be removed by trimming.

2. Bruised or injured carcasses that show 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 nonseptic bruises or injuries is eligible for animal food (pet food) provided:

A. The Frontline Supervisor has granted permission. (Regulations 314.11)

B. All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 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 postmortem descriptive term and does not in any way apply to antemortem inspection.

(2) A thin animal may be a normal animal with small amounts of body fat.

(3) Cachexia is an antemortem descriptive term that indicates a chronic wasting condition.

Antemortem findings

Poor condition, tight skin or wrinkled skin

Weakness, debilitation

Rough hair coat, may be patchy

Sunken eyes

Gauntness

Depression

Antemortem disposition

Condemn: This should not occur; emaciation is a postmortem 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 antemortem inspection.
Emaciation

Postmortem 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 fairly 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 the 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.

Postmortem disposition (Regulation 311.16)

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. (Regulations 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 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.

Antemortem 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

Antemortem disposition

Condemn: When the condition has progressed to advanced stages and is characterized by an extensive edema

Suspect: When the condition appears on antemortem to be localized

Postmortem findings may include the following:

Edema in brisket, shoulder, and shanks.

Hydropericardium

Ascites

Hydrothorax

Postmortem disposition

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. (Regulations 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 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.

Antemortem 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

Antemortem Disposition

Condemn: When the condition has progressed to advanced stages and is characterized by an extensive edema

Suspect: When the condition appears on antemortem to be localized

Postmortem 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

Postmortem Disposition

Condemn: When the condition is in advanced state and is generalized

Pass: When localized, after removal and condemnation of affected tissues

Uremia

Uremia is an intoxication caused by the accumulation of waste materials in the blood which is normally excreted through the kidneys.

Antemortem findings may include the following:

Variable temperature

Urine infiltration of ventral body wall from urethral rupture

Urinary odor to exhaled breath

Special Note:

Animals showing early signs of blockage of urinary tract, e.g., anxious expression, twitching of ears, restlessness, tenesmus, and possibly frequent attempts to urinate.

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.

Antemortem 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

Postmortem 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

Postmortem Disposition

Condemn:

(1) Carcasses that exhibit a urine odor, regardless of the cause

(2) When it is possible to identify the primary cause based on postmortem 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.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem findings may include the following:

Any sex odor of carcass or viscera of any swine

Postmortem disposition (Regulations 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.

Antemortem findings may include the following:

Muscular incoordination

Inability to stand and walk normally

Lack of muscular development
Antemortem 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.

Postmortem findings may include the following:

Muscle tissues have 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
Postmortem disposition

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.

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 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 unknown at this time.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem 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.

Special Notes:

Some other conditions are noteworthy as possibly being confused with eosinophilic myositis, especially by less experienced inspectors:

(1) Cysticercosis—however, the lesions are usually much larger than EM lesions

(2) Steatosis—where normal fat has replaced muscle tissue

(3) Muscle degeneration

(4) 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.

(7) When lesions of eosinophilic myositis are observed during routine postmortem inspection, the following procedures should be used:

(a) Thoroughly incise and observe the lateral and medial masticatory muscles and heart

(b) Observe and palpate the esophagus.

(c) Make several deep longitudinal incisions into the tongue.

(d) Thoroughly incise and observe diaphragm and pillars after removal of peritoneum.

(e) Observe cut surfaces of muscles exposed during the dressing operations (ventral muscles of neck, brisket, medial muscles of round).

(f) When lesions are in any of the locations in (a-e) 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.

(g) If lesions are in any cut surface exposed during the preceding procedures, the affected primal part should be freely slashed and closely examined.

(8) 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.

(9) Incisions made transverse to muscle fibers usually give the best exposure of lesions.

(10) When performing the expanded inspection procedures, you should strive to avoid excessive carcass mutilation.

Postmortem disposition (Regulations 311.35)]

When lesions are extensive and impractical to remove:

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.

When lesions are slight or complete removal is uncertainly accomplished:

Pass for comminuted cooked product: If the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness, 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.

Condemn affected parts when localized lesions are present and only certain parts are affect (head, tongue, heart, esophagus, diaphragm, and pillars).

When lesion removal is practical:

If muscular lesions are found to be distributed in such a manner or to be of such character that removal is practical, the following rules shall govern the disposal of the carcasses, edible organs, and other parts of carcasses:

(1) If a part has numerous lesions, or if the character of the lesion is such that complete removal is difficult and uncertainly accomplished, or if the lesion renders the part in any way unfit for human food, the part shall be condemned.

(2) If the lesions are localized in such a manner and are of such a 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 would be as summarized in the following chart:

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
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. (Regulations 314.11)

(2) All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 314.11)

Skin Conditions

Skin conditions are varied and many are very nonspecific, including conditions such as dermatitis, erythema, urticaria, and photosensitization.

Antemortem findings may include the following:

Erythema

Photosensitization

Burns

Parasites—lice and mites

Pruritis

Alopecia

Ringworm

Antemortem 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.

Postmortem 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 as a result of being in the scald vat for too long or at too high a temperature

(2) Erythema and bruising caused by improper antemortem handling

Postmortem dispositions

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.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem findings may include the following:

Generalized hyperemic appearance to carcass and viscera

Possible absence of stick wound

Water-logged lungs

Postmortem disposition

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 makes a very unsound product and also 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.

Antemortem findings—not applicable

Antemortem dispositions—not applicable

Postmortem 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

Postmortem disposition (Regulations 311.25(b)]

Detailed Examination Procedure: When cysticercosis is detected during routine postmortem 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.

Antemortem findings—not specific for disease, so cannot correlate disposition to disease

Antemortem disposition—disease signs not specific for disease, so can't correlate disposition to disease

Postmortem 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.

Postmortem disposition

Detailed Examination Procedure: When sarcocystosis is detected during routine postmortem 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:

The Frontline Supervisor has granted permission. (Regulations 314.11)

All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 314.11)

Stephanuriasis (Swine Kidney Worms)

A parasitic condition due to the presence of *Stephanurus dentatus* in the carcass tissues.

Antemortem findings—not specific for disease, so can't correlate disposition to disease

Antemortem disposition—signs not specific for disease, so cannot correlate disposition to disease

Postmortem findings may include the following:

Adult kidney worms
Lesions:

Pelvic inlet, pelvic and femoral canal

Abdominal lining

Muscle-primarily loin and ham muscles

Organs-primarily kidney, liver, pancreas, spleen, and lungs

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.

Postmortem disposition

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. Check in particular 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 in 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 antemortem, 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.

Antemortem findings may include the following:

Anemia, pale mucous membranes

Icterus

Variable temperature

Debilitation

Listlessness

Polypnea

Antemortem disposition

Condemn: All animals showing signs of this disease on antemortem.

Suspect: All animals that have reacted to a test for the disease, but which show no signs

Postmortem 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.

Postmortem disposition

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.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem findings may include the following:

Melanin pigment in lungs, liver or other organs

Melanin in skin

Melanin in eye

Melanin associated with inflammation

Postmortem disposition (Regulation 311.13)

Condemn:

Carcasses with generalized pigmentary deposits shall be condemned

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

Slight melanin deposits in spinal meninges are insignificant. However, when extending into spinal nerves and into meat, they must be removed.

Pass:

When localized, pigmentary deposits can be effectively removed and condemned.

Uniform melanin deposits over or in circumscribed skin areas of swine are not required to be removed unless they are tumorous or smeary.

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 an intoxication, such as copper toxicity.

Antemortem findings may include the following:

Yellowish discoloration of sclera

Extensive greenish-yellow discoloration of skin (white hogs only)

Antemortem disposition

Special Note: Findings of icterus are inconclusive making condemnation for icterus on antemortem 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 definitely established that the animal is icteric

Suspect: All animals with inconclusive evidence of icterus should be handled as suspects.

Postmortem 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 Note: 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.

Note: Fat may be yellow due to diet, breed, and age changes that are essentially normal. Yellow fat is normal in some animals.

Postmortem disposition (Regulation 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 with the exogenous pigments. When carotenoid pigments are deposited in the fat tissues and liver to the extent they become grossly visible, the resulting discoloration of tissues is carotenosis.

Antemortem findings—not applicable

Antemortem disposition—not applicable

Postmortem 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)

Postmortem disposition Regulation 311.31(a)

Condemn: Livers with carotenosis are to be condemned

Special Notes:

Deposition of carotenoid pigments in the fatty tissue does not affect carcass disposition.

Place a white paper towel or napkin on the cut surface of the liver. A bronze-orange stain indicates carotenoid pigment.

Xanthosis (Brown Atrophy)

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 postmortem. More commonly affects heart and head musculature.

Antemortem findings—not relevant

Antemortem disposition—not relevant

Postmortem findings may include the following:

Cardiac muscle

Muscle of head

Carcass muscle less frequently

Special Note: Affected muscle has dark brown or coffee-colored discoloration of otherwise normal tissue.

Postmortem Disposition

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.

Antemortem findings may include the following:

Cutaneous growths (warts)

Antemortem disposition

These affect the skin and should not impact postmortem decisions.

Condemn: When livestock plainly show any disease or condition that would cause condemnation of their carcasses on postmortem

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 postmortem

Postmortem findings may include the following:

esophageal lesions

rumen lesions

Postmortem disposition

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.

Antemortem findings— not a consideration

Antemortem disposition—not relevant on antemortem

Postmortem 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

Postmortem disposition

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.

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 multicentric origin of neoplasm. The tumors may be firm or soft and often have gelatinous centers and appears as a shiny, glistening, white-to-gray, lobulated, firm nodular growth on or within the nerve. When identified on postmortem inspection, be sure to examine brachial and coeliac plexus for lesions.

Antemortem findings—not normally recognized on antemortem

Antemortem disposition—not relevant

Postmortem findings

Along spine

Along ribs

Brachial plexus

Celiac plexus

Heart

Tongue

Note: Examine the brachial and celiac plexus for lesions when IPP find neurofibromas when performing post-mortem inspection.

Postmortem disposition

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.

Antemortem findings—not recognized on antemortem

Antemortem disposition—not relevant

Postmortem findings may include the following:

Peritoneum, parietal serosa—nodular lesions

Peritoneum, visceral serosa—nodular lesions

Pleura, parietal serosa—nodular lesions

Postmortem disposition

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.

Antemortem findings—not recognized on antemortem

Antemortem disposition—not a consideration

Postmortem findings may include the following:

Neoplastic adrenal gland

Cortical tumor

Tumor of adrenal medulla

Metastasis to lung

Growth into and along vena cava

Postmortem disposition

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.

Antemortem 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

Antemortem disposition

Condemn: (Regulation 309.6)

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.

Suspect: Regulation 309.2 (e)

(1) When epithelioma case does not require condemnation

(2) When the eye is missing from any bovine presented for antemortem inspection

Postmortem 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

Postmortem disposition (Regulation 311. 12)

Condemn the carcass of animals affected with epithelioma of the eye or the orbital region if one of the following three exists:

The affection has involved the osseous structures of the head with extensive infection, suppuration, and necrosis; or

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

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:

The Frontline Supervisor has granted permission. (Regulations 314.11)

The neoplastic tissue has been removed and condemned to tankage.

All parts are freely slashed and adequately identified in an inedible area under FSIS supervision. (Regulations 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.

(2) 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.

Antemortem findings may include the following:

Enlargement of superficial lymph nodes

Bloat due to abomasal neoplasms

Debilitated cachetic condition

Ocular protrusion due to retrobulbar neoplastic tissue

Antemortem disposition

Condemn: Cannot be adequately diagnosed on antemortem; however, can be suspected.

Suspect: Antemortem signs may very well suggest malignant lymphoma and so animal would be suspected.

Postmortem 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

Postmortem disposition

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.

Antemortem 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, tail-head and flanks, while in equines these are most often seen in the perineal region.

Antemortem disposition

Condemn: Condemnation is not recommended on antemortem examination since it cannot be determined to have metastasized or not.

Suspect: Those animals that have a melanoma that are likely to be condemned on postmortem.

Postmortem 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

Postmortem disposition

Condemn:

An individual organ or part of a carcass affected with a neoplasm shall be condemned.

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.

Note: Carcasses condemned for malignant melanoma should be recorded on PHIS under “Carcinoma” in Animal Disposition.

Poultry 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 (381.81).

Leukosis Complex

This category includes several neoplastic diseases caused by various viruses. All produce tumors in domestic poultry and present similar gross lesions.

The age and species of bird affected by leukotic tumors suggests which viral agent is involved. The most common manifestations of the leukosis complex are:

1) Marek's disease, which is an important disease only in young chickens less than six months of age

2) Lymphoid leukosis, which is most common in semi-mature and mature chickens

3) Reticuloendotheliosis, which occasionally produces liver and spleen tumors in turkeys and, rarely, runting disease in chickens

4) Lymphoproliferative disease, which affects turkeys, producing a greatly enlarged spleen as well as tumors in other organs.

There is no evidence that viruses of the leukosis complex are pathogenic for humans.

Disposition for leukosis falls under 9 CFR 381.87. Tumors, which includes those 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 carcass has not been affected by the size, position, or nature of the tumor.

Synovitis

Synovitis is caused by a number of 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 (381.86)

Neoplasia

This category refers to neoplasia. Some of the more common ones include squamous cell carcinomas, adenocarcinomas, leiomyomas, and fibromas.

- Squamous cell carcinomas are skin tumors found in young chickens.
- Adenocarcinomas generally are located on 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. They 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.

Condemn a carcass for tumors if there is gross evidence of metastasis (more than one tumor indicating spread). The general rule is: one tumor - trim and pass; two or more tumors - condemn (381.87).

NOTE: The exception to the rule is for squamous cell carcinomas: Condemn young chickens showing generalized signs of avian keratoacanthoma (squamous cell carcinomas) with large coalescing or large multiple dermal ulcers. Trim all tumors and pass chickens with localized or only a few small squamous cell carcinomas.

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 (381.89).

Cadavers

Poultry that die from causes other than slaughter are condemned under the cadaver category. These birds are not physiologically dead when they enter the scald vat. When submerged in the water, they drown and their physiological reaction to the heat is to dilate the vasculature in the skin. This is what causes the skin to become red.

Birds that die from slaughter 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 (381.90).
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Overscald

Carcasses that are cooked in the poultry scalder are condemned. The muscle must be cooked through the level of the deep pectoral muscle in order 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 (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 colored and/or cheesy exudates (which is generally a chronic lesion). The 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, and 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 (381.84).

Microorganisms which may be involved in causing airsacculitis include the following:

Aspergillus fumagatus-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. Antemortem 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 (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. Antemortem 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 a primary airsacculitis caused by *Mycoplasma gallisepticum* and is demonstrated as a marked airsacculitis, pericarditis, and a well-developed fibrinous pneumonia.

One organism that causes airsacculitis in birds, *Chlamydia psittaci*, also can 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. Antemortem 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 that show signs suspicious for this disease.

Two viral poultry diseases of significance that may involve the air sac system are Exotic Newcastle Disease (END) and Avian Influenza (AI).

Inflammatory Process (IP)

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 (381.86). Otherwise, it may be trimmed and passed.

Turkey Osteomyelitis Complex

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.

In order to distinguish lots of turkeys affected by TOC from those showing external sings compatible with TOC but caused by other conditions, the Agency requires PHV's to conduct special diagnostic examinations on suspicious lots. If the presence of TOC is confirmed during the diagnostic exam, the PHV requires the establishment to conduct additional examination procedures on all carcasses identified as suspects at the postmortem inspection stations.

When osteomyelitis is detected during the establishment examination, all tissues to the next normal joint must be removed and condemned. Product that is salvaged must be held for re-examination by FSIS personnel before it is allowed to enter normal production flow. All aspects of the TOC procedure must be consistently performed in accordance with FSIS policy and in a manner acceptable to the IIC or approval can be rescinded and the procedure discontinued.

Affected tissues must be removed from TOC carcasses. If this is not possible or if the carcass is showing signs of systemic disturbance, the entire carcass would be condemned.

Ascites

Carcasses with ascites fluid in the body cavity should be condemned only when the fluid prevents inspection of the interclavicular air sacs. (381.83).

Fractures and Luxations

A fracture with no associated hemorrhage is passed. A fracture with hemorrhage in the affected part is trimmed and the remainder of the carcass is passed. A compound fracture, one in which the bone goes through skin, is trimmed whether or not there is hemorrhage present (381.91).

Luxation is a simple disjointment without breaking the skin and without hemorrhage. It does not have to be trimmed. If hemorrhage does not extend into the musculature, trim

or slit/wash out the hemorrhage. Do not trim simple redness of skin. Disposition of luxations is the same as it is for fractures.

Establishment Rejects

When the establishment rejects a carcass before inspection, condemn as a "Plant Reject". Carcasses rejected by the establishment at salvage should also be recorded under this category.

Carcasses condemned because there are no viscera to inspect - Carcasses are classified as no viscera if none of the three major organs- heart, liver, and spleen- are present for inspection. Disposition of no-viscera carcasses are determined by the veterinarian in charge and are based upon flock incidence of disease. Carcasses should be hung back and the veterinarian in charge notified.

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
- extensive petechiae
- inflammation
- an abscess
- a necrotic area
- necrosis
- cirrhosis
- a single non-leukotic tumor
- cysts
- discoloration due to a biliary system disorder or post mortem changes
- contamination from intestinal content or noxious materials

Condemn kidneys when:

- the carcass has renal pathology,

- 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 (vacuum the kidneys from the carcass or salvaged portion.

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.

Workshop III

This workshop will be facilitated by the instructor. The facts of the case will be presented, slides of the associated pathologies will be shown, then you will be asked to use the **disposition thought process** to arrive at a **sound, supportable disposition**.

Case Number 1

Antemortem - a normal appearing dairy cow was presented.

Postmortem - carcass had evidence of mastitis with extensive ventral inflammatory edema. The carcass was dark and moderately dehydrated. There were massive hemorrhages on the spleen and epicardium. The lungs also had large zones of hemorrhages and there were petechial hemorrhages around the great vessels. The liver was enlarged, dark and congested - large amounts of blood drained from its cut surface. There were petechial hemorrhages throughout the carcass evident on fascial planes between muscle groups.

Case Number 2

Antemortem – subject was a normal appearing dairy cow

Postmortem - a ruptured spleen was evident. The spleen was greatly enlarged. The cut surface of the spleen had very prominent 1-2 mm white nodules. Several abdominal lymph nodes were enlarged, congested, and had normal cortico-medullary anatomy on cut section. There was a large quantity of dark red watery fluid in the abdominal cavity.

Case Number 3

Antemortem – normal appearing market hog

Postmortem - petechial hemorrhages were present on the skin, kidneys, lungs, small intestine, stomach, and peritoneal cavity. The carcass lymph nodes were hemorrhagic and the liver was slightly enlarged.

Case Number 4

Antemortem – normal appearing market hog

Postmortem - both kidneys were enlarged with diffuse sawdust-like lesions concentrated at the distal ends. The bladder was markedly enlarged (3X) and the lumen was hemorrhagic with fibrous and reactive tissue present. The renal lymph node showed reactive change.

Case Number 5

Antemortem – normal appearing dairy cow

Postmortem - large abscess/cellulitis was present on the right cranioventral abdomen. There was hemorrhage, congestion, and areas of necrosis associated with the lesion. There were also multifocal areas of consolidation throughout both lungs. The heart and liver were grossly normal.

Case Number 6

Antemortem – normal appearing dairy cow

Postmortem - there was a marked thickening of the intestinal mucosa. Mucosal redundancy was so pronounced that it was observable through the serosal surface. The entire small intestine from the distal duodenum to the ileo-colic junction was involved.

Case Number 7

Antemortem – normal

Postmortem - cranioventral consolidation of both lungs was evident. There was also a fibrinous pleuritis. Lesions were more extensive and severe in the left lung. On cut surface there was interlobular fibrin and edema. Smaller bronchi and bronchioles contained purulent exudate. The carcass was well hydrated and well fleshed.

Case Number 8

Antemortem - a normal fattened beef breed heifer from northern Michigan was presented.

Postmortem - a large 6 cm x 3 cm x 3 cm granuloma was replacing the caudal mediastinal lymph node. A large 5 cm x 5 cm x 4 cm pyogranuloma-like lesion was present in the diaphragmatic lobe of the left lung. Several smaller granulomas up to 1 cm diameter were present throughout both lung fields.

Case Number 9

Antemortem – a normal dairy cow was presented

Postmortem - greenish discoloration of the liver was evident. A more intense green pigment was observed in the hepatic lymph nodes. The mediastinal lymph nodes and kidneys were normal.

Case Number 10

Antemortem - 6 month old market hog - there was a large, raised black mass on the side of the head.

Postmortem - numerous black, flat masses were present on the carcass trunk. Spots of black pigment were scattered throughout the liver, spleen, and pancreas. There was diffuse pigment seen in most of the peripheral lymph nodes.

Case Number 11

Postmortem- 60 day old chicken in good condition. The spleen is 4 times normal size with large and small white foci visible, but not protruding from the surface. The liver is enlarged and has the same foci. The bursa of fabricius is about normal for that age. The kidneys are slightly pale.

Case Number 12

Gross description of lesions - 53 day old bird with small yellow glistening masses in the anterior thorax. Air sac membranes reddened and thickened with some areas of exudate on and inside them. Liver has a fibrinous coating firmly attached; the pericardial sac is thick and whitish with areas of exudate and redness. The heart has a whitish coating on it with areas of hemorrhage and redness.

Case Number 13

Description of gross lesions - 46 day old chicken. All skin and viscera are bright red and appear to have petechia and ecchymosis. The liver is dark reddish brown, the lungs are a bright pink and the spleen appears normal. Intestinal and mesenteric vessels are prominent.

Case Number 14

This young turkey was in poor body condition, dehydrated, and dark in color. The liver was greatly enlarged (3-4 x normal) with areas of white, very firm tissue, light green and small areas of normal appearing liver tissue.

Case Number 15

Gross description of lesions - 55 day old bird in good condition. The left leg has an area about 1 inch wide by 3-4 inches long that is raised, yellow, and firm. On incision, a yellow-gray leathery material is exposed. The surface of all visible muscles is reddened and inflamed. The spleen is pale but other tissues are normal.

Bovine Spongiform Encephalopathy (BSE): Key Points for the Public Health Veterinarian

OBJECTIVES

- Describe the responsibilities of the PHV when presented with a non-ambulatory disabled bovine on ante-mortem inspection.
- List the tissues that are considered to be specified risk material (SRM).
- Describe the FSIS policies related to specified risk materials (SRMs) and the FSIS responsibilities related to implementing those policies.
- Define the FSIS policies related to mechanically separated (MS) beef.
- Define the FSIS policies related to advanced meat recovery (AMR).
- Explain the reason for the prohibition of air injection stunning.
- Identify the key aspects of the BSE surveillance program.

INTRODUCTION

In this module we will look at the regulatory requirements that were implemented as a result of the positive finding of BSE in the US. In December 2003, a positive case of BSE was confirmed in a cow presented for slaughter at a federally inspected establishment in Washington State. In response to this finding, in January 2004, FSIS issued three interim regulations and a notice in the Federal Register. The purpose of these policy issuances is to minimize human exposure to the BSE agent.

The interim regulations (69 FR 1862-1892) issued in January 2004 include:

- Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle (Docket No. 03-025IF)
- Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems (Docket No. 03-038IF)
- Prohibition of the use of certain stunning devices used to immobilize cattle during slaughter (Docket No. 01-033IF)

On July 13, 2007, FSIS issued Docket 03-025F entitled "*9 CFR Parts 309, 310 and 318 Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Rule*. This document finalized several of the interim regulations that were issued in 2004.

The Federal Register notice (Docket No. 03-048N) issued in 2004 is titled “Bovine Spongiform Encephalopathy Surveillance Program”. The following sections provide an overview of each of these policies and the inspection duties associated with them.

Non-ambulatory disabled cattle

Non-ambulatory disabled cattle are those cattle that cannot rise unassisted 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 (9 CFR 309.2(b)).

Non-ambulatory disabled cattle are not allowed to enter the slaughter establishment. They must be humanely handled, killed in a timely manner and removed from the premises to prevent insanitary conditions. Disposal must be in accordance with 9 CFR 309.13. FSIS will record non-ambulatory animals as “condemned” and verify that the carcass is appropriately treated so that it does not enter into the human food chain.

As a result of the policies regarding non-ambulatory disabled cattle, FSIS will also no longer allow the delayed slaughter or emergency slaughter of cattle as prescribed in 9 CFR 311.27.

Specified risk materials

The BSE regulations (9 CFR 310.22) identify specified risk material (SRM) as:

- the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the tail vertebrate, thoracic and lumbar transverse processes, and sacral wings) and dorsal root ganglia (DRG) of cattle 30 months of age and older, and

- the tonsils and distal ileum of the small intestine of all cattle, regardless of age.

These materials were identified as SRMs because scientific studies have shown them to contain the infective agent for BSE. Except for the skull and vertebral column, SRMs have demonstrated infectivity in cattle either naturally or experimentally. The skull and vertebral column are included because they contain the trigeminal ganglia (skull) or the spinal cord and DRG (vertebral column).

Specified risk materials are declared as inedible and cannot be used for human food (9 CFR 310.22 (b)). The interim final rule on SRMs explained , *“Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs identified in this document are unfit for human food. Thus, the status of most of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRM.”* Therefore, in accordance with 9 CFR 310.22 (e)(1) establishments must develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. These procedures must be incorporated into the establishment’s HACCP plans, Sanitation SOPs or other prerequisite program.

Corrective actions must be taken by the establishment when either the establishment or FSIS determines that the establishment's SRM removal procedures have failed. This direction is reflected in the 9 CFR 310.22 (e)(2) regulation, which states, "*Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section."* If SRM removal is included in the HACCP plan, then corrective actions described under 9 CFR 417.3 should be addressed. If it is included in the Sanitation SOP, the corrective actions identified under 9 CFR 416.15 should be addressed.

The establishment must also routinely evaluate the effectiveness of their procedures and revise the procedures as necessary. 9 CFR 310.22 (e)(3) states, "*Establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials."* Custom-exempt establishments must comply with the adulteration provisions of the FMIA and SRM must be handled as inedible.

Establishments must maintain daily records sufficient to document the implementation and monitoring of all SRM procedures. The regulations (310.22 (e)(4)(i)) state, "*Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken."*

Required establishment records may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data (9 CFR 310.22 (e)(4)(ii)).

Records must be retained for at least one year and must be accessible to FSIS. All such records must also be maintained at the official establishment 48 hours following completion (310.22 (e)(4)(iii)). After 48 hours records may be maintained off-site provided they can be made available to FSIS within 24 hours of request.

The SRMs are considered to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter (9 CFR 310.22 (h)). One of an establishment's first activities should be to identify the age of cattle because SRMs are different for cattle 30 months of age and older. If the establishment does not have records on the age and is not using dentition, it should handle <u>all</u> carcasses and parts as if they were from cattle 30 months of age and older. Documentation (records-based age verification), rather than dentition, provides the best means for determining the age of cattle. While dentition can be useful in the absence of documentation, it only provides a means of making general determinations about age.

In the final regulations issued in July 2007, FSIS added a regulatory requirement for the sanitation of equipment used to cut through SRMs (310.22 (f). The regulations allow the establishment flexibility to choose if they will segregate young cattle (less than 30 months of age) from older cattle in their establishment In establishments that slaughter both young cattle and cattle 30 months and older, FSIS recommends that young cattle be slaughtered first. When cattle 30 months of age and older are slaughtered first, inspection program personnel should verify that equipment is sanitized and cross-contamination of carcasses younger than 30 months does not occur.

All SRMs are prohibited from being used in edible rendering (9 CFR 318.6 b (4)). However, SRM material may be used in inedible rendering unless the animal is being tested for BSE.

Vertebral columns / spinal cord

The vertebral column and spinal cord of cattle 30 months of age and older are considered to be SRM. 9 CFR 310.22(c) contains requirements that direct that the spinal cord from cattle 30 months of age and older be removed at the establishment where the animal was slaughtered. Any spinal cord found on the carcass is considered to be contamination and must be addressed by the establishment. After carcass-splitting, it is acceptable to remove visible spinal cord outside of the spinal canal with knife trimming.

The vertebral column does not have to be removed during the slaughter operation. Establishments are permitted to transport such carcasses or parts to another official establishment for processing. The only SRMs that are permitted to be transported from one federally-inspected facility to another are vertebral columns. 9 CFR 310.22(g) prescribes the conditions under which establishments may ship carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing. There are four conditions that must be met. The establishment must:

> (1) Maintain control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;
>
> (2) Ensure that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter;
>
> (3) Maintain records that identify the official establishment that received the carcasses or parts;
>
> (4) Maintain records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph

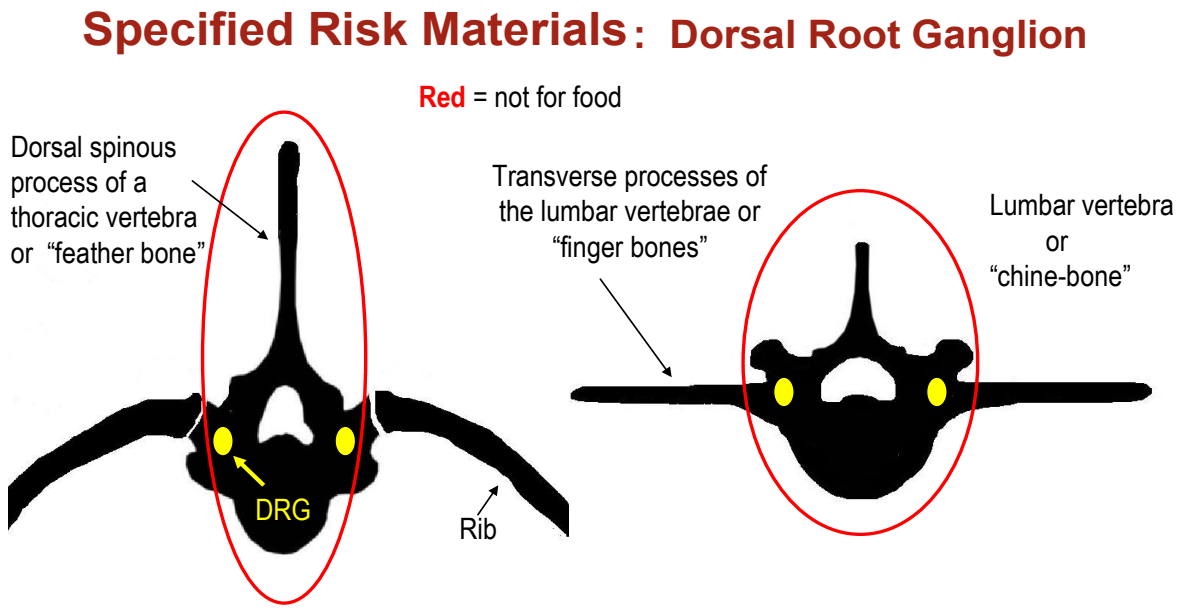
Inspection program personnel are to conduct verification activities to ensure that establishments that ship beef carcasses or parts are complying with 9 CFR 310.22(g). Verification procedures for FSIS inspection program personnel are detailed in FSIS Directive 6100.4. “Verification instruction related to specified risk materials".

Dorsal Root Ganglion (DRG)

The dorsal root ganglia are nodular enlargements of nervous tissue connected to the spinal cord, that are located in close proximity to the intervertebral foramina. Processing establishments that use bone-in carcasses or parts from cattle 30 months of age and older must properly address SRM removal and control.

Traditional T-bone or porterhouse steaks and bone-in rib roasts can no longer come from cattle older than 30 months. A portion of the vertebral column bone defining these cuts of meat must be removed (see the figure below), resulting in a semi-boneless cut of meat. As long as the cut made by the saw is perpendicular to the blade of the transverse process and far enough out on the transverse processes that neither the dorsal or ventral parts of the articular processes of the vertebrae are transected, the ends of the transverse processes will be oval, there will be no other bone in the roast portion of the product, and DRG should be left in the waste bone portion.

Figure 1.



Heads

Since stunning may result in contamination of head surfaces, heads from cattle 30 months of age or older, are to be condemned unless the establishment can ensure that the stunning does not result in brain leakage onto the head.

Tonsillar Material

If the establishment will be harvesting beef tongues or market heads for human food, procedures must be in place to effectively remove tonsillar tissue from each tongue and head. The establishment can use any verifiable method of removing tonsillar tissue. Two methods currently being used are:

- Transverse cut - The edible portion of the tongue can be separated from affected portions of the tongue by making a transverse cut behind the last vallate papilla. (IKE 06-04)
- Skinning - A new technology, using a skinning machine allows the establishment to salvage most of the muscular portion of the tongue typically removed with the transverse cut method. The skinning machine removes a minimum of 5 mm from the surface of the affected part of the tongue, removing the tonsillar material sitting just below the mucosal surface. Guidance to inspection program personnel about verification procedures associated with the removal of tonsillar material using a skinning machine is provided in FSIS Directive 6100.4.

Small Intestines

On September 7, 2005 FSIS amended the regulations to permit, under certain conditions, the use of beef small intestines, excluding the distal ileum, to be used for human food. Initially the use of the entire beef small intestine was prohibited. Under the 2005 amendment, beef small intestine may be used for human food if (1) it is derived from cattle slaughtered from an official establishment in the U.S., or a certified foreign establishment in a foreign country that is eligible to export beef products to the U.S. **and** (2) the distal ileum is removed by a procedure that detaches 80 inches of uncoiled and trimmed small intestine, measuring from the ceco-colic junction, proximally towards the jejunum.

Subsequently, natural casings of beef small intestines, and beef small intestines can be used as containers for meat food products (9 CFR 318.6(b)(8)), and beef small intestines can be used in meat food products and edible rendering (9 CFR 318.6 (b)(1)) provided the establishment can demonstrate, through documentation, that the small intestines comply with 9 CFR 310.22 (d).

Guidance to inspection program personnel about verification tasks associated with beef small intestines is provided in FSIS Directive 6100.4. Additional guidance about verifying compliance with SRM regulations is in FSIS Notice 09-15, Specified Risk Material (SRM) Control Verification Task.

SRM Non-compliance

When an establishment does not meet the regulatory requirements for controlling SRM, inspection program personnel are to issue a non-compliance record (NR) and cite 9 CFR 310.22 in the *Relevant Regulation* section of the NR. In addition to selecting 9 CFR 310.22, inspection program personnel are to select **all** other regulations with which there has been noncompliance. The IIC is responsible for notifying the appropriate establishment official of the SRM non-compliance and for verifying that the corrective actions implemented by the establishment meet the requirements of 9 CFR 310.22, the HACCP requirements of 9 CFR 417.3(a) or Sanitation SOP requirements of 9 CFR

416.15; or pre-requisite program requirements documented under record-keeping requirements in 9 CFR 417.5 before issuing the NR. Refer to FSIS Directive 6100.4 and the Interactive Knowledge Exchange, (IKE) 01-07 "Citing Relevant Regulations When Documenting SRM Noncompliance" for more detailed guidance. Also review FSIS Notice 09-15 Specified Risk Material (SRM) Control Verification Task, which specifies the regulations cited when documenting a SRM noncompliance.

Mechanically separated (MS) beef

Mechanically separated (MS) beef is prohibited from use for human food. This product has a paste-like consistency as a result of forcing beef, pork or chicken 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.

There are currently no regulatory restrictions on the incorporation of spinal cord and DRG into MS (beef) meat food product and such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that MS (beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

Advanced Meat Recovery (AMR)

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. A "baader type" machine is an example of a mechanism used for the AMR process.

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 dorsal root ganglia (DRG).

Skulls and vertebral column bones of cattle 30 months of age and older are now prohibited from being used in AMR product. 9 CFR 318.24 (a) of the regulations state, "*Meat, as defined in § 301.2 of this subchapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older as provided in § 310.22 of this sub-chapter, using advances in mechanical meat/bone separation machinery (i.e., AMR systems).*"

Brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG) tissue may not be present in any product prepared using AMR. Any product that contains SRM material from cattle 30 months of age and older is considered adulterated. Meat that contains unlabeled brain, trigeminal ganglia, spinal cord or DRG from cattle less than 30 months of age is considered "misbranded". Therefore, the AMR production process is not in control if skulls entering the AMR system contain any brain or trigeminal ganglia tissue, or if the vertebral column bones entering the AMR system contain any spinal cord.

Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system may not be used as an ingredient of a meat food product. The regulation limits the amount of bone solids or bone marrow as measured by the presence of calcium and iron. AMR product must not contain more than 130 mg of calcium per 100 grams or more than 3.5 mg of iron per 100 grams (9 CFR 318.24 (c)(1)).

9 CFR 318.24(b) provides that establishments operating AMR systems are required to develop, implement, and maintain procedures that ensure that their production process is in control. The interim final rule (Docket N0. 03-038IF) states*, "The establishment must incorporate its production process procedures in a written program that is designed to ensure the ongoing effectiveness of the process control program. Because of the food safety concerns presented by SRMs, for establishments that process cattle, the written program must be in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan, or in its Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program."* The establishment must document its production process controls in writing. The program must be in its HACCP plan, Sanitation SOP, or other prerequisite program.

The program must describe on-going verification activities including:

- observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord;
- the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG;
- the use of the product and spent bone materials exiting the AMR system; and
- the frequency with which these activities will be performed.

Furthermore, 9 CFR 318.24 (b)(2) of the regulations states, *"The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed."*

The establishments must maintain records on a daily basis sufficient to document the implementation and verification of its production process. These records must be made available to FSIS personnel.

The production process is not in control if:

- the skulls entering the AMR system contain any brain or trigeminal ganglia tissue;
- the vertebral column bones entering the AMR system contain any spinal cord;
- the recovered product contains DRG or spinal cord; or
- the recovered product exceeds calcium or iron levels.

In addition, the production process is not in control if:

- the product is not properly labeled; or
- the spent bone materials are not properly handled.

Additional guidance on verifying AMR product is in FSIS Notice 05-15 Interpreting Results of FSIS Verification Sampling of Domestic Beef Product Derived from Advanced Meat Recovery Systems (AMR01/FAMR01).

Prohibition of air injection stunning

Air injection stunning is defined as captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle. Studies have shown that air injection stunning can force visible pieces of brain and other CNS tissues into the circulatory system of cattle.. This can result in brain (SRM) emboli being disseminated into edible tissues. Therefore air injection stunning devices are prohibited. The regulation 9 CFR 313.15 (b)(2)(ii) states, "C*aptive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle."*

BSE surveillance

The USDA has taken aggressive measures to prevent the introduction and potential spread of BSE. Surveillance for this disease has been conducted since 1990, but was expanded in scope and intensity in December 2003 following the confirmation of BSE in a cow imported from Canada. This expanded surveillance effort was designed to estimate the prevalence of disease present in the United States and provide input for designing a long-term surveillance plan.

On July 20, 2006, USDA-APHIS released an updated surveillance plan entitled "Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan". The plan is intended to inform and educate USDA's partners and stakeholders on approaches to be employed in ongoing BSE surveillance in the U.S. The plan retains the USDA's ability to detect BSE at 1 infected animal per 1,000,000 adult cattle in the population with a high degree of confidence, maintains surveillance at levels that exceed international standards, emphasizes sample collection from cattle subpopulations where BSE is most likely to be detected, and retains sample collections from all important surveillance sources.

The plan follows surveillance system design standards and guidelines established by the USDA's Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Surveillance Unit (NSU). This system is based on current World Organization for Animal Health (OIE) guidelines that emphasize obtaining quality samples from high risk subpopulations rather than an arbitrary number of animals. Thus, meaningful surveillance can occur with a fairly low number of animals. For this reason, a major focus of the *Ongoing BSE Surveillance Program* will be to obtain samples from cattle that are "clinical suspects". This subpopulation of cattle, particularly cattle over 30 months of age, has been found to exhibit the highest prevalence of BSE.

Subpopulations of animals targeted for sampling will be those of any age with CNS signs, and cattle 30 months of age or older condemned for any other reason on ante-mortem inspection. Many of these animals will be identified at federally inspected slaughter establishments by FSIS inspection program personnel. How BSE sampling will be handled is dependent on whether or not the establishment has an alternative off-site sample collection agreement with USDA-APHIS.

FSIS responsibilities regarding the collection of brain samples for the APHIS guided BSE Ongoing Surveillance Program are outlined in FSIS Directive 10,400.1 “Sample Collection from Cattle under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program.” The FSIS role in the collection procedures is contingent on whether an establishment has entered into an agreement with APHIS to have brain samples collected at an approved alternative off-site location.

If the establishment is operating under an approved agreement with USDA-APHIS, the USDA-APHIS personnel will provide for the collection of brain samples on these animals at the alternative location. FSIS is responsible for providing establishment management with the “U.S. Condemn” tag (Z-tag) numbers and disposition information for each animal. In these instances, specific controls must be in-place for FSIS to recognize the arrangements establishments have with USDA-APHIS to test condemned cattle.

If the establishment is not under an approved alternative off site collection agreement with USDA-APHIS, the FSIS PHV will collect the BSE samples from cattle of all ages that display CNS symptoms and ensure final disposition of the condemned cattle are in accordance with 9 CFR 309.

If the establishment plans to work with USDA-APHIS to begin off-site sampling, until USDA-APHIS approves that arrangement, or until FSIS is advised that an off-site agreement will not be forthcoming, FSIS PHVs are to identify all CNS animals with a "U.S. Condemned" tag, contact the USDA-APHIS AVIC so collection of the brain sample can be arranged, and ensure that the animals are humanely euthanized and remain on premise, unless USDA-APHIS requests otherwise.

Samples collected by the FSIS PHV will be shipped to the USDA APHIS National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another USDA_APHIS designated laboratory. Additional information about BSE sampling can be found on the FSIS website at Bovine Spongiform Encephalopathy (BSE) and Specified Risk Material (SRM) Guidance Material and Resources.

Marks of Inspection

Under the *Ongoing BSE Surveillance Program*, cattle identified for testing at federally inspected establishments is limited those that are condemned on ante-mortem inspection. Therefore, marks of inspection would not be applied.

Canadian Cattle

On January 4, 2005, USDA-APHIS published the final rule, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Docket No. 03–080–8, 70 FR 460 – 553). This final rule amended USDA-APHIS regulations (9 CFR parts 93-96, Attachment 1) to provide for the importation of certain ruminants, and ruminant products and byproducts from regions that pose a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States (U.S.), and designated Canada as the first minimal-risk region. The rule was promulgated under the Animal Health Protection Act.

The rule covers the importation of cattle, bison, sheep and goats. Under this rule, only cattle and bison born after March 1, 1999 and sheep and goats that are less than 12 months of age are eligible for importation into the U.S. from Canada and eligible for slaughter. The importation and slaughter of cattle or bison 30 months of age or older or of sheep and goats 12 months of age or older is prohibited. Bison, sheep and goats shipped from Canada have no applicable SRM requirements.

Animals imported from Canada will go through specific ports of entry. An USDA-APHIS veterinarian reviews documents and inspects the shipment at the port of entry to ensure that it is being imported in compliance with the regulations. Animals will either be shipped directly to slaughter, or may be shipped to a feedlot prior to being shipped to slaughter. Animals shipped from Canada directly to slaughter will arrive at slaughter establishments under seal.

Only an authorized USDA representative can break the seal on the truck containing Canadian animals upon arrival at an official establishment. Under a Federal Register Notice issued 11/28/2005, the definition of "authorized USDA representative was broadened to include an USDA-APHIS Veterinary Services employee, USDA FSIS inspection program personnel, a State representative, an accredited veterinarian, or an employee of an accredited veterinarian, slaughtering establishment, or feedlot who is designated by the accredited veterinarian or management of the slaughtering establishment or feedlot to perform the function involved.

If an establishment chooses for a establishment employee to qualify as an authorized USDA representative, the slaughtering establishment must enter into an agreement with USDA-APHIS. Contact the Policy Development Division for details and additional information about these arrangements.

For Animals shipped directly for slaughter

- go to official establishments in sealed trucks,
- will bear a Canadian ear tag,
- will be accompanied by VS Form 17-33 and a Canadian Health Certificate,
- are to be slaughtered or euthanized within two weeks of entry into the U. S.
- are not to leave the official premises.

Sheep and goats that are shipped to a feedlot and then to an official establishment for slaughter

- will bear a Canadian ear tag (or other official identification if the animal lost its eartag at the feedlot and required re-tagging),
- will be accompanied by VS Form 1-27 and a copy of the Canadian Health Certificate

In certain circumstances, if FSIS personnel find that animals that have been delivered for slaughter do not comply with USDA-APHIS regulations, inspection program personnel are delegated the authority to hold the animals under the Animal Health Protection Act (AHPA). For additional information on cattle, sheep, and goats imported from Canada, review FSIS Directive 9350.1 “Importation of Live Canadian Cattle, Sheep, and Goats into the United States”.

REFERENCE DOCUMENTS

Docket No. 03-025F " Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter " (FR 72 No.1347, July 13, 2007).

Docket No. 03-038IF "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (FR 69 No. 7, Jan 12, 2004).

Docket No. 03-048N "Bovine Spongiform Encephalopathy Surveillance Program" (FR 69 No. 7, Jan 12, 2004).

Docket No. 03–080–8 "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Unsealing of Means of Conveyance and Transloading of Products" (FR 70 No.227, November 28, 2005).

Docket No. FSIS-2010-0017 “Notice of Request for Revision of a Currently Approved Information Collection (Specified Risk Materials)” (FR 75 No. 141, July 23, 2010)

9 CFR Parts 309.2; 309.13; 310.22; 311.27; 313; 318.6; 318.24; 417.3; 417.4

FSIS Directive 9530.1 “Importation of Live Canadian Cattle, Sheep, and Goats into the United States:

IKE 06-04 "Illustration of FSIS Notice 50-04 Concerning Tonsils"

IKE 01-07 "Citing Relevant Regulations When Documenting SRM Noncompliance"

WORKSHOP

1. What is the disposition of a non-ambulatory bovine at ante-mortem inspection?

2. What must the establishment do with a non-ambulatory bovine according to the regulations?

3. What tissues are considered as SRM?

4. What skeletal materials are not allowed to be used to produce AMR product?

5. Which captive bolt stunning method is not allowed under the regulations? What is the rationale for focusing on this method of stunning?

6. When will a carcass sampled for BSE testing be marked as “U.S. Inspected and Passed”?

APPENDIX 1: 9 CFR 310.22 From Docket 03-0125F, July 13, 2007)

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
9 CFR Parts 309, 310, and 318
[Docket No. 03–025F]
RIN 0583–AC88
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Affirmation of interim final rules with amendments.

PART 310—POST-MORTEM INSPECTION

_ 4. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53._ 5. Section 310.22 is revised to read as follows:

§ 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials, except when they are from cattle from a country that can demonstrate that its bovine spongiform encephalopathy (BSE) risk status can reasonable be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older and

(2) The distal ileum of the small intestine and the tonsils from all cattle.

(b) Specified risk materials are inedible and prohibited for use as human food.

(c) Specified risk materials must be removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with § 314.1 or § 314.3 of this subchapter. The spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.

(d) *Requirements for use of the small intestine for human food.* (1) The small intestine from all cattle may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

(iii) If the conditions in paragraphs (d)(1)(i) or (ii) of this section are not met, the entire small intestine must be removed from the carcass, segregated from edible materials, and disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.

(2) The requirements in paragraph (d)(1) of this section do not apply to materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States.

(e) *Procedures for the removal, segregation, and disposition of specified risk materials.*

(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. These procedures must address potential contamination of edible materials with specified risk materials before, during, and after entry into the establishment. Establishments must incorporate their procedures for the removal, segregation, and disposition of specified risk materials into their HACCP plans or Sanitation SOPs or other prerequisite programs.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of these procedures, have failed to ensure that specified risk materials are adequately and effectively removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and must revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) *Recordkeeping requirements.*

(i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to

meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and
(ii) The distal ileum is removed by a procedure that on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.
(iii) Records required by this section must be retained for at least one year and must be accessible to FSIS. All such records must be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.
(f) *Sanitation of equipment used to cut through specified risk materials.*
(1) If an establishment that slaughters cattle, or that processes the carcasses or parts from cattle, does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations it must:
(i) Use dedicated equipment to cut through specified risk materials; or
(ii) Clean and sanitize equipment used to cut through specified risk materials before the equipment is used on carcasses or parts from cattle younger than 30 months of age.
(2) If an establishments that slaughters cattle, or that process the carcasses or parts from cattle, segregates the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months of age during processing operations, and processes the carcasses or parts from the cattle younger than 30 months first, it may use routine operational sanitation procedures on equipment used to cut through specified risk materials.
(g) Slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally inspected establishment for further processing if the establishment shipping these materials:
(1) Maintains control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;
(2) Ensures that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter;
(3) Maintains records that identify the official establishment that received the carcasses or parts;
(4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph (a)(1) of this section and disposed of them in accordance with § 314.1 or § 314.3 of this subchapter.
(h) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate through documentation that the document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.
(ii) Records required by this section may be maintained

materials are from an animal that was younger than 30 months of age at the time of slaughter.

Reportable and Foreign Animal Diseases

OBJECTIVES

1. From a list of animal diseases, be able to select those which are Notifiable to OIE and should be reported to APHIS.

2. Recognize clinical signs and/or lesions suspicious of a reportable or foreign animal disease.

3. Describe the appropriate procedures to follow when a reportable or foreign animal disease is suspected in an animal presented for slaughter.

4. Be able to identify and submit possible lesions of bovine tuberculosis for identification.

5. Describe and follow the appropriate procedures when TB reactors, suspects, or exposed animals are presented for slaughter.

REPORTABLE AND FOREIGN ANIMAL DISEASES: TABLE OF CONTENTS

VI. Bovine Tuberculosis Eradication Awards Program
VII. Paper: “Surveillance of Zoonotic Diseases”
VIII. Internet Resources
IX. FSIS Directive 6000.1

I. Introduction:

As a FSIS Public Health Veterinarian (PHV) in a slaughter facility, you have the responsibility of conducting ante mortem and postmortem inspection on up to thousands of animals each day. For this reason, you play a valuable role in detecting 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. As a FSIS PHV, you can play a valuable role in detecting and assisting in the control and eradication of reportable and foreign animal diseases.

FSIS Field Operations (OFO) cooperates with Veterinary Services in their various activities and plays an important role in the disease eradication program that Veterinary Services administers. The intent 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 Veterinary Services (VS).

Your work in the packing 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 Public Health Veterinarian any symptoms seen on ante mortem or lesions seen on postmortem that could be part of a disease entity that should be reported.

Veterinary Services (VS) and OFO are both in the U.S. Department of Agriculture. VS, however, is a discipline of the Animal and Plant Health Inspection Service (APHIS), while OFO is a discipline of the Food Safety and Inspection Service (FSIS). The overall mission of VS as a regulatory agency is to administer an important part of the animal health program of our nation. Primarily this means controlling or eradicating specified animal diseases already in this country. Since VS has so few personnel compared to OFO, it becomes very important that OFO food inspectors at the packing establishment serve as vigilantes in discovering unusual symptoms or lesions.

Notifiable diseases are those that are designated by World Animal Health Organization (Office International des Epizooties or OIE). When suspected, either on ante mortem or postmortem, they must be reported to your APHIS AVIC. The list of notifiable diseases includes anthrax, bluetongue, bovine spongiform encephalopathy (BSE), cysticercosis, scabies, tuberculosis, contagious ecthyma, myiasis (screwworm), scrapie, and vesicular diseases. Of these diseases anthrax, cysticercosis, tuberculosis, and contagious ecthyma are transmissible to humans.

Emergency diseases are defined as those foreign animal diseases that are not currently found in this country. They are classed also as *reportable* diseases, but reportable diseases of especially profound significance. The list of emergency diseases includes

foot and mouth disease, rinderpest, African swine fever, hog cholera (classical swine fever), contagious bovine pleuropneumonia, and Teschen's disease.

II. Reportable and Foreign Animal Diseases:

Notifiable Diseases

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) follows standards and rules in concert with the World Organization for Animal Health (Office of International Epizooties or "OIE"). As a member country, the United States monitors animal diseases from a list of "Notifiable diseases" that is generated by OIE.

The OIE is an intergovernmental organization that was created by the International Agreement of 25 January 1924. This agreement was signed by 28 countries. Over the years OIE has grown considerably and in May 2004, the OIE totaled 167 member countries.

OIE member countries report animal diseases that are detected on its territory to OIE, and the OIE then disseminates the information to other countries. This dissemination of information allows neighboring countries to take the necessary preventive actions to minimize the chances of the disease entering into their country. This information also includes diseases transmissible to humans and intentional introduction of pathogens. Information is sent out immediately or periodically depending on the seriousness of the disease. This objective applies to diseases or natural origin as well as those that have been deliberately introduced. Dissemination is via the OIE Web site, e-mail and the following periodicals: *Disease Information*, published weekly and the annual compilation *World Animal Health*.

The current list of diseases that are reportable to the OIE are included at the end of this module. The list may also be found at the following weblink: OIE-Listed diseases 2013: OIE - World Organisation for Animal Health

Critical Foreign Animal Disease Issues for the 21st Century

Animal health officials define an exotic or foreign animal disease (FAD) as an important transmissible livestock or poultry disease believed to be absent from the United States and its territories that has a potential significant health or economic impact. The USDA - APHIS is working vigilantly with State animal health officials and veterinary professionals to identify, control, and eradicate these animal diseases and diminish their impact. As a preface to the updated disease information, this introductory article will provide an overview of the ways in which FADs may impact U.S. consumers and producers. It will also highlight the new challenges facing those involved in prevention, management, and recovery from FAD threats to the United States.

IMPACTS OF FADs ON THE U.S. ECONOMY

Foreign animal diseases are considered a threat to the United States when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. Diseases such as classical swine fever (hog cholera), foot-and- mouth disease (FMD), and highly pathogenic avian

influenza (HPAI) can cause high death rates or severe illness and production losses. This loss of productivity can increase the cost of food products obtained from those animal sources. For example, during the 1983-84 outbreak of HPAI, the average cost of one dozen eggs increased by 5 percent (1). McCauley et al. predicted that the price of beef would increase by $0.19 per pound because of an outbreak of FMD (2). Other diseases such as tuberculosis (TB) and brucellosis affect human and animal health. These two diseases, although very prevalent in other countries, will soon be eradicated from U.S. domestic livestock and will thus become exotic.

To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled. In the United States, control usually means disease eradication. These eradication efforts can present significant short-term costs to industry and government. For example, in 1983-84 the control and eradication of a highly pathogenic avian influenza outbreak cost the USDA $60 million. In the final stages of hog cholera eradication (1971-1977), the U.S. government spent $79 million (3).

In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the United States will be the loss of export markets. U.S. animal agriculture is becoming more dependent on exports. The long-term strategic plans of these industries call for increasing the amount of goods sold abroad. As the percentage of total production destined for export grows, the impact of a domestic FAD outbreak also grows. Other countries will not allow the importation of animals or animal products that pose a risk to their industry. In 1997, the total value of exported U.S. animals and animal products exceeded $7 billion: $2.3 billion in poultry, $1 billion in pork, and $2.6 billion in cattle and cattle products. Theoretically, the long-term trade impacts of a FAD occurrence can be reduced by applying regionalization concepts. A country could, during a FAD outbreak, recognize specified regions of the United States as affected with the disease. The remaining unaffected areas might be free to continue exporting. However, it would take considerable time to have these regions identified and other regions certified as disease-free. In the meantime, all trade in that commodity would be stopped.

NEW CHALLENGES FOR THE MANAGEMENT OF FADs

As we move into the 21st century, many new issues and factors are affecting FAD prevention, control, management, and recovery. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Evidence is accumulating that these factors are having an impact. For example, hog producers in Taiwan recently experienced a devastating outbreak of FMD for the first time since 1929. Over four million animals were destroyed. Virtually all export markets were lost. The Netherlands recently sustained an outbreak of hog cholera that resulted in major export losses of 65 percent of their production. Other countries in the European Union struggle to eradicate hog cholera. As this book goes to press, hog cholera is active in the Dominican Republic, which is situated only 150 miles from the continental United States.

The world is moving toward more open market access. Free trade agreements such as GATT (General Agreement on Tariffs and Trade) and NAFTA (North American Free Trade Agreement) stipulate that trade in animals and animal products should only be restricted if there is a valid human or animal health risk to the importing country. To stop

trade the importing country must show, with a scientifically valid analysis that a risk exists. This policy will increase responsibility for the United States to evaluate risks carefully. It also will probably increase the flow of animals and animal products into the United States.

A related element of free trade agreements is the concept of regionalization. As an importing country, the United States is required to evaluate geographic regions of potential importers. More effort and information will be required for the United States to evaluate the risk of a disease from a region that may be smaller than or larger than an area defined by political borders. The United States must have some methods to evaluate the security of the region's boundaries. The acceptance of regionalization puts increased pressure on the United States to remain vigilant for the presence of disease at home and in various countries exporting or hoping to export, to our shores. Examples of regionalization include recognizing the northern U.S. states as Bluetongue free, northern Spain as free from African horse sickness, and portions of Argentina as FMD free.

Around the world countries are joining into free trade blocks. They hope these alliances will give them a competitive advantage against other trading blocks such as the European Union and the NAFTA countries. Problems arise as livestock or animal products are allowed to move freely within these blocks because we may not always know the origin of the products we import.

The volume of international passenger travel is steadily increasing. In 1980, 20 million passengers arrived in the United States on international flights. In 1995, this number rose 131 percent to 47 million (4). The airline industry expects this trend to continue. International travelers may unknowingly bring contaminated animal products from FAD infected countries. Contaminated foodstuffs have often served as a source of a FAD in the United States and other countries (5).

As the world population grows and animal production intensifies, the risks and impacts of FAD incursions increase. Today, infection at one premises can affect 300,000 laying hens, 100,000 hogs, or 100,000 feedlot cattle. When one company owns a large number of animals, frequent and rapid interstate movement occurs. This movement can spread infection across many states before clinical signs are manifest in the source herd.

Lastly, the infectious disease agents and vectors are changing. For example, as the importation of reptilian pets increases, potential disease-transmitting vectors such as *Amblyomma* ticks are finding new routes of entry. Also, natural selection pressures predict that the FAD of the next decade will be different from the last. Recent examples include the swine-specific FMD virus in Taiwan, *Salmonella DT104*, and *Salmonella enteritidis*. Actions and information that accurately prevented disease or predicted risk in the past may not be effective in the future. Around the world, new agents never before a threat to U.S. agriculture have become an important human health or economic concern. Examples include bovine spongiform encephalopathy and porcine reproductive and respiratory syndrome. Today's new emerging disease may be tomorrow's significant exotic disease.

U.S. RESPONSES TO CHANGING EXOTIC ANIMAL DISEASE THREATS

The Animal and Plant Health Inspection Service has taken the lead in publishing a rule on regionalization expectations. This rule will contribute to international negotiations on animal trade. To define optimal methodologies for conducting risk analyses, APHIS is

working with universities, consultants, and the Economic Research Service (ERS). Also, APHIS is beginning to educate animal health officials, the animal agricultural industry, and our trading partners about the concepts and impacts of regionalization.

Disease surveillance data are a critical element for early FAD detection and for accurate risk analyses. Consequently, APHIS is constantly exploring different methodologies for monitoring the health of the U.S. livestock and poultry population. As traditional program diseases such as tuberculosis and brucellosis are eradicated and funding decreases, new surveillance systems will be needed. The U.S. animal health surveillance systems are therefore being reviewed by APHIS to achieve the highest efficiency and breadth without compromising disease detection abilities. Also, APHIS is working with our Latin American trading partners to design feasible surveillance systems for the region. In protecting American agriculture, APHIS is playing a key role in collaborating with international health organizations such as OIE (Office of International Epizootics), IICA (Inter-American Institute for Cooperation on Agriculture), FAO (Food and Agriculture Organization), and others to harmonize trading regulations, risk analysis methods, disease surveillance, and diagnostic methods.

The USDA, state animal health officials, universities, and the animal agricultural industry are taking many steps in response to these changing threats and risks. The diagnostic laboratory system is constantly improving and applying state of the art technology for FAD diagnosis and differentiation. International contacts are used to maintain awareness of disease occurrence. Consolidating the Agricultural Research Service (ARS) and APHIS and remodeling laboratory facilities at Plum Island will strengthen the opportunities for collaboration on FAD research and diagnostic programs.

The emergency management plan is being revised with greater involvement of partners to ensure rapid detection and response. These efforts are discussed in Part III, Protecting Livestock and Poultry Industries from Foreign Animal Diseases, in “Foreign Animal Diseases” published by the United States Animal Health Association, Richmond Virginia, 2004. Veterinary Services (VS) has downsized just like other U.S. government agencies. In that process, VS has gone from four regional emergency response teams to two. However, in doing this, VS has also created small Rapid Response Teams that can quickly be deployed to investigate possible FAD outbreaks. Additionally, VS is working more with State departments of agriculture, private veterinary practitioners, and other veterinary specialty groups to formulate better responses to these new threats. Moreover, VS has been examining the distribution of specially trained diagnosticians to determine any needed changes to improve the availability of these individuals. Key diagnosticians to be sent to outbreaks in other countries have also been identified by VS. This adds to our current knowledge base of the disease outside the laboratory and of the real-life problems involved in control and eradication.

Finally, VS has made efforts to create a manageable data base to collect information on all potential FAD investigations. This begins by having the diagnostician corps enter the most accurate and inclusive data into a computer data base. The future goal is to be able to look at trends and give values back to the reporting producer and veterinary practitioner. The trends may help VS to distribute and train its corps of diagnosticians better. It is hoped that the returned added value will stimulate more reporting by the private sector.

CONCLUSION

Exotic or emerging animal diseases continue to threaten the health and productivity of U.S. livestock and poultry. All of those with the potential of being affected are working to manage these threats by responding to these new challenges.

By Joan M. Arnoldi, D.V.M., M.S in "Foreign Animal Diseases", published by United States Animal Heath Association, Richmond Virginia, 2004

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Protecting Livestock and Poultry Industries from Foreign Animal Diseases

Protecting the livestock and poultry industries of the United States from foreign animal diseases (FADs) involves four basic principles or phases of emergency management. They are prevention, preparedness, response, and recovery. To be effective, these principles require the support and cooperation of persons, groups, and organizations at the local, State, regional, and national levels. Livestock and poultry owners, veterinarians in private clinical practice, industry groups, the Federal government, State government, State universities, veterinary diagnostic laboratories, and the traveling public must all be included.

PREVENTING THE INTRODUCTION OF FOREIGN ANIMAL DISEASES

The responsibility for preventing the introduction of FAD' into the United States has been assigned to several Government agencies. The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) (Fig. 1) has the primary responsibility for preventing the introduction of FADs through importation regulations governing animals, poultry, and animal and poultry products. To accomplish this objective, APHIS cooperates with other Federal agencies, including the Department of Homeland

Security, the U.S. Customs Service, the U.S. Fish and Wildlife Service, the U.S. Department of Agriculture's Food Safety and Inspection Service, and State Animal Health Agencies.

The port inspectors of Plant Protection and Quarantine (PPQ), originally part of APHIS, but now a part of the Department of Homeland Security (DHS), Customs and Border Protection (CBP) is responsible for inspecting ships and planes and their cargo, private and commercial vehicles, and passengers and their luggage arriving from foreign countries. Working closely with their fellow inspectors originally from U.S. Customs Service, this unit intercepts animals, poultry, animal and poultry products, and disease vectors at U. S. ports of entry.

Veterinary Services (VS) within APHIS administers laws and regulations pertaining to the importation of animals, poultry, pet birds, semen, embryos, hatching eggs, and other animal products to ensure that those imported from foreign countries are free from certain disease agents.

International Services (IS) within APHIS cooperates with its counterparts in foreign countries to reduce the international spread of animal and poultry diseases. The focus is to protect U.S. livestock and poultry by reducing the disease risk through participation in disease-management strategies before animals and poultry are imported into the United States.

State Animal Health Agencies, especially those located along the international borders with Canada and Mexico, cooperate with all regulatory entities at the land ports-of-entry. Among their activities are stray animal control, providing inspection services when imported animals are re-assembled after importation, and assistance with notification of livestock movement to receiving states.

PROTECTING THE LIVESTOCK AND POULTRY INDUSTRIES FROM DISEASE INCURSIONS

The responsibility for rapidly detecting and effectively responding to incursions of FAD's is primarily that of the livestock and poultry owners, veterinarians in private clinical practice, personnel from the State Animal Health Agency , APHIS, and the local community where the outbreak is occurring. The State Animal Health Official, usually the State Veterinarian, and the USDA, APHIS, VS Area Veterinarian in Charge (AVIC) and their staff routinely conduct surveillance activities to detect any FAD outbreaks quickly. These activities require the support of state veterinary diagnostic laboratories, the Cooperative Extension Service of the USDA, State and Federal meat and poultry inspection services, animal scientists, livestock market operators, and again, livestock and poultry producers and their private veterinarians.

To detect FAD outbreaks early, suspicious signs of a FAD must be promptly reported to the State Veterinarian, the AVIC , or both. Private veterinarians in clinical practice are conversant with the occurrences of domestic animal diseases in their area and are likely to be the first to suspect the presence of a FAD. Prompt reporting of suspicious signs will enable responsible agencies to conduct an investigation, obtain a diagnosis, and contain a FAD outbreak before it spreads.

When suspicious FAD cases are reported, an investigation of the affected herd or flock is immediately conducted by a specially trained FAD diagnostician (FADD). There are

over 500 State and Federal FADDs throughout the United States, strategically located so that a suspicious case anywhere in the U.S. can be investigated within 8 hours of notification. On the basis of history, signs, lesions, and species involved, specimens are collected and submitted to the National Veterinary Services Laboratories (NVSL), Ames, IA, or to the Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, NY, to confirm the presence or absence of a FAD.

On the basis of initial FAD investigation findings, often before the laboratory has completed testing of the samples, State and Federal officials in the affected state(s) will take action to quarantine suspect animals or poultry, increase area surveillance, restrict movement of animals and initiate steps to characterize and control the outbreak. An Early Response Team (ERT) composed of a senior FAD diagnostician, a senior laboratory pathologist from NVSL, and a senior epidemiologist can be called upon to provide greater technical assistance in the investigation, further assessment of the situation, and assistance in identifying needs of local officials to combat the problem.

LEADERSHIP, PARTNERSHIP, AND MEMORANDUMS OF UNDERSTANDING

Veterinary Services has the critical leadership role for the rapid detection of and the effective response to incursions of potentially devastating FAD's. However, in the event of an international introduction of an FAD, the Department of Homeland Security will assume the lead role to manage law enforcement aspect of the disease but will cooperate with VS and State Animal Health Officials to control and mitigate the outbreak. Veterinary Services is also responsible for providing FAD training. In conjunction with State Animal Health Officials, they help maintain an awareness of FAD threats and conduct test exercises. State Animal Health Agencies implement their state emergency response plan and initiate the response. VS Emergency Management oversees submission of samples for FADs and coordinates further Federal response activities to the outbreak.

Veterinary Services has established Memorandums of Understanding (MOUs) to obtain resources and cooperation from State animal health and wildlife agencies and the Department of Defense. Wildlife specialists from all 50 States and the Commonwealth of Puerto Rico have agreed to assist in FADs involving wildlife. In addition, MOUs have been signed with State veterinary diagnostic laboratories to provide for FAD surveillance and laboratory support in the event of an outbreak.

The National Animal Health Laboratory Network supports diagnostic activities at NVSL and FADDL and is designed to provide additional surveillance capacity, and in the event of an outbreak of an FAD, additional surge capacity. This network incorporates a number of state diagnostic laboratories that have capabilities for rapid nucleic acid-based testing for some of the more devastating FADs.

EMERGENCY RESPONSE TO A FAD OUTBREAK

When field investigations and laboratory tests confirm that a FAD is present, VS will immediately activate a response. If the FAD is on the OIE disease list for immediate notification, USDA is obligated to notify OIE within 24 hours. The OIE then transmits the news to all member nations.

The emergency response follows guidelines set out in the National Incident Management System (NIMS) The NIMS was created as a result of Homeland Security

Presidential Directive 5 and is designed to address all hazards, including FADs. It formalizes the Incident Command System (ICS) developed by the Forest Service in the 1970's to mobilize resources and people in the management of forest fires. ICS is composed of five major sections and is highly flexible with sections growing or shrinking depending on the extent of the outbreak and its complexity. It can involve individuals from a number of different agencies and is designed to streamline activities, maximize resources, and clarify chains of command. For an FAD outbreak, the incident command structure might include veterinarians, technicians, disease specialists and support personnel drawn from the military, universities, industry, private practice, as well as state and federal governments.

The five majors sections of Incident Command Management are: Command, Finance, Logistics, Operations and Planning. Duties and responsibilities of the sections are outlined below.

The Command Section is led by a single Incident Commander and this section controls all personnel and equipment, maintains accountability for task accomplishment, and serves as a liaison with outside agencies. In the event of an ICS for an FAD outbreak, the Incident Commander position would be occupied, at least initially, by the State Veterinarian and the AVIC.

The Planning Section is responsible for creating the Incident Action plan. The incident Action plan defines the response activities and use of all resources. During an FAD outbreak response, the Planning section will also be concerned with animal welfare issues, formulatio9n of a vaccination plan, epidemiology, wildlife interaction, laboratory coordination, Geographic Information System (GIS), development of surveillance plan for the control area, and reporting of the disease outbreak situation.

The Operations Section carries out the operational aspects of the response primarily on the affected premises. The response activities and duties here include quarantine, vector control, euthanasia, disposal of carcasses, and further disease detection activities as called for in the surveillance plan.

The Logistics Section is responsible for providing facilities, materials, and services. Functions of this section are geared toward addressing the needs of the responders themselves.

The Finance Section manages the expenditures required by all sections and participants to respond to a disaster.

From: "Foreign Animal Diseases" published by the United States Animal Heath Association, Richmond Virginia, 2004

USDA - APHIS RESPONSIBILITIES

The primary agency within the USDA that will address animal disease and plant disease events is the Animal Plant Health Inspection Service (APHIS). Events occurring on the farm or at land, sea or air port are a USDA APHIS responsibility. APHIS supplies border inspections, animal import testing, and quarantine, as well as training of veterinarians for Foreign Animal Disease (FAD) detection. Each year, APHIS oversees over 850 FAD investigations, with usually only 1-2 responses.

Veterinary Services (VS) has the primary responsibility to protect, detect, contain, and eliminate foreign animal diseases and promote animal health in the United States. VS have 45 state offices in the United States and Puerto Rico.

- Federal Veterinarians. Most states have an area veterinarian in charge (AVIC) and a variable number of veterinary medical officers (VMO) to investigate possible disease events. The VS personnel work closely with the State Veterinarian to protect animal health. The AVIC for your area can be found at http://www.aphis.usda.gov/about_aphis/programs_offices/veterinary_services/index.shtml An updated list of AVICs can also found at the end of this module.

- Foreign Animal Disease Diagnosticians (FADD) are either State Department of Agriculture or USDA APHIS VS veterinarians who have received specialized training in the detection of FADs. Upon notification of a suspicious disease, an FADD will be sent to the site within 8-16 hours.

- The USDA APHIS VS operates the National Veterinary Services Laboratory (NVSL) in Ames, Iowa and the other is the Foreign Animal Disease Diagnostic Laboratory (FADDL) at Plum Island, New York. These diagnostic laboratories perform laboratory testing to diagnose and confirm all FAD suspect samples.

- AERO (Animal Emergency Response Organization),are state-level organizations that involve cooperative agreements between states and the USDA APHIS VS as a response system using ICS that will enhance disease surveillance and emergency preparedness capabilities. Personnel are trained animal health emergency managers and can be mobilized to support and fight an outbreak. They may include veterinarians, technicians, disease specialists, and administrative or clerical personnel.

FSIS Responsibilities and FSIS Directive 6000.1, Rev. 1

FSIS Directive 6000.1, Rev. 1 provides instruction to FSIS Public Health Veterinarians when they suspect that animals may have a foreign animal disease (FAD), or when PHVs observe symptoms of FADs or other reportable diseases.

If a reportable or FAD is suspected, inspection program personnel should find out as much history as possible. This may be gathered from animal records, ante-mortem pen cards, verbal information from driver, or any other source of information or materials. Much of this information may not be available; however, if information of this type is available, it needs to be accurately passed on to the District Office (DO).

Signs of FADs

If program personnel observe the following signs or findings, or come across the following information relative to animals presented for slaughter, FAD may be suspected:

- high morbidity;
- high mortality;
- severe abortion storms of unknown etiology;
- avian disease with acute deaths or central nervous system (CNS) signs;

- history of foreign travel; foreign visitors; foreign mail or gifts; or importation of animals, embryos, or semen.

Ante-mortem signs:

- findings that do not fit with the typical conditions for a specific disease
- vesicular lesions;
- severe respiratory conditions;
- pox or lumpy skin conditions;
- CNS diseases (or undiagnosed encephalitic conditions);
- mucosal diseases;
- larvae in wounds;
- unusual myiasis or ascariasis; or
- unusual or unexplained illness or symptoms.

Postmortem conditions such as:

- hemorrhagic septicemia;
- suspicious or unusual post-mortem (necropsy) findings;
- findings that do not fit with the typical conditions for a specific domestic disease.
- lesions such as necrotic foci on tonsils, enlarged spleen, or hydro-pericardium, if coupled with suspicious information (antemortem findings, records, etc.) should warrant further investigation.

PHV RESPONSIBILITIES

If PHVs observe animals exhibiting the signs described above, the animals are to be considered “U.S. Suspects” under 9 CFR 309.2. PHVs are to notify the DO, as soon as possible, when they suspect that any undiagnosed or unusual disease condition is reportable, foreign, or both. This module will cover the conditions and symptoms associated with FADs. The APHIS Foreign Animal Disease CDs should be reviewed for pictures and movie clips of these conditions. Extra copies of the CDs may be acquired from the Center for Learning.

PHVs are to gather, and provide to the DO, as much of the following information as possible:

- 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 diseases or conditions are suspected to be present;
- any gross lesions seen;
- the PHVs contact information, including name, address, and relevant phone numbers.

The DO will notify the APHIS Area Veterinarian-in-Charge (AVIC), the State Animal Health Official (SAHO) or both, and provide the information gathered by the PHV.

In most cases, APHIS or the State Animal Health Official will want the animal held so they can examine it. The veterinarian will 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 veterinarian or some other animal health official.

The State Animal Health Official or APHIS AVIC will determine how the case is to be handled and give the DO specific instructions at that time. If it is determined that an investigation is warranted, a Foreign Animal Disease Diagnostician from APHIS or the State will be assigned.

There are two types of animals specially identified before being sent to slaughter that you need to be familiar with: TB reactors (tuberculin reactors) and brucellosis reactors. These animals may show no abnormal signs; however, they still require your special attention. Details on how to handle TB reactors and brucellosis reactors will be covered under subsequent section of this training.

Lists of the current AVIC and State Veterinarians are provided at the end of this module. They may also be located at the following web links:

CONTACT OF APHIS – AVIC and State Veterinarian Area Offices

For State animal health offices see: http://www.aphis.usda.gov/vs/sregs/official.html

For APHIS AVIC offices see:
http://www.aphis.usda.gov/about_aphis/programs_offices/veterinary_services/index.shtml

Exotic Newcastle Disease

(Velogenic Newcastle disease, Asiatic Newcastle disease)

Definition

Velogenic Newcastle disease (VND) is the most severe form of Newcastle disease and is likely the most serious disease of poultry throughout the world (2,4,13). In chickens it is characterized by lesions in the brain or gastrointestinal tract, morbidity rates near 100 percent, and mortality rates as high as 90 percent in susceptible chickens. Neurologic signs or severe depression are the most obvious clinical sign, and some nonvaccinated birds may be found dead with no detected sign of prior illness.

Etiology

Newcastle disease viruses (NDV's) occur as three pathotypes: lentogenic, mesogenic, and velogenic, reflecting increasing levels of virulence. The most virulent (velogenic) isolates are further subdivided into neurotropic and viscerotropic types. The velogenic isolates are considered exotic to the United States, and the disease caused by these VND isolates is the subject of this chapter.

The Newcastle disease viruses belong to the *Paramyxoviridae* virus family and, like other members of this group, possess two surface proteins that are important to the identification and behavior of the virus. The first, hemagglutinin/neuraminidase (HN) is important in the attachment and release of the virus from the host cells in addition to its serologic identification. The other very important surface protein is the fusion (F) protein, which has a critical role in the pathogenesis of the disease. There are at least nine known types of avian paramyxoviruses based on the antigenic makeup of the hemagglutinin. NDV is the prototype virus for Type 1 avian paramyxoviruses.

Host Range

Inapparently infected carriers that are the most likely source for introduction of VND include numerous species of exotic pet and exposition birds, waterfowl, and domestic poultry (18). A persistent carrier state has been demonstrated in psittacine (8) and in certain other wild birds (19) whereas virus can be recovered from chickens for shorter periods of time, usually 14 days or less.

Geographic Distribution

Velogenic Newcastle disease is endemic in many countries of Asia, the Middle East, Africa, and Central and South America. Some European countries are considered free of VND. VND has caused high mortality in wild cormorants in Canada and the United States.

Transmission

In many parts of the tropics VND is recurrent in the poultry populations. One possibility is that they are infected from a wild bird reservoir. Additional studies will be required before it can be established which species, if any, are true carriers and which are only transiently infected. It is not known whether the occurrence of VND in wild birds moving in international trade can be reduced by avoiding the capture of certain species or their

collection at certain time periods or places. Once introduced into poultry, the virus spreads farm-to-farm by the movement of inapparently infected poultry species; on contaminated objects such as boots, sacks, egg trays, and crates; or by flies (5) or mice. Reports from England (11) that the virus can be wind-borne under certain conditions should be considered even though there was no evidence of airborne transmission between premises with the virus that caused the 1971 outbreak in California. Free-flying wild birds apparently had no role in the spread of VND during that outbreak (16).

Incubation Period

The incubation period for Newcastle disease after natural exposure varies from 2 to 15 days. For VND in chickens, an incubation period of 2 to 6 days is common. The incubation period in other species of birds may be longer.

Clinical Signs

Velogenic Newcastle disease is a devastating malady in unvaccinated chickens of any age. The first sign in laying chickens is usually a marked drop in egg production followed within 24 to 43 hours by high death losses. At the onset, 10-15 percent of a flock may be lost in 24 hours. After 7 to 10 days, deaths usually subside, and birds surviving 12 to 14 days generally do not die but may display permanent paralysis and other neurologic signs. The reproductive system may be permanently impaired, and thus egg production does not return to previous levels. In vaccinated chickens, or chicks protected by parental antibodies, the clinical signs are less severe and are proportional to the level of protective antibodies.

With viscerotropic strains (VVND), edema of the head, especially around the eyes may become apparent after birds have been sick for 2 or 3 days (9). This edema usually does not involve the comb and wattle to the extent of highly pathogenic avian influenza (HPAI). A dark ring sometimes forms around the eye, probably due to cyanosis and poor blood circulation in the edematous tissue. This "black eye" appearance is especially visible in white chickens.

Bile-stained, greenish-dark diarrhea may be noted 2 to 3 days after onset of illness. Some birds in an affected flock usually have diarrhea throughout the course of the disease.

The most noteworthy clinical sign in unvaccinated flocks is sudden death without prior indications of illness. The peracute onset often causes the owner to suspect poisoning.

Respiratory distress and signs of neurological disturbances, such as drooping wings, torticollis, and ataxia. may not be as marked as they are with the neurotropic forms of the disease. However, these neurologic signs are frequently observed in chickens that survive infection with the viscerotopic strains for 2 or 3 weeks. Because of lack of experience with viscerotropic strains, poultry owners throughout the United States and Canada may not consider Newcastle disease as a possible diagnosis unless they see the neurologic signs they have seen with the domestic neurotropic viruses.

Neurotropic strains cause respiratory signs soon followed by neurologic signs, including muscular tremors, paralysis of legs or wings, torticollis, and opisthotonos. There is a marked decline in egg production but usually no diarrhea. Disease signs may differ markedly, depending on the host species. Psittacines or pigeons infected with the viscerotropic strains of virus may display neurologic signs typical of the disease caused

by the strains of neurotropic ND in chickens (7). These same viscerotropic viruses may cause typical signs and lesions of VVND when inoculated into chickens (6). In some species, such as finches and canaries, clinical disease may not be observed.

Gross Lesions

No gross lesion may be observed in many of the first birds dying in a commercial poultry operation. Peracute deaths are generally due to collapse or dysfunction of the reticuloendothelial system before discernible gross lesions have developed. There is no pathognomonic gross lesion for VVND, but, generally, sufficient lesions can be found to make a tentative diagnosis if enough birds are examined (14). Because of the marked similarities between the gross lesions of VVND and highly pathogenic avian influenza, a final diagnosis in the first flocks must await virus isolation and identification. In a continuing outbreak where numerous flocks are involved, gross observations may eventually be all that is necessary when typical lesions are present.

Edema of the interstitial tissue of the neck, especially near the thoracic inlet, may be marked. After the trachea and esophagus are exposed during necropsy examination, straw colored fluid may drip from these tissues. Congestion and occasionally hemorrhage may be seen in the trachea generally corresponding to the rings of cartilage.

Proventriculus

Petechial and small ecchymotic hemorrhages may be present on the mucosa of the proventriculus. These small hemorrhagic foci tend to be found near the base of the papillae and concentrated around the posterior and anterior orifices.

Intestine

Peyer's patches, cecal tonsils, and other focal aggregations of lymphoid tissue in the gut wall usually are markedly involved and are responsible for the term viscerotropic applied to this form of Newcastle disease. These areas progressively become edematous, hemorrhagic, necrotic, and ulcerative. In chickens that have died from VVND, these involved lymphoid areas can often be observed without opening the gut.

Reproductive System

Ovaries may be edematous, hemorrhagic, or degenerated. Yolk peritonitis can frequently be observed in layers as a result of VVND, and rough, misshapen eggs are frequently laid by recovering hens.

Neurotropic strains of VND may cause few gross lesions other than in the trachea and lungs. There will be no gross lesion in the brain of diseased birds. Gross lesion patterns usually differ markedly between the disease caused by the viscerotropic and neurotropic velogenic viruses.

Morbidity and Mortality

Clinical VND is most severe in chickens, peafowl, guineas, pheasant, quail and pigeons. Turkeys may develop a milder form of the disease. Severity of disease in psittacine and passerine birds is variable. In susceptible chickens, the morbidity and mortality rates can

be as high as 100 percent and 90 percent, respectively. In some species such as finches and canaries, clinical disease may not be observed.

Diagnosis

Field Diagnosis

A tentative diagnosis of VND may be made on the basis of history, clinical signs, and gross lesions, but because of similarities to other diseases such as fowl cholera and highly pathogenic avian influenza, confirmation requires virus isolation and identification.

Specimens for Laboratory

Virus can readily be recovered from sick or recently dead birds. Swabs are the most convenient way to transfer VND virus from tissues or secretions of the suspect bird to brain and heart infusion broth or other cell culture maintenance medium containing high levels of antibiotics (1). Trachea, lung, spleen, cloaca, and brain should be sampled. Swabs should be inserted deeply to ensure obtaining ample epithelial tissue. If large numbers of dead or live birds are to be sampled, cloacal swabs from up to five birds can be pooled in the same tube of broth. An alternate technique is to place 0.5 cm^3 of each tissue into the broth. If the specimens can be delivered to a laboratory within 24 hours, they should be placed on ice. If delivery will take longer, quick-freeze the specimens and do not allow them to thaw during transit.

Laboratory Diagnosis

In the laboratory, virus isolation is attempted by inoculating 9- to 11-day-old embryonating chicken eggs. Chorioallantoic fluid (CAF) is collected from all embryos dying after 24 hours postinoculation and tested for hemagglutination (HA) activity. If positive, the hemagglutination-inhibition (HI) test is used with known NDV-positive serum to confirm the presence of NDV in the CAF (3). If NDV is found, it is characterized by inoculating 4- to 6-week-old chickens free of ND antibodies with the suspect CAF by swabbing the cloaca, instilling into the nares or conjuctival sac, or injecting into the thoracic air sac. If VVND virus is present, the inoculated chicks usually die in 3 to 7 days, revealing typical visceral lesions on postmortem examination. Neurotroph ic VVD viruses will cause severe neurologic and respiratory signs in inoculated chickens but no visceral lesions. If no bird dies in 10 days, the NDV is not considered to be the velogenic, viscerotropic type but is either a lentogen or mesogen.

Differential Diagnosis

The viscerotropic, velogenic Newcastle disease in poultry can be confused with highly pathogenic avian influenza, infectious laryngotracheitis, fowl cholera, and coryza.

Vaccination

Vaccination with viable or inactivated oil emulsion vaccines, or both, can markedly reduce the losses from VND in poultry flocks. If eradication of the virus is not the goal of the control program, vaccines can be used to lessen the impact of the disease. Their use, however, can make the complete eradication of the virus much more problematic by increasing the difficulty of identifying infected flocks. There is little doubt, however, that vaccination makes the flock more refractive to infection when exposed and reduces the quantity of virus shed by infected flocks.

Control and Eradication

Before 1972, VND was introduced into the United States on several occasions by unrestricted introduction of exotic pet birds, especially psittacine birds. Because pet birds are not usually associated with domestic poultry, VND outbreaks were rare (20). Since 1973, restrictions on the importation of exotic birds requiring the quarantining and testing of imported birds in approved quarantine facilities have reduced but not eliminated the threat of VND in the United States. Illegally imported exotic bird species remain the source of frequent outbreaks of VND in private or commercial aviaries.

The establishment of a strict quarantine and destruction of all infected and exposed birds with financial indemnification for losses followed by thorough cleaning and disinfection of premises were the main features necessary for eradication of VND virus from the poultry producing area of southern California. Flocks may be safely and humanely destroyed using carbon dioxide in air-tight chambers and the carcasses disposed of by burying, composting, or rendering, depending upon the geographic area and the numbers involved. The VND virus has been recovered from effluent water for as long as 21 days and from carcasses for 7 days when the daytime temperatures were over 90o F. It is recommended that premises be kept free of domestic poultry for an additional 30 days after cleaning and disinfection are completed.

Insects and mice associated with the poultry should be destroyed before depopulation of a flock begins (5,12). Usually 48 hours is sufficient to control these vectors. As soon as all birds are killed and the manure and feed removed, all equipment and structural surfaces should be thoroughly cleaned using high-pressure spray equipment. The entire premises should then be sprayed with an approved residual disinfectant such as the cresylics or phenolics. Preliminary disinfection will probably inactivate most of the viruses on the surface of floors, equipment, cages, etc., but no disinfectant is effective unless it is applied to scrupulously cleaned surfaces free of all organic material.

Cleaning and disinfecting commercial poultry premises are time-consuming and expensive operations. All manure must be removed down to a bare concrete floor. If the floor is earthen, at least the top inch of soil should be removed with the manure. Manure can be safely disposed of by burying it at least 5 feet deep or by composting. If composting is used, the manure piles should be tightly covered with black polyethylene sheets in a manner to prevent access by birds, insects, and rodents during composting. These piles of manure should remain tightly covered and undisturbed at least 90 days during warm weather and for longer periods during cold weather. Recent studies indicate that proper composting can decompose carcasses and manure, and thus inactivate viruses in only a few weeks.

Feathers, usually numerous around commercial poultry premises, can be burned outside the buildings, and in some cases inside, with the careful use of a flame thrower, or they can be removed and the area wet down with disinfectant. The hot sun and high daytime temperatures will assist in destroying the virus in the area of the houses. Extremely cold temperatures will make the cleaning and decontamination process much more difficult, and the results more uncertain.

In 1997, because neither the neurotropic or viscertropic strain of velogenic Newcastle disease was known to exist in the United States, USDA-APHIS declared both types to be exotic and therefore indistinguishable as to the response of disease control officials should they occur in the United States.

Surveillance

The most difficult part of the VND eradication program is locating inapparently infected and exposed birds.

Repeated vaccination at 30 to 50 day intervals protects most chickens against clinical manifestation of VND. However, vaccine does not prevent all chickens in a flock from becoming infected, showing no disease sign, or shedding virulent virus. As individual chickens become susceptible and get exposed to the virus, they become infected and also shed the virus for a time. Thus, the virulent virus continues to be present in apparently healthy, vaccinated flocks. The advantages of using vaccines as part of a VND eradication program must be weighed against the difficulty created in finding asymptomatic but infected and virus-shedding flocks. In such instances owners should be encouraged to observe strict biosecurity measures to reduce the chances of their flocks being exposed to VND virus.

Infected carriers in vaccinated flocks can be detected using one of two systems. In the first, all birds dying during a 24-hour period are collected twice a week, and cloacal swabs and brains are collected and cultured for the presence of VND virus using the diagnostic sampling procedures described earlier. Birds in VND-infected flocks that die from Marek's disease, leukosis, gout, and numerous other disease conditions may yield VND virus—especially if their immune system was impaired by those diseases before death. In the second virus detection system, susceptible sentinel birds are placed in vaccinated flocks (18). The sentinel birds must be unvaccinated and obtained from a specific pathogen-free source to be certain that they do not inadvertently serve as a source of diseases for the suspect flock. In most instances the sentinel birds die from VND within a week or so after placement if there is VND virus present in the flock; however, in some cases it is sometimes difficult to place sentinel birds so they are adequately exposed to any VND virus that may be in the flock — especially in caged-layer flocks.

Public Health

Although people may become infected with VND virus, the resulting disease is typically limited to a conjunctivitis. Recovery is usually rapid, and the virus is no longer present in eye fluids after 4 to 7 days. Infections have occurred mostly in laboratory workers and vaccinating crews with rare cases in poultry handlers. No instance of transmission to humans through handling or consuming of poultry products is known. Individuals with conjunctivitis from VND virus should not enter poultry premises or come in contact with live avian species.

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Avian Influenza (Fowl Plague)

General

The historic and dreaded synonym used to describe the disease caused by highly pathogenic (HP) avian influenza virus is fowl plague. Less pathogenic strains of avian influenza have caused problems in many US turkey flocks and live poultry markets since the 1960's, while few commercial chicken flocks were involved. However in 1983, a virus originally characterized as relatively nonpathogenic began to produce a fowl-plague-like disease with high death losses in Pennsylvania. Control and eradication of this 1983 outbreak cost over $63 million in Federal funds and an additional $350 million in increased consumer costs. As of 1998, viruses related to those involved in the 1983 outbreak continue to circulate in North America and to pose a threat to the US Poultry industry. The recent highly publicized outbreak of H5N1 avian influenza (AI) in chickens and people in Hong Kong illustrates the potential public health concerns that may surface as a result of AI infections.

Definition

Avian influenza (AI) is a disease of viral etiology that ranges from a mild or even asymptomatic infection to an acute, fatal disease of chickens, turkeys, guinea fowls, and other avian species, especially migratory waterfowl (1,2,3,4,8,9,10,11).

Etiology

Fowl plague was described in 1878 as a serious disease of chickens in Italy. It was determined in 1955 that fowl plague (FP) virus is actually one of the influenza viruses. The AI viruses, along with the other influenza viruses, make up the virus family Orthomyxoviridae. The virus particle has an envelope with glycoprotein projections with hemagglutinating and neuraminidase activity. These two surface antigens, hemagglutinin (HA) and neuraminidase (NA), are the basis of describing the serologic identity of the influenza viruses using the letters H and N with the appropriate numbers in the virus designation e.g., H7N2. There are now 16 hemagglutinin and 9 neuraminidase antigens described among the Type A influenza viruses. The type designation (A, B, or C) is based upon the antigenic character of the M protein of the virus envelope and the nucleoprotein within the virus particle. All influenza viruses affecting domestic animals (equine, swine, avian) belong to Type A, and Type A influenza virus is the most common type producing serious epidemics in humans. Types B and C do not affect domestic animals.

Classical fowl plague viruses have H7 as one of the surface antigens but can have different N antigens. It was once believed that all H7 viruses are highly pathogenic fowl plague viruses and that no other avian influenza viruses could produce a fowl-plague-like disease. When avirulent AI viruses with the H7 antigens were demonstrated in turkeys in 1971 and highly virulent AI viruses with the H5 antigen were first found in chickens in 1959, the necessity for redefining the term fowl plague or using other terminology became apparent. Because there are highly virulent AI viruses that possess H antigen other than the H7 and H7 AI viruses that do not produce clinical fowl plague, an international assembly of avian influenza specialists proposed that the term fowl plague no longer be used. They suggested that any AI virus, regardless of its HA designation, meeting specified virulence requirements in the laboratory be designated

highly pathogenic avian influenza (HPAI). The criteria that serve as the basis for classifying an AI virus as HPAI has more recently been modified to include molecular considerations such as the type of amino acids at the cleavage site of its HA. This chapter will be limited to describing the HPAI and not the AI viruses of less virulence and pathogenicity.

Host Range

Most avian species appear to be susceptible to at least some of the AI viruses. A particular isolate may produce severe disease in turkeys but not in chickens or any other avian species. Therefore, it would be impossible to generalize on the host range for HPAI, for it will likely vary with the isolate. This assumption is supported by reports of farm outbreaks where only a single avian species of several species present on the farm became infected. Swine appear to be important in the epidemiology of infection of turkeys with swine influenza virus when they are in close proximity. Other mammals do not appear to be involved in the epidemiology of HPAI. The

infection of humans with an H5 avian influenza virus in Hong Kong in 1997 has resulted in a reconsideration of the role of the avian species in the epidemiology of human influenza.

Geographic Distribution

Highly pathogenic avian influenza viruses have periodically occurred in recent years in Australia (H7), England (H7), South Africa (H5), Scotland (H5), Ireland (H5), Mexico (H5), Pakistan (H7), and the United States (H5). Because laboratory facilities are not readily available in some parts of the world to differentiate Newcastle disease and HPAI, the actual incidence of HPAI in the world's poultry flocks is difficult to define. It can occur in any country, regardless of disease control measures, probably because of its prevalence in wild migratory waterfowl, sea birds and shore birds.

Avian influenza has produced losses of variable severity, primarily in turkeys in the United States, since the mid-1960's. The disease outbreaks in turkeys in the United States have been caused by AI viruses with many of the HA designations. It was in the fall of 1983 that a highly virulent H5 virus produced severe clinical disease and high mortality in chickens, turkeys, and guinea fowl in Pennsylvania. This severe disease, clinically indistinguishable from classical fowl plague, occurred after a serologically identical but apparently mild virus had been circulating in poultry in the area for 6 months.

Outbreaks of less virulent AI have frequently been described in domestic ducks in many areas of the world. The AI viruses are often recovered from apparently healthy migratory waterfowl, shore birds, and sea birds worldwide. The epidemiologic significance of these isolations relative to outbreaks in domestic poultry has led to the generally accepted belief that waterfowl serve as the reservoir of influenza viruses.

Transmissions

There is a considerable body of circumstantial evidence to support the hypothesis that migratory waterfowl, sea birds, or shore birds are generally responsible for introducing the virus into poultry. Once introduced into a flock, the virus is spread from flock to flock

by the usual methods involving the movement of infected birds, contaminated equipment, egg flats, feed trucks, and service crews, to mention a few. Preliminary trapping evidence indicates that garbage flies in the Pennsylvania outbreak were sources of virus on the premises of the diseased flocks. Virus may readily be isolated in large quantities from the feces and respiratory secretions of infected birds. It is logical to assume, therefore, that because virus is present in body secretions, transmission of the disease can take place through shared and contaminated drinking water. Airborne transmission may occur if birds are in close proximity and with appropriate air movement. Birds are readily infected via instillation of virus into the conjunctival sac, nares, or the trachea. Preliminary field and laboratory evidence indicates that virus can be recovered from the yolk and albumen of eggs laid by hens at the height of the disease. The possibility of vertical transmission is unresolved; however, it is unlikely infected embryos could survive and hatch. Attempts to hatch eggs in disease isolation cabinets from a broiler breeder flock at the height of disease failed to result in any AI-infected chickens. This does not mean that broken contaminated eggs could not be the source of virus to infect chicks after they hatch in the same incubator. The hatching of eggs from a diseased flock would likely be associated with considerable risk.

Incubation Period

The incubation period is usually 3 to 7 days, depending upon the isolate, the dose of inoculum, the species, and age of the bird.

Clinical Signs

Infections of HPAI result in marked depression with ruffled feathers, inappetance, excessive thirst, cessation of egg production, and watery diarrhea. Mature chickens frequently have swollen combs, wattles, and edema surrounding the eyes. The combs are often cyanotic at the tips and may have plasma or blood vesicles on the surface with dark areas of ecchymotic hemorrhage and necrotic foci. The last eggs laid, after the onset of illness, are frequently without shells. The diarrhea begins as watery bright green and progresses to almost totally white. Edema of the head, if present, is often accompanied by edema of the neck. The conjunctivae are congested and swollen with occasional hemorrhage. The legs, between the hocks and feet, may have areas of diffuse hemorrhage. Respiratory signs can be a significant feature of the disease, depending on the extent of tracheal involvement. Mucus accumulation can vary. It is not unusual in caged layers for the disease to begin in a localized area of the house and severely affect birds in only a few cages before it spreads to neighboring cages.

Death may occur within 24 hours of first signs of disease, frequently within 48 hours, or be delayed for as long as a week. Some severely affected hens may occasionally recover.

In broilers, the signs of disease are frequently less obvious with severe depression, inappetence, and a marked increase in mortality being the first abnormalities observed. Edema of the face and neck and neurologic signs such as torticollis and ataxia may also be seen.

The disease in turkeys is similar to that seen in layers, but it lasts 2 or 3 days longer and is occasionally accompanied by swollen sinuses.

In domestic ducks and geese the signs of depression, inappetence, and diarrhea are similar to those in layers, though frequently with swollen sinuses. Younger birds may exhibit neurologic signs.

Gross Lesions

Birds that die with the peracute disease and young birds may not have significant gross lesions other than severe congestion of the musculature and dehydration. In the less acute form, and in mature birds, significant gross lesions are frequently observed. They may consist of subcutaneous edema of the head and neck area, which is evident as the skin is reflected. Fluid may exit the nares and oral cavity as the bird is positioned for postmortem examination. The conjunctivae are severely congested— occasionally with petechiation. The trachea may appear relatively normal except that the lumen contains excessive mucous exudate. It may also be severely involved with hemorrhagic tracheitis similar to that seen with infectious laryngotracheitis. When the bird is opened, pinpoint petechial hemorrhages are frequently observed on the inside of the keel as it is bent back. Very small petechia may cover the abdominal fat, serosal surfaces, and peritoneum, which appears as if it were finely splattered with red paint. Kidneys are severely congested and may occasionally be grossly plugged with white urate deposits in the tubules.

In layers, the ovary may be hemorrhagic or degenerated with darkened areas of necrosis. The peritoneal cavity is frequently filled with yolk from ruptured ova, causing severe airsacculitis and peritonitis in birds that survive for 7 to 10 days.

Hemorrhages may be present on the mucosal surface of the proventriculus — particularly at the juncture with the gizzard. The lining of the gizzard peels easily and frequently reveals hemorrhages and erosions underneath. The intestinal muscosa may have hemorrhagic areas — especially in the lymphoid foci such as the cecal tonsils. The gross lesions are not distinctly different from those observed with velogenic viscerotropic Newcastle disease (VVND). The lesions in turkeys and domestic ducks are similar to those in chickens but may not be as marked.

Morbidity and Mortality

The prognosis for flocks infected with HPAI is poor. Morbidity and mortality rates may be near 100 percent within 2 to 12 days after the first signs of illness. Birds that survive are usually in poor condition and resume laying only after a period of several weeks.

Diagnosis

Field Diagnosis

Highly pathogenic avian influenza is suspected with any flock where sudden deaths follow severe depression, inappetence, and a drastic decline in egg production. The presence of facial edema, swollen and cyanotic combs and wattles, and petechial hemorrhages on internal membrane surfaces increases the likelihood that the disease is HPAI. However, an absolute diagnosis is dependent upon the isolation and identification of the causative virus. Commercially available type A influenza antigen-capture enzyme linked immunosorbent assay kits designed for use in human influenza have recently shown promise as a possible rapid diagnostic test for poultry.

Specimens for Laboratory

Specimens sent to the laboratory should be accompanied by a history of clinical and gross lesions, including any information on recent additions to the flock. Diagnosis depends upon the isolation and identification of the virus from tracheal or cloacal swabs, feces, or from internal organs (5). Specimens should be collected from several birds. It is not unusual for many of the submitted specimens to fail to yield virus. Swabs are the most convenient way to transfer AI virus from tissues or secretions of the suspect bird to brain and heart infusion broth or other cell culture maintenance medium containing high levels of antibiotics. Dry swabs should be inserted deeply to ensure obtaining ample epithelial tissue. Trachea, lung, spleen, cloaca, and brain should be sampled. If large numbers of dead or live birds are to be sampled, cloacal swabs from up to five birds can be pooled in the same tube of broth. An alternative technique is to place 0.5 cm^3 of each tissue into the broth. Blood for serum should be collected from several birds. If the specimens can be delivered to a laboratory within 24 hours, they should be placed on ice. If delivery will take longer, quickfreeze the specimens and do not allow them to thaw during transit.

Laboratory Diagnosis

Nine to 11-day-old embryonated chicken eggs are inoculated with swab or tissue specimens. Avian influenza virus will usually kill embryos within 48-72 hours. If the virus isolated is identified as a Type A influenza virus, through the AGP or ELISA tests, it is then tested using a battery of specific antigens to identify its serologic identity (HA and NA type). Sera from infected chickens usually yield positive antibody tests as early as 3 or 4 days after first signs of disease.

Differential Diagnosis

Highly pathogenic avian influenza is easily confused with VVND, because the disease signs and postmortem lesions are similar, and may also be confused with infectious laryngotracheitis and acute bacterial diseases such as fowl cholera and *Escherichia coli.* However, in an area where AI is prevalent, such as during an outbreak, sound presumptive diagnoses can be made by flock history, signs, and gross lesions.

Treatment

Amantadine hydrochloride has been licensed for use in humans to treat influenza since 1966. The medication is effective in reducing the severity of influenza Type A in humans. Experimental evidence indicated possible efficaciousness in poultry when the drug was administered in drinking water to reduce disease losses, but drug-resistant viruses quickly emerged, negating the initial beneficial effects. Thus, the drug is not recommended for use in poultry.

Vaccination

Inactivated oil-emulsion vaccines, although fairly expensive, have been demonstrated to be effective in reducing mortality, preventing disease, or both, in chickens and turkeys (7). These vaccines may not, however, prevent infection in some individual birds, which go on to shed virulent virus. More economical viable vaccines prepared using naturally avirulent or attenuated strains have the disadvantage of the possible creation of reassortant influenza viruses with unpredictable characteristics. These reassortants could result when a single host bird is simultaneously infected with both the vaccine and

another HPAI virus. Owing to the segmented nature of the influenza virus genome, a reassortment of genetic material can readily occur, creating new influenza viruses. The basic drawback to any vaccine approach for the control of HPAI is the large number of HA subtypes that can cause the disease. Because there is no cross-protection among the 15 known HA subtypes, either a multivalent vaccine will be needed or vaccination postponed until the prevalent disease-causing subtype in the area is identified. A recombinant fowl pox virus vaccine containing the gene that codes for the production of the H5 antigen has recently been licensed. The use of a recombinant insect virus containing the gene for either the H5 or H7 antigen has been used to make these vaccine proteins in insect cell cultures.

Control and Eradication

The practice of accepted sanitation and biosecurity procedures in the rearing of poultry is of utmost importance. In areas where waterfowl, shore birds, or sea birds are prevalent, the rearing of poultry on open range is incompatible with a sound AI prevention program (12).

Appropriate biosecurity practices should be applied, including the control of human traffic and introduction of birds of unknown disease status into the flock. Cleaning and disinfection procedures are the same as those recommended in the chapter on velogenic Newcastle disease.

FSIS Directive 6020.1, Rev. 1 provides guidance to IPP in the event that USDA APHIS identifies an outbreak of HPAI in the U. S. **The guidance in this directive will be implemented by IPP only if FSIS issues specific instruction via an FSIS user notice.** The Directive contains the following key points:

USDA's Animal and Plant Health Inspection Service (APHIS) has responsibility for the critical activities in the event of an outbreak, defines the control areas, and must issue permits for flock movement from control areas.

Public Health Veterinarians (PHVs) are to examine every truck load of birds, from control areas, during ante-mortem inspection.

On-line inspectors are to retain (e.g., hang back) all carcasses exhibiting signs of HPAI for veterinary disposition.

When PHVs suspect that birds or carcasses exhibit clinical signs or lesions consistent with HPAI, they are to stop the establishment from further slaughtering the flock, retain all affected birds, carcasses and parts, and contact the District Office (DO).

IPP are to comply with the same sanitary and hygiene procedures and biosecurity measures that establishments have in place for their personnel.

Public Health

The AI viruses are Type A influenza viruses, and the possibility exists that they could be involved in the development, through genetic reassortment, of new mammalian strains. An influenza virus isolated from harbor seals that died of pneumonia had the HA and NA surface antigens of an influenza virus isolated from turkeys a decade earlier. The infection and deaths of 6 of 18 humans infected with an H5 avian influenza virus in Hong Kong in 1997 has resulted in a reconsideration of the portentous role that the avian

species have on the epidemiology of human influenza. Previously there was only one report of a human becoming infected with an H7 AI virus. It is impossible to predict the importance of AI virus in determining the strains of virus that infect humans. There was no evidence to indicate that humans coming in contact with large quantities of the H5N2 virus during depopulation efforts in the HPAI outbreak of 1983 in Pennsylvania became infected with the virus.

In the current news, an HPAI virus has been spreading across Asia, Europe and Africa. This highly pathothogenic H5N1 virus has infected people as well as bird populations. Since December 2003, when the first bird-to-human transmission occurred in Viet Nam, 166 people have been infected. The World Health Organization reports as of February 9, 2006 the H5N1 strain of the bird flu has killed 88 people in 7 countries. The most recently confirmed death occurred in Iraq. This H5N1 virus spread west from Southeast Asia to the fringe of Europe in late 2005. In early February 2006, it reached Iraq. On February 8, 2006 it has recently been identified in bird populations in Nigeria.

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Bovine Tuberculosis

Incidence and Etiology

Tuberculosis is a reportable disease, which has not been eradicated from the United States. It is still seen in imported animals, wildlife, and some livestock herds in California, New Mexico, Texas, Minnesota, and Michigan. The TB eradication program depends heavily on the efforts of meat inspection, and all granulomas of unknown origin should be submitted for analysis. Your submission of positive tuberculosis lesions assists APHIS Veterinary Services in eradicating Tuberculosis from American U.S. cattle herds.

Bovine tuberculosis is caused by *Mycobacterium bovis*, and in some cases, *Mycobacterium avium*. *Mycobacterium tuberculosis* is the species most often implicated in human cases of tuberculosis, although *M. bovis* can cause human disease. *M. avium* can cause disease in cattle and in swine.

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. Tuberculosis 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.

Tuberculosis is an ancient disease, as evidence of bovine tuberculosis has been found in Egyptian mummies. The eradication program began in the U.S. in 1917 when 5% of the nation's cattle were said to be TB-infected. In fact, 50,000 cattle carcasses were condemned for the disease that year alone.

Today, bovine TB is more prevalent in beef cattle than in dairy cattle, probably due to the early emphasis on eradication in the dairy breeds. The bovine TB eradication effort is becoming more dependent on efforts of food inspectors, since routine testing of cattle for TB has been de-emphasized. APHIS has implemented the National Tuberculosis Surveillance Program as the most efficient way of finding bovine TB. FSIS personnel play a key role in the program’s goal, which is to collect and submit a minimum of one tissue sample per 2,000 slaughtered adult cattle.

Granulomas in Regular Kill Animals

Now, let's explore the methods by which you as an FSIS Public Health Veterinarian cooperate with VS in the TB eradication effort. Let's suppose you are performing postmortem inspection on cattle viscera and you find a lung lesion that *could* possibly be TB. What would be your action?

Your first action would be to retain the carcass and all its parts, including the lesions. As a part of this step, you would want to collect and coordinate any identification information pertaining to the animal such as backtags, eartags, sales tags, etc. M-branded Mexican cattle will have a blue metal ear tag. Establishment personnel are required to collect all man made identifications from such animals and attach them to the carcass. Mexican cattle have a higher incidence of TB granulomas than do U.S. origin cattle.

Subsequently, lesions should be sent to the National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another laboratory officially approved by APHIS, for confirmation or non-confirmation of suspicions. Granulomas must be divided into the two bottles provided: one is for histopathology and the other for bacteriology. Use the VS Form 6-35, "Report of Tuberculous Lesions or Thoracic Granulomas in Regular Kill Animals" to submit these specimens to the laboratory.

If specimens are found by the laboratory to be positive for TB, then VS, with the aid of identifying information OFO has given them, can accomplish traceback to the herd of origin. This is and will continue to be the "backbone" of the TB eradication program. It is by far the most economical method of locating infected cattle herds. In other words, because of the high cost of routine "down the road" testing of cattle for TB and the low possibility of finding infection, Veterinary Services must rely more and more on the submission of suspicious lesions from slaughtered animals by OFO personnel utilizing the VS 6-35 Forms. Your role as an FSIS Public Health Veterinarian is to facilitate the traceback testing effort, thereby greatly enhancing the TB eradication effort.

Veterinary Services is quite optimistic about the chances of complete eradication of bovine tuberculosis and sees several factors that would tend to *favor* its complete eradication in the near future. Those factors are as follows:

1. Better procedures for testing high-risk herds and areas for tuberculosis.

2. Decline in the prevalence of *Mycobacterium bovis,* the causative agent of tuberculosis in cattle.

3. Cattle are generally slaughtered younger now, with less chance of infection spread.

4. Increased slaughter inspection coverage through laws requiring inspection.

5. Improved animal identification systems.

6. Increased federal indemnities (payments to producers for their losses), thereby enhancing the use of depopulation (total slaughter) of infected herds as a method of *eradicating* the disease rather than merely *controlling* it.

However, Veterinary Services sees certain factors that could hamper the eradication effort. These are as follows:

1. Development, from time to time, of other crises that divert funds and manpower from the TB surveillance program.

2. *Failure* of inspectors to detect TB lesions on postmortem or to submit those that are suspicious to the VS laboratory.

3. *Failure* to collect and submit identification devices with laboratory specimens to aid in possible traceback procedures.

4. Inadequate animal identification and record-keeping at feedlots and markets, as many of the unsuccessful tracebacks dead end at feedlots or livestock markets.

In order to more fully recognize the importance of the food inspector and the Public Health Veterinarian in the bovine TB eradication effort, Veterinary Services has implemented an incentive awards program, known as the APHIS Bovine Tuberculosis Eradication Performance Awards Program. Under this program, food inspectors and Public Health Veterinarians will be considered for cash awards as follows:

1. A cash award of $100 for steers and $500 for adult animals to be shared equally each time Mycobacteriosis is reported on histopathology by the National Veterinary Services Laboratories (NVSL).
   - If the specimen is positive for *Mycobacterium tuberculosis (complex)* on Polymerase Chain Reaction (PCR) test, or *M. bovis* is isolated, the cash award will be increased to a total of $200 for steers and fed heifers and $1,000 for adult animals.
   - Tissues submitted only to FSIS field service laboratories or to other approved, diagnostic laboratories that are indicative of tuberculosis shall be forwarded to NVSL for reconfirmation in order to qualify for an award.

2. A second cash award of $6,000 to be shared equally when an infected herd located in the United States is initially found as a result of the information provided to Veterinary Services (VS) regarding the identification of the lesioned animal.

Each award is shared with the Food Inspector(s) responsible for retaining the affected carcass and the PHV initiating the VS 6-35 report. In the event of multiple cases in the same slaughter lot, awards will be granted for as much as three cases from such a lot. Specimens from animals sent to slaughter under permit because of tuberculosis (reactors, suspects, animals from quarantined herds, exposed animals being depopulated, and exposed animals traced to new herds) will not qualify as a basis for an award.

3. A team award of **$**300 per team member will be awarded annually to high submitting FSIS slaughter inspection groups irrespective of histopathology results. High submitting establishments will qualify, at the end of each 12-month period (Fiscal Year), when the establishment is credited with one or more suspicious tuberculosis lesions or thoracic granulomas submitted per 1,000 cattle killed.

To be considered for an award, the food inspector must recognize the possibility of lesions of TB in a *regular* kill animal, collect and coordinate identification of the animal, and immediately report the facts to the PHV. The PHV is then responsible for retaining the carcass and submitting the samples for analysis. Two or more cases from the same source will be considered one submission. Specimens from animals slaughtered under permit because of TB, such as reactors, suspects, animals from quarantined herds, and exposed animals being depopulated will not qualify for an award.

TB Reactors and Suspects

A TB reactor is an animal that has reacted to an official test for tuberculosis and the reaction is such that the animal is determined to be a reactor. When an animal is identified as a TB reactor, it may be branded with a "T" brand on the left hip, near the tailhead and a TB reactor tag is placed in its left ear before being sent to a packing establishment for slaughter.

When a TB reactor arrives at the establishment, it is handled differently during ante mortem inspection. The establishment must place the animal in the suspect pen and notify the FSIS Public Health Veterinarian. All TB reactors must be examined for signs of TB. If you condemn a TB reactor on ante mortem, you must have the animal removed to an inedible department where an expanded postmortem examination is performed. FSIS is required to do this for live TB reactors condemned on ante mortem, as well as those reactors that have died either en route to the establishment or in the pens. FSIS needs to ensure that all permitted animals are actually slaughtered, and collect samples or assist Veterinary Services employees in collecting samples for submission to NVSL.

A TB reactor is further identified by a form (VS Form 1-27 Permit for Movement of Restricted Animals) that serves as a permit for the movement of the animal. A copy of the form is mailed in advance to the veterinarian at the establishment where the animal is to be slaughtered and a copy of the form accompanies the animal during shipment. Establishment management must segregate the animals, notify the FSIS PHV of their presence, and give a copy of VS Form 1-27 to the FSIS PHV.

TB reactors and suspects will have an approved blue or silver metal eartag bearing a serial number and inscription "U.S. Reactor" or a similar State reactor tag attached to the left ear.and a “T” brand for reactor, or an “S” brand for suspect on the left hip near the tailhead. If animals are unbranded, they must meet the following provisions in order to be moved to slaughter:

- TB reactors must have a legible, permanent “TB” tattoo in the left ear and be sprayed on the left ear with yellow paint.
- TB reactors and suspects must be shipped in a vehicle closed with an official seal or accompanied directly by a State or Federal animal health official.

FSIS PHVs should note any discrepancies on the VS Form 1-27. If any animals are presented for antemortem with an identification mark for TB, but without the proper accompanying paperwork identifying the animal, contact the District Office. PHVs should complete VS Form 1-27 after they have verified that the animals have been slaughtered.

TB reactors are handled as U.S. Suspects, and the reactor number is used in place of the suspect tag number. The time of slaughter is determined by the FSIS PHV. You need to perform a complete ante mortem physical examination of these animals. If they are DOA or DIP, you will perform postmortem examination using expanded procedures.

TB suspects or exposed animals are handled differently from TB reactors. They must be segregated and identified by the establishment to the PHV, but require no special handling unless they are showing clinical signs. If they are dead or are inspected and antemortem condemned by the PHV, they will receive expanded postmortem inspection procedures.

On postmortem, TB reactors must have all identification devices kept with the carcass, and you must perform expanded postmortem procedures. If you do not find granulomatous lesions, you collect a representative sample of lymph nodes of the head and thorax and submit them to NVSL. Once you have conducted your postmortem examination, you must document your findings on FSIS Form 6200-14.

On postmortem, TB suspects are handled differently. All identification devices must be kept with the carcass and you must perform the modified expanded postmortem procedure by incising the supramammary and mesenteric lymph nodes in addition to routine postmortem procedures. Your postmortem findings must be recorded on FSIS Form 6200-14.

On postmortem, TB exposed animals must have the modified expanded procedure performed if they are designated as Category 1, which means that they were moved from an infected herd before the infection was identified by after the herd apparently became infected. If the TB exposed animals are designated as Category 2, animals that are part of a known affected herd that have tested negative or are untested, you perform the regular postmortem inspection procedures. With FLS approval based on adequate facilities to ensure IPP safety, PHVs may direct IPP to perform, observe, and further inspect the routine PM inspection procedures performed on these cattle. Such inspections may be performed at a reduced speed as determined by the PHV per 9 CFR 310.1(b)(1). If no category is designated on VS Form 1-27, handle the animals as Category 2. Your postmortem findings must be recorded on FSIS Form 6200-14.

For all TB reactors, suspects and exposed animals, if thoracic granulomas or other lesions suspected of being tuberculus are found, you are to perform the expanded postmortem inspection procedure. Submit all suspect tissues to NVSL for histopathological analysis.

APHIS Veterinary Services Bovine Tuberculosis Fact Sheet

Tuberculosis (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: *Mycobacterium bovis, M. avium,* and *M. tuberculosis.*

Bovine TB, caused by *M. bovis*, can be transmitted from livestock to humans and other animals. No other TB organism has as great a host range as bovine TB, which can infect all warmblooded vertebrates. *M. avium* can affect all species of birds, as well as hogs and cattle. *M. tuberculosis* primarily affects humans but can also be transmitted to hogs, cattle, and dogs.

Bovine TB has affected animal and human health since antiquity. Once the most prevalent infectious disease of cattle and swine in the United States, bovine TB caused more losses among U.S. farm animals in the early part of this century than all other infectious diseases combined. Begun in 1917, the Cooperative State–Federal Tuberculosis Eradication Program, which is administered by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), State animal health agencies, and U.S. livestock producers, has nearly eradicated bovine TB from the Nation's livestock population. This disease's presence in humans has been reduced as a result of the eradication program, advances in sanitation and hygiene, the discovery of effective drugs, and pasteurization of milk.

The Disease

In general, disease-causing mycobacteria live only a few weeks outside a host's body because they cannot tolerate prolonged exposure to heat, direct sunlight, or dry

conditions. Under cold, dark, and moist conditions, the organisms can survive longer.

Mycobacteria do not grow outside of a host except in cultured media, where they multiply approximately once every 20 hours. Because of this relatively slow rate of growth, the disease usually takes many months to develop. In some instances, the organisms lie dormant within the host's body for its lifetime, both in animals and in humans, without causing progressive disease.

Bovine TB is a chronic disease, seldom becoming apparent until it has reached an advanced stage in cattle, captive cervids, and swine. Some infected livestock seem to be in prime condition, showing no evidence of infection until they are slaughtered, yet they may be found so seriously infected during slaughter inspection that their carcasses must be condemned.

TB Transmission

Bovine TB can be transmitted from animals to humans and vice versa. Although young animals and humans can contract the disease by drinking raw milk from infected dams, the most common means of transmission is through respiration. Invisible droplets (aerosols) containing TB bacteria may be exhaled or coughed out by infected animals and then inhaled by susceptible animals or humans. The risk of exposure is greatest in enclosed areas, such as barns. Inhalation of aerosols is the most common route of infection for farm and ranch workers and veterinarians who work with diseased livestock. Livestock also are more likely to infect each other when they share a common watering place contaminated with saliva and other discharges from infected animals. Calves, hogs, and humans can contract bovine TB when they drink unpasteurized milk from infected cows.

Diagnosis

TB lesions may be found in any organ or body cavity of diseased animals. In early stages of the disease, these lesions are difficult to find, even during post mortem examination. But in later stages, the nodules or lumps caused by bovine TB become very evident in the lungs and associated lymph nodes and in the lymph nodes of the head and intestinal tract. Lesions may also appear in the abdominal organs, reproductive organs, nervous system, superficial body lymph nodes, and bones.

Humans and animals with TB develop an immune response, which can be detected by the tuberculin skin test. Tuberculin is a sterile laboratory product made by growing TB bacteria, killing them with heat, removing them from the substance on which they were grown, and properly diluting and preserving the remaining mixture. About 72 hours after tuberculin is injected into animals affected with TB, a characteristic swelling reaction appears at the point of injection. This reaction is a positive test result, indicating exposure to one type of mycobacteria.

Further diagnostic methods are necessary to confirm the presence of bovine TB. In humans, these tests include chest x rays and sputum cultures. For animals, the comparative cervical tuberculin test, serological tests, post mortem examinations, and other laboratory procedures are used.

The course of treatment for humans with bovine TB takes 6 to 9 months, and the success rate following treatment is more than 95 percent. In livestock, bovine TB can be controlled within an affected herd through regular testing and slaughter of any single animal that tests positive until the entire herd tests negative for this disease. However, because there is no method available to ensure that bovine TB has been eliminated from an affected herd, APHIS recommends herd depopulation.

Control and Eradication

The most effective way of handling the problem of bovine TB in humans is to eradicate it in livestock. At the start of the cooperative eradication program at the beginning of this century, all cattle herds were systematically tested, and all reactors were sent to slaughter. Federal and State agencies shared in the payment of indemnities. Premises were cleaned and disinfected after infected cattle were removed. As a result of this program, the reactor rate in cattle was reduced from about 5 percent to currently less than 0.02 percent. Consequently, the incidence of human TB caused by M. bovis also decreased significantly. The resurgence of human TB in recent years is attributable to *M. tuberculosis.*

Today, with a very low rate of bovine TB, the most efficient way of finding the disease is through a nationwide surveillance program in slaughter establishments. State or Federal meat inspectors check the glands and organs of cattle for signs of TB. If these inspectors find lesions indicative of TB infection, tissue samples are sent to APHIS' National Veterinary Services Laboratories in Ames, IA, for confirmation. If the laboratory confirms that the lesions are the result of bovine TB, an exhaustive attempt is made to trace the infected livestock back through market channels to the originating herd, which is then tuberculin tested.

If the herd of origin is diagnosed with M. bovis, every effort is made to eliminate all animals in the herd. Indemnities, as available, are paid to help compensate owners for their losses. If the herd cannot be depopulated, it is held under quarantine and tested repeatedly until all evidence of infection is eliminated.

Veterinary epidemiologists also attempt to determine the date the herd was probably infected. They then undertake a concerted effort to trace all cattle that moved into or out of the affected herd to try to find out where the disease came from and where it might have gone.

Area Accreditation

For a State to be accredited free of bovine TB, there must have been no confirmed cases of the disease for at least 5 years, and the State must have a set of stringent laws and regulations governing livestock dealers. The State must also maintain surveillance of cattle in marketing channels and require that records be kept that would allow animal health officials to trace infected animals back to their source.

Herd Accreditation

Livestock owners may achieve accredited TB status for their individual herds by following the "Accredited Herd Plan." Details can be found in the publications, "Bovine

Tuberculosis Eradication, Uniform Methods and Rules" (UM&R) and "Tuberculosis Eradication in Cervidae, UM&R."

For a herd to qualify as accredited, a negative finding on two annual TB tests must be attained for all cattle over 24 months of age and cattle of any age that are not natural additions to the herd. Deer and elk herds must test negative for 3 consecutive years. To qualify and continue as an accredited herd, livestock must be tested annually within 10 to 14 months of the anniversary of the original test. Livestock from any herd in an accredited free State may be added to an accredited herd without a qualifying test.

Brucellosis

Handling of Brucellosis Reactors

Brucellosis is a reportable disease. Brucellosis (Bangs) reactors are identified by APHIS Veterinary Services with reactor tags and permit VS Form 1-27. Brucellosis is zoonotic: it causes undulant fever in humans. This disease has been largely eradicated from the United States, but is still present in Louisana, Montana, Wyoming, and Texas. Brucellosis reactors will come to slaughter accompanied by appropriate Veterinary Services documentation (VS Form 1-27).

Now let's talk about the brucellosis eradication program and how you as an FSIS PHV assist in this program. You will need to verify the reactor status by examining brands and documentation. You need to work cooperatively with APHIS Veterinary Services employees to collect and submit blood and tissue samples. Disposition of reactor carcasses is the same as for regular slaughter animals, and should be based on FSIS disposition guidelines. Remember that when you handle brucellosis reactor carcasses to take care: brucellosis is zoonotic.

The Brucellosis Eradication Program

The accelerated brucellosis eradication program began in 1954 and has gone through many changes in the past 45 plus years. OFO has had an increasingly important role in this program in that we are responsible for collecting blood samples at federally inspected establishments from *all* mature cattle. The market cattle testing (MCT) guidelines in Section 21.6 of the MPI Manual define mature cattle as those bulls and cows 2 years of age or over and cows that are giving or about to give birth, or those that have given birth and are *less* than 2 years old. Samples should be taken from those animals branded as reactors.

The blood samples can be taken at any adequate site, but the heart at the time of postmortem inspection is the preferred site of collection.

The blood tubes should be filled to about one-half to three-fourth's capacity for laboratory handling. Each blood sample should be placed in a plastic bag with all identifying devices (including reactor tags, if any) and sent to the appropriate laboratory. Proper care and handling of the samples is very important. Assuring that the samples are protected from freezing, moisture, and contamination cannot be overemphasized. Refrigeration at 35-40 degrees F after serum separation is important. When possible, blood samples should be mailed daily or at least every other day. Franked labels addressed to the proper laboratory are provided, as well as blood sample tubes, mailing boxes, and record forms. In establishments where OFO personnel are unable to collect samples, it is usually arranged through VS for a establishment employee or contract technician to collect the samples under OFO supervision.

The brucellosis eradication program depends very heavily on you as a food inspector and how efficiently you submit the blood samples to the laboratory for analysis. This is especially important since the number of blood samples taken at places other than packing establishments is on the decline.

Before we leave our discussion of brucellosis, we should mention a few points about its transmissibility to man. The potential for inspectors contracting brucellosis from cattle or swine is great and you should take all possible precautions to decrease the likelihood of becoming a victim of the disease. In recent years, most of the reported human brucellosis cases have been of swine origin, probably due to the concentrated bovine eradication effort of former years. When performing routine postmortem you should practice sound hygienic principles to include frequent washing of the hands, and avoiding as much as possible open cuts in the hands through which the bacteria could gain entry. Also, you should strive not to be splattered in such areas as the eyes and mouth with blood and reproductive tract fluids. You should not place your contaminated hands around your mouth at any time. Although you cannot totally eliminate this hazard of your profession, you should always be aware of the things you can do to decrease chances of infecting yourself.

The other type of specially identified animal mentioned above is a brucellosis reactor. Brucellosis (Bang's disease) is another disease that we have been attempting to eradicate from this country for a long time. The identification of these animals is similar to tuberculosis reactors. Animals that react to a brucellosis or Bang's test must be identified and sent to slaughter. A Bang's reactor tag is placed in the animal's left ear and a "B" is branded on the left hip. A shipping permit form is completed and sent along with the Bang's reactor to the slaughter establishment.

APHIS Brucellosis Fact Sheet

1. What is brucellosis?

It is a contagious, costly disease of ruminant animals that also affects humans. Although brucellosis can attack other animals, its main threat is to cattle, bison, and swine. The disease is also known as contagious abortion or Bang's disease. In humans, it's known as undulant fever because of the severe intermittent fever accompanying human infection or Malta fever because it was first recognized as a human disease on the island of Malta.

2. How serious is brucellosis?

Considering the damage done by the infection in animals-decreased milk production, weight loss in animals, loss of young, infertility, and lameness, it is one of the most serious diseases of livestock. The rapidity with which it spreads and the fact that it is transmissible to humans makes it all the more serious.

3. What disease agents cause brucellosis?

The disease is caused by a group of bacteria known scientifically as the genus *Brucella*. Three species of *Brucella* cause the most concern: *B. abortus*, principally affecting cattle and bison; *B. suis*, principally affecting swine and reindeer but also cattle and bison; and *B. melitensis*, principally affecting goats but not present in the United States. In cattle and bison, the disease currently localizes in the reproductive organs and/or the udder. Bacteria are shed in milk or via the aborted fetus, afterbirth, or other reproductive tract discharges.

4. What are the signs of brucellosis?

There is no effective way to detect infected animals by their appearance. The most obvious signs in pregnant animals are abortion or birth of weak calves. Milk production may be reduced from changes in the normal lactation period caused by abortions and delayed conceptions. Not all infected cows abort, but those that do usually abort between the fifth and seventh month of pregnancy. Infected cows usually abort once, but a percentage will abort during additional pregnancies, and calves born from later pregnancies may be weak and unhealthy. Even though their calves may appear healthy, infected cows continue to harbor and discharge infectious organisms and should be regarded as dangerous sources of the disease. Other signs of brucellosis include an apparent lowering of fertility with poor conception rates, retained afterbirths with resulting uterine infections, and (occasionally) enlarged, arthritic joints.

5. How is brucellosis spread?

Brucellosis is commonly transmitted to susceptible animals by direct contact with infected animals or with an environment that has been contaminated with discharges from infected animals. Aborted fetuses, placental membranes or fluids, and other vaginal discharges present after an infected animal has aborted or calved are all highly contaminated with infectious *Brucella* organisms. Cows may lick those materials or the genital area of other cows or ingest the disease-causing organisms with contaminated food or water. Despite occasional exceptions, the general rule is that brucellosis is carried from one herd to another by an infected or exposed animal. This mode of transmission occurs when a herd owner buys replacement cattle or bison that are infected or have been exposed to infection prior to purchase. The disease may also be spread when wild animals or animals from an affected herd mingle with brucellosis-free herds.

6. What is being done to fight brucellosis?

Before 1934, control of brucellosis was limited mainly to individual herds. Today, there is a Cooperative State Federal Brucellosis Eradication Program to eliminate the disease from the country. Like other animal disease-eradication efforts, success of the program depends on the support and participation of livestock producers. The program's Uniform Methods and Rules set forth the minimum standards for States to achieve eradication. States are designated brucellosis free when none of their cattle or bison are found to be infected for 12 consecutive months under an active surveillance program. As of June 30, 2000, 44 States, plus Puerto Rico and the U.S. Virgin Islands, were free of brucellosis. Six States currently have a herd infection rate of less than 0.25 percent and are considered to be in Class A status. There are no States in Class B (herd infection rate between 0.26 percent and 1.5 percent) or Class C status (herd infection rate greater than 1.5 percent).

7. What about free-ranging bison herds?

The presence of brucellosis in free-ranging bison in Yellowstone National Park and Grand Teton National Park threatens the brucellosis status of the surrounding States and the health of their livestock herds, which are free of the disease. Reintroduction of the disease into a brucellosis-free State could have a serious economic impact on domestic livestock markets and potentially threaten export markets. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS)

is working cooperatively with other State and Federal agencies toward containing the spread of brucellosis from bison to domestic livestock and eliminating the disease from the Yellowstone and Teton herds while maintaining viable free-roaming bison herds in the Parks.

8. How do epidemiologists help fight brucellosis?

Epidemiologists are specially trained veterinarians who investigate disease sources and the means of eliminating infection in affected herds and areas. Epidemiologists are concerned with disease in a group or population of animals and evaluate circumstances connected with the occurrence of disease. These veterinarians help eliminate brucellosis by identifying factors essential to its control and prevention.

9. How costly is brucellosis to the livestock industry?

The livestock and dairy industries and the American consumer have realized great financial savings from the success of the Cooperative State Federal Brucellosis Eradication Program. Annual losses from lowered milk production, aborted calves and pigs, and reduced breeding efficiency have decreased from more than $400 million in 1952 to less than $1 million today. Studies have shown that, if brucellosis eradication program efforts were stopped, the costs of producing beef and milk would increase by an estimated $80 million annually in less than 10 years.

10. How effective is the Brucellosis Eradication Program?

At the beginning of the program, brucellosis was widespread throughout U.S. livestock, but eradication efforts have had dramatic results. In 1956, there were 124,000 affected herds found by testing in the United States. By 1992, this number had dropped to 700 herds, and as of June 30, 2000, there were only 6 known affected herds remaining in the entire United States. USDA, APHIS expects the Cooperative State Federal Program to achieve the goal of nationwide eradication of brucellosis from domestic cattle and bison in the very near future.

11. What is the basic approach to eradication?

The basic approach has always been to test cattle for infection and send infected animals to slaughter. Identification of market animals for tracing, surveillance to find infected animals, investigation of affected herds, and vaccination of replacement calves in high-risk areas are important features of the current program.

12. How is infection found in cattle?

Two primary surveillance procedures are used to locate infection without having to test each animal in every herd. Milk from dairy herds is checked two to four times a year by testing a small sample obtained from creameries or farm milk tank for evidence of brucellosis. Bison herds and cattle herds that do not produce milk for sale are routinely checked for brucellosis by blood-testing animals sold from these herds at livestock markets or at slaughter. In addition, some States require adult cattle and bison to be subjected to blood tests for brucellosis upon change of ownership even if sold directly from one farm to another. The cattle and bison remaining in the herds from which such animals originated are not tested unless evidence of brucellosis is disclosed among the market animals.

13. What happens when evidence of disease is found by surveillance testing?

Once an infected herd is located, the infection is contained by quarantining all infected and exposed cattle and bison and limiting their movement to slaughter only, until the disease can be eliminated from the herd. Diagnostic tests are used to find all infected cattle and bison. Also, Federal and State animal health officials check neighboring herds and others that may have received animals from the infected herd. All possible leads to additional infection are traced.

14. How does the brucellosis ring test (BRT) surveillance work?

The BRT procedure makes it possible to do surveillance on whole dairy herds quickly and economically. Milk or cream from each cow in the herd is pooled, and a sample is taken for testing. A suspension of stained, killed *Brucella* organisms is added to a small quantity of milk. If the milk from one or more infected animals is present in the sample, a bluish ring forms at the cream line as the cream rises.

15. How does market cattle identification (MCI) work?

Numbered tags, called backtags, are placed on the shoulders of adult breeding animals being marketed from beef, dairy, and bison herds. Blood samples are collected from the animals at livestock markets or slaughtering establishments and tested for brucellosis. If a sample reacts to a diagnostic test, it is traced by the backtag number to the herd of origin. The herd owner is contacted by a State or Federal animal health official to arrange for testing of his or her herd. Once the animals have been gathered, all of the eligible animals in the herd are tested at no cost to the owner.

16. Which animals are eligible for MCI testing?

At slaughter, all cattle and bison 2 years of age or older are tested, except steers and spayed heifers. At market, all beef cattle and bison over 24 months of age and all dairy cattle over 20 months of age are tested except steers and spayed heifers. Pregnant or postparturient heifers are also eligible for testing regardless of their age. Herd tests must include all cattle and bison over 6 months of age except steers and spayed heifers.

17. Why is identification of market cattle important?

The key to the MCI program is proper identification of all animals so they can be traced to their herds of origin. Most livestock markets identify cattle and bison with numbered USDA-approved backtags. Backtags, as well as eartags and other identification devices, are collected and sent to the diagnostic laboratory along with the matching blood samples to aid in identifying ownership of test-positive animals.

18. What are the advantages of MCI?

MCI provides a means of determining the brucellosis status of animals marketed from a large area and eliminates the need to round up cattle and bison in all herds for routine testing. MCI, along with other preliminary testing procedures, is effective in locating infection so control measures can be taken to contain the disease and eliminate it.

19. What is a blood agglutination test?

It is an effective method of diagnosing brucellosis. To pinpoint infection within a herd, a blood sample is taken from each animal and tested in the field or at a laboratory. The blood serum is mixed with a test fluid or antigen containing dead *Brucella* organisms. When the organisms in the test fluid clump together in a reaction known as agglutination, the test is positive.

20. What is the brucellosis card test?

It is a rapid, sensitive, and reliable procedure for diagnosing brucellosis infection. It is similar to the blood agglutination test but employs disposable materials contained in compact kits. Brucella antigen is added to the blood serum on a white card. Results of the test are read 4 minutes after the blood serum and antigen are mixed.

21. Are there any other tests for brucellosis?

There are a number of supplemental tests based on various characteristics of antibodies found in the blood and milk of infected animals. These tests are especially useful in identifying infected animals in problem herds in which chronic brucellosis infection exists and from which infection is difficult to eliminate. Another diagnostic method involves culturing Brucella organisms from infected tissues, milk, or other body fluids, from aborted calves or fetal fluids and membranes.

22. What animals are eligible for testing?

With certain exceptions, herd tests must include all cattle and bison over 6 months of age except steers and spayed heifers.

23. What is the incubation period of brucellosis?

An incubation period is the interval of time between exposure to an infectious dose of organism and the first appearance of disease signs. The incubation period of brucellosis in cattle, bison, and other animals is quite variable ranging from about 2 weeks to 1 year and even longer in certain instances. When abortion is the first sign observed, the minimum incubation period is about 30 days. Some animals abort before developing a positive reaction to the diagnostic test. Other infected animals may never abort. Generally, infected animals that do not abort develop a positive reaction to the diagnostic test within 30 to 60 days after infection, although some may not develop a positive reaction for several months to over a year.

24. Can brucellosis in animals be cured?

No. Repeated attempts to develop a cure for brucellosis in animals have failed. Occasionally, animals may recover after a period of time. More commonly, however, only the signs disappear and the animals remain diseased. Such animals are dangerous sources of infection for other animals with which they associate.

25. Can brucellosis be prevented?

The disease may be avoided by employing good sanitation and management practices. Replacement animals should be tested when purchased and retested after a 30- to 60-day isolation period during which they are kept separate from the remainder of the herd.

These practices will allow detection of animals that were in the incubation period of the disease when acquired.

26. What about vaccination?

For cattle and bison in heavily infected areas or replacement animals added to such herds, officials recommend vaccinating heifers with an approved *Brucella* vaccine. The vaccine is a live product and must be administered only by an accredited veterinarian or State or Federal animal health official. For best results, female calves should be vaccinated when they are 4 to 6 months old. At the time of vaccination, a tattoo is applied in the ear; that tattoo identifies the animal as an "official vaccinate." The tattoo identifies the year in which vaccination took place.

27. How does the vaccine work?

Brucella abortus vaccine produces a bodily response that increases the animal's resistance to the disease. However, vaccination is not 100-percent effective in preventing brucellosis; it typically protects about 65 percent of the vaccinated cattle from becoming infected by an average exposure to *Brucella*.

28. Is Strain 19 the only approved *Brucella* vaccine?

No. USDA recently licensed a new *Brucella* vaccine, called Strain RB51, for use in cattle. Strain RB51 is as efficacious as Strain 19 vaccine but virtually eliminates adverse post vaccination reactions in cattle, such as abortions and localized inflammation at the vaccine injection site. Most importantly, unlike Strain 19, Strain RB51 does not stimulate the same type of antibodies that can be confused on standard diagnostic tests with those antibodies produced by actual infection.

29. Is Strain RB51 vaccine approved for use in bison?

As of June 2000, *B. abortus* Strain RB51 had not yet been approved for use in bison. Preliminary studies indicate that RB51 is safe and efficacious in bison calves. However, in order for RB51 to be conditionally licensed in bison, additional safety and efficacy trials must be completed.

30. Where or when is calf-hood vaccination most important?

Owners whose herds are located in areas of relatively heavy infection or who ship replacement cattle or bison to, or receive animals from, such areas should carry out a vigorous calf-hood vaccination program. Every cattle or bison owner, regardless of location, should discuss the advantages and disadvantages of vaccination with his or her veterinarian. Some States do not allow cattle and bison to be imported for breeding if they are not official vaccinates and they are beyond the age at which they should have been vaccinated.

31. Where is vaccination less important?

In many areas of the country, low herd infection rates coupled with improvement in the detection of early infection through BRT, MCI, and other surveillance systems have lessened the need to continue calf-hood vaccination. Vaccination should be reduced in such areas, provided that adequate regulatory measures are in effect to prevent reintroduction of the disease.

32. How does brucellosis affect humans?

People infected with the brucellosis organism usually develop symptoms similar to a severe influenza, but this disease, called undulant fever, persists for several weeks or months and may get progressively worse. Farmers, ranchers, veterinarians, and packing establishment workers are infected most frequently because they come into direct contact with infected animals. The initial symptoms are fatigue and headaches, followed by high fever, chills, drenching sweats, joint pains, backache, and loss of weight and appetite. Undulant fever does not often kill its victims, but the disease is too serious to be dealt with lightly.

33. What are the main sources of human infection?

In years past, prior to pasteurization, raw milk was considered the prime source of brucellosis in humans. Today, most humans contract the disease by coming in direct contact with aborted fetuses, afterbirth, and uterine discharges of diseased animals or with infected carcasses at slaughter. However, one 1994 study suggests that human brucellosis in California is most likely to be a food-borne illness (unpasteurized milk or cheese products) acquired in Mexico or from Mexican products consumed in California. Rarely, if ever, does a human contract the disease from another human.

34. How common is human brucellosis in this country?

Fortunately, the combination of pasteurization of milk and progress in the eradication of the disease in livestock has resulted in substantially fewer human cases than in the past. Ninety eight cases of human brucellosis were reported in 1997, a fraction of the 6,400 cases reported in 1947. Sixty two (62) cases of brucellosis in humans have been reported to the Centers for Disease Control and Prevention for 1998 (provisional data).

35. Can people get brucellosis by eating meat?

There is no danger from eating cooked meat products because the disease-causing bacteria are not normally found in muscle tissue and they are killed by normal cooking temperatures. The disease may be transmitted to humans when slaughtering infected animals or when processing contaminated organs from freshly killed animals.

36. How can people be protected from brucellosis?

Ranchers, farmers, or animal managers should clean and disinfect calving areas and other places likely to become contaminated with infective material. All individuals should wear sturdy rubber or plastic gloves when assisting calving or aborting animals, and scrub well with soap and water afterward. Precautions against drinking raw milk or eating unpasteurized milk byproducts are also important. Ultimately, the best prevention is to eliminate brucellosis from all animals in the area.

Bovine Spongiform Encephalopathy (BSE)

Definition

Bovine spongiform encephalopathy (BSE), widely known as "mad cow disease," is a chronic, afebrile, degenerative disease affecting the central nervous system (CNS) of cattle.

Bovine spongiform encephalopathy belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSE's). These diseases are caused by a transmissible agent that is yet to be fully characterized. They share the following common characteristics:

a. A prolonged incubation period of months or years;

b. A progressive debilitating neurological illness that is always fatal;

c. When examined by electron microscopy, detergent-treated extracts of brain tissue from animals or humans affected by these diseases reveal the presence of scrapie-associated fibrils (SAF's);

d. Pathological changes appear to be confined to the CNS and include vacuolation and astrocytosis;

e. The transmissible agent elicits no detectable specific immune response in the host.

Specific types of TSE's include scrapie, which affects sheep and goats; transmissible mink encephalopathy; feline spongiform encephalopathy; chronic wasting disease of deer and elk; and five rare diseases in humans: kuru, Creutzfeldt-Jakob disease (CJD), Gerstmann-Sträussler-Scheinker syndrome, fatal familial insomnia (FFI), and new variant Creutzfeldt-Jakob disease (nvCJD).

Etiology

The clinical, pathological, and molecular genetic features of BSE, as well as other transmissible spongiform encephalopathies, have led to speculation on the nature of the etiologic agent and the pathogenic mechanisms of the disease. There are three main theories on the nature of the scrapie agent:

1. The virus theory, in which the virus would have to have unusual biochemical and biophysical characteristics that would help explain the remarkable physicochemical properties (12, 24, 39, 40).

2. The prion theory, in which the agent is conceived of being composed exclusively of a host-coded normal cellular protein (PrP^{c}) that becomes partially protease resistant (PrP^{BSE}) — most likely through a post-translational conformation change after infection. In this theory there is no nonhost component of the agent. That is, a specific informational molecule (nucleic acid e.g., RNA or DNA) is not present (5, 36).

3. The virino theory, which states that the agent consists of a host-derived protein coat, (PrP being one of the candidates for this protective protein) and a small noncoding regulatory nucleic acid (14, 21).

All of the proposed theories have some degree of validity. Proponents of the virus and virino theories have concluded that the existence of different scrapie strains unequivocally proves the presence of a nucleic acid component of the infectious agent which, as in conventional viruses, may undergo mutations responsible for phenotypic variations. The problem with these theories is that no agent-specific nucleic acid has been convincingly identified to copurify with infectivity (15, 25, 28, 32, 42). Moreover, chemical, enzymatic, or physical treatments that usually inactivate or degrade nucleic acids have no effect on the transmissible properties of the infectious agent (3, 4, 27, 31). Possible reasons for this are that the amount of nucleic acid of the putative agent is too small to be detected with available techniques and that its tight bond to the protein protects it from chemical or physical inactivation. Also weakening the virus and virino theories is the inability to identify any virus particles under the electron microscope (6, 10), and the failure of an infected host to generate an immune response. Recently small particles resembling virus structures have been observed by electron microscopy (33).

The prion model involves propagation of a protein-only agent (PrP^{BSE}) whereby PrP^{c} can assume various tertiary structures caused by a combination of host genetics and the introduction of altered (infectious) PrP (PrP^{BSE}). More simply stated, the structure of the infecting PrP^{BSE} imprints upon the normal cellular precursor (PrP^{c}) and results in a conformation change to the protease-resistant form. It is suspected that "strain" differences result from mutations in the PrP gene that may cause proteins "flip" and change shape. Several explanations for scrapie strain genetics in the context of the prion theory have been suggested but none have been proven (35, 41, 46).

It should be pointed out that the prion theory fails to explain a) how the PrP of the infecting agent originally assumed the aberrant structure associated with infectivity, and b) how the different structures originated as a function of the different strains. Although numerous scrapie strains can be differentiated in a single host (i.e., sheep), the PrP agents associated with these strains have not shown any biochemical and molecular differences; thus, BSE seems to be caused by a single strain type. This BSE strain is different from historical or contemporary isolates from sheep or goats with natural scrapie, as determined by study of incubation periods and brain "lesion profiles" in mice.

Regardless of whether the prion (PrP^{BSE}) is or is not the etiologic agent, the partially protease-resistant form of the prion protein is a marker of infection.

Host Range

Bovine spongiform encephalopathy has been experimentally transmitted to the following species via intracerebral (IC) inoculation: cattle, sheep, and goats (17), mink (38), pigs (13), marmosets (1), macaques (22), and mice (16). Intracerebral transmission was attempted in hamsters but was not successful. Via the oral route, BSE has been successfully transmitted to cattle, sheep, and goats (17); mice (2); and mink (38). Oral transmission has not been successful in swine. Parenteral and oral transmission has also been attempted in chickens with no evidence of disease thus far.

A transmissible spongiform encephalopathy has been diagnosed in eight species of captive wild ruminants as well as exotic (cheetahs, pumas, a tiger, and an ocelot) and domestic cats. There have been about 81 domestic cat cases of feline spongiform encephalopathy (FSE) in Great Britain and in 1 domestic cat each in Norway, Northern Ireland, and Liechtenstein. The agent isolated from several of these cases using strain typing in mice is indistinguishable from BSE in cattle, which suggests that FSE is

actually BSE in exotic and domestic cats. This also appears to be true for the other ruminants. Epidemiological evidence suggests BSE-contaminated feed to be the primary source of infection in these species (30).

Other cases of spongiform encephalopathy have been reported in kudu, eland, nyala, gemsbok, and a few exotic cats. These too are thought to be linked to contaminated feed.

It has also been suggested that 23 cases (as of January 31, 1998) of a variant form of CJD (nvCJD) (a human disease) in Great Britain (U.K. Department of Health, March 2, 1998) and 1 case in France may be linked to exposure to BSE before the introduction of a specified bovine offal (SBO) ban at slaughter in 1989. The SBO ban excludes from human consumption brain, spinal cord, and other tissues with potential BSE infectivity.

Geographic Distribution

Worldwide there have been more than 170,000 cases since the disease was first diagnosed in 1986 in Great Britain. Over 95 percent of these cases have occurred in the United Kingdom. The disease has also been confirmed in native-born cattle in Belgium, France, Ireland, Luxembourg, the Netherlands, Northern Ireland, Portugal, and Switzerland. One case has been reported in the United States (Washington state, December 2003).

Transmission

Different scientific hypotheses have been advanced concerning the origins of BSE. The epidemiologic data suggest that BSE in Great Britain is an extended common source epidemic involving feed containing TSE-contaminated meat and bone meal as a protein source. The causative agent is suspected to be from either scrapie-affected sheep or cattle with a previously unidentified TSE.

Changes in rendering operations in the early 1980's — particularly the removal of a solvent-extraction process that included a steam-heat treatment — may have played a part in the appearance of the disease and the subsequent amplification of the agent in the food chain. A ban on feeding animal protein of ruminant origin to ruminants was enacted in Great Britain in July 1988(50).

In Great Britain the epidemic peaked in 1992-93, when approximately 1,000 cases were being reported per week. In 1998 it remains on the decline with approximately 100 cases reported per week. Cases that have been detected in other countries appear be a result of importations of live cattle or, more significantly, contaminated feed from Great Britain.

There is no evidence that BSE spreads horizontally; that is, by contact between unrelated adult cattle or from cattle to other species.

New evidence suggests that maternal transmission may occur at an extremely low level. Results of British research show low levels of transmission of BSE from affected cows to their offspring. These results demonstrated that there is approximately a 9 percent increase in the occurrence of BSE in offspring of BSE-affected dams as compared with calves born to dams where BSE was not detected. The study did not ascertain if this was the result of genetic factors or true transmission. The research did, however, point out that, at this level, if maternal transmission does occur, it alone will not sustain the epidemic (51).

In the naturally infected animals, the agent has been identified by mouse bioassay in the brain, spinal cord, and retina. The route of inoculation into the mice was intracranial. The naturally infected animals were adult cattle exhibiting clinical signs of disease (16).

Mice fed milk, mammary gland, placenta, lymph nodes, or spleen have failed to develop the disease or to establish subclinical infection of the lymphoreticular system within their natural lifespan (29).

Another study was conducted to examine the pathogenesis of BSE in cattle; that is the replication (tissue distribution) of the agent during the incubation period. This study, which has not yet been completed, has identified the agent via mouse bioassay in the distal ileum of the experimentally infected calves. It is thought that the agent may be associated with the lymphoid tissue of the intestines. The calves were 4 months of age at the time of oral dosing. First isolation of the agent in the distal ileum was made at 6 months after oral dosing. Subsequent isolations from the distal ileum were made at 10, 14, and 18 months after dosing (47). Recently this study has also identified infectivity in bone marrow, trigeminal ganglion, dorsal root ganglion, brain, and spinal cord (48).

No infectivity has been found by parenteral or oral challenge, or both, in over 40 other tissues from clinically ill cattle using the mouse bioassay. It appears as if the distribution of the BSE agent is not as diverse as the scrapie agent in sheep. However, there is a possibility that the agent is present but is at such low levels that the bioassay is not sensitive enough to detect it (30).

Incubation Period

The incubation period usually ranges from 2 to 8 years. Following the onset of clinical signs, the animal's condition gradually deteriorates until the animal becomes recumbent, dies, or is destroyed. This usually takes from 2 weeks to 6 months. Most cases in Great Britain have occurred in dairy cows (Friesians) between 3 and 6 years of age (50). The youngest confirmed case occurred in a 20-month-old heifer, and the oldest case was found in a cow 18 years of age.

Clinical Signs

Cattle affected by BSE develop a progressive degeneration of the nervous system. Affected animals may display changes in temperament, abnormalities of posture and movement, and changes in sensation. More specifically, the signs include apprehension, nervousness or aggression, incoordination, especially hind-limb ataxia, tremor, difficulty in rising, and hyperaesthesia to sound and touch. In addition, many animals have decreased milk production or loss of body condition, or both, despite continued appetite.

Gross Lesions

There is no gross lesion associated with BSE.

Morbidity and Mortality

In Great Britain, 19 percent of the dairy herds and 1.6 percent of the beef herds have had one or more cases of BSE. This difference is believed to result from the fact that dairy calves were fed a higher level of protein supplement. The average incidence in herds in Great Britian has been 1.75 cases. However, there have been a few herds with over 30 cases. Affected animals die.

Diagnosis

Field Diagnosis

A field diagnosis of BSE is based on the occurrence of clinical signs of the disease. A bovine animal that has signs of a CNS disturbance should be observed over time (at least 2 weeks) to determine whether the signs become progressively more severe. If, after this interval, improvement or recovery has not taken place, BSE should be suspected and the animal humanely euthanized. As a USDA FSIS Veterinarian, you will not be diagnosing BSE in this manner.

Specimens for Laboratory

Because the BSE agent is considered a human pathogen, protective clothing, gloves, and face protection should be worn when performing the necropsy. The entire brain should be removed intact with a portion of the cranial cervical spinal cord attached. Portions should be placed in a plastic bag and submitted unfixed. The remainder of the brain should be fixed in 10 percent buffered formalin solution. One cerebral hemisphere is removed by cutting the brain stem through the space between the cerebellum and cerebrum with a longitudinal cut between the cerebral hemispheres.

Laboratory Diagnosis

Bovine spongiform encephalopathy currently must be confirmed by histopathological examination of brain tissue. Bilaterally symmetrical degenerative changes are usually seen in the gray matter of the brain stem. These changes are characterized by vacuolation or microcavitation of nerve cells in the brain stem nuclei. The neural perikarya and axons of certain brain stem nuclei contain intracytoplasmic vacuoles of various sizes, that give the impression of a spongy brain. Hypertrophy of astrocytes often accompanies the vacuolation (49). A diagnosis may also be made by the detection of SAF's using electron microscopy.

Two supplemental tests are available to enhance the diagnostic capabilities for BSE. These are immunohistochemistry and the Western blot technique. In the past, if the brain tissue was not harvested shortly after the animal's death, autolysis often made it very difficult to confirm a diagnosis by histopathology. These tests allow for the possibility of confirming a diagnosis of BSE by detecting PrP^{BSE} even if the brain has been frozen or autolyzed .

Differential Diagnosis

Differentials for BSE include rabies, listeriosis, nervous ketosis, milk fever, grass tetany, lead poisoning, and other toxicities or etiological agents affecting the nervous or musculoskeletal system of adult cattle.

Treatment

There is no known treatment for BSE or any of the TSE's.

Vaccination

There is no preventative vaccine.

Control and Eradication

Bovine spongiform encephalopathy from foreign sources may be prevented by the implementation of import regulations prohibiting live ruminants and ruminant products (especially meat, bone meal, and offal) from countries where BSE may exist. Because the origin of BSE remains unknown, preventing an epidemic of BSE would involve, at a minimum, the prohibition of feeding ruminant proteins to ruminants. The prevention program of any country should also include an active surveillance effort focused on high-risk cattle for the early detection of BSE. Most countries of the world have prohibited the importation of cattle and bovine products from countries known to have BSE. In addition many countries have taken steps to enact regulations prohibiting the feeding of ruminant proteins to ruminants. This is true even in countries such as Australia and New Zealand with no known animal TSE's.

Agricultural officials in countries known to have BSE have taken a series of actions to control and, it is to be hoped, eradicate BSE. These include making BSE a notifiable disease, prohibiting the inclusion of certain animal proteins in ruminants' rations (the feed bans vary depending on the amount of BSE detected), and depopulating certain populations of cattle thought to be of higher risk because of epidemiological findings.

To prevent human exposure to the BSE agent numerous countries have established prohibitions on the inclusion of high risk material in foods, pharmaceuticals, cosmetics, and so forth.

U.S. Actions

With an active surveillance program in place, BSE has been detected in three cows in the United States. Only two of those animals originated from the US. The United States Department of Agriculture (USDA), Food and Drug Administration (FDA), and industry groups are actively working to prevent any additional cases. The measures USDA, Animal and Plant Health Inspection Service (APHIS), has taken in this regard include prohibitions or restrictions, or both, on certain animal and product imports, ongoing surveillance for the disease in the United States, preparation of an emergency response plan in the unlikely event an introduction were to occur, and continuing educational efforts. The Animal and Plant Health Inspection Service actively shares information and coordinates closely with other Federal agencies, as well as the States, livestock and affiliated industries, veterinary and research communities, and consumer groups, to ensure that the United States has a uniform approach to transmissible spongiform encephalopathies based on sound scientific information.

A comprehensive surveillance program has been implemented by APHIS in the United States to ensure timely detection and swift response in the unlikely event that an introduction of BSE were to occur. This surveillance program entails the location of imports from countries known to have BSE and targeted active and passive surveillance for either BSE or any other TSE in cattle.

The United States has had an aggressive, active surveillance program for BSE since May 1990. Bovine spongiform encephalopathy is a notifiable disease, and there are more than 250 Federal and State regulatory veterinarians specially trained to diagnose foreign animal diseases, including BSE. The Animal and Plant Health Inspection Service leads an interagency surveillance program, which includes the Food Safety Inspection Service (FSIS) and the Centers for Disease Control (CDC). The surveillance samples

include field cases of cattle exhibiting signs of neurological disease, cattle condemned at slaughter for neurological reasons, rabies-negative cattle submitted to public health laboratories, neurological cases submitted to veterinary diagnostic laboratories and teaching hospitals, and random sampling of cattle that are nonambulatory at slaughter. As of February 21, 1998, over 6,600 brains had been examined for BSE or another form of a transmissible spongiform encephalopathy in cattle. No evidence of either condition has been detected by histopathology or immunohistochemistry.

The Food and Drug Administration (FDA) has recently established regulations that prohibit the feeding of most mammalian proteins to ruminants. The effective date of this regulation was August 4, 1997.

Public Health

BSE and CJD — Human Health Concerns

On March 20, 1996, the U.K.'s Spongiform Encephalopathy Advisory Committee (SEAC) announced the identification of 10 cases of a new variant form of CJD (nvCJD). All of the patients developed onset of illness in 1994 or 1995. The following features describe how these 10 cases differed from the sporadic form of CJD:

· The affected individuals were much younger than the sporadic CJD patient. Typically, sporadic CJD patients are over 63 years old. The average patient age for the variant form of CJD is 27.5 (range of 16 to 42) years.

· The course of the disease in the nvCJD averaged 13 months. Sporadic CJD cases average a 6-month duration.

· In the variant cases, electroencephalographic (EEG) electrical activity was not typical of sporadic CJD.

· Although brain pathology was recognizable as CJD, the pattern was different from normal CJD, and evidenced large aggregates of prion protein plaques.

Epidemiologic and case studies have not revealed a common risk factor among the cases of nvCJD. According to the SEAC, all victims were reported to have eaten beef or beef products in the last 10 years, but none had knowingly eaten brain material. One of the affected individuals had been a vegetarian since 1991 (52).

The SEAC concluded that, although there was no direct scientific evidence of a link between BSE and nvCJD, on the basis of current data and in the absence of any credible alternative, the most likely explanation was that the cases were linked to exposure to BSE before the introduction of control measures; namely, the specified bovine offal (SBO) ban in 1989.

Research reported in later 1996 and 1997 has presented further evidence to support a causal association between nvCJD and BSE. Two significant studies published in the October 2, 1997, edition of Nature led the SEAC to conclude that the BSE agent is very likely to be the cause of nvCJD. Dr. Moira Bruce and colleagues at the Institute for Animal Health in Edinburgh, Scotland, inoculated three panels of inbred mice and one panel of crossbred mice with BSE, nvCJD, and sporadic CJD. Interim results indicate that mice inoculated with BSE show the same pattern of incubation time, clinical signs, and brain lesions as mice inoculated with tissues from patients with nvCJD. This

provides evidence that BSE and nvCJD have the same signature or are the same "strain." In addition classical CJD and known scrapie strains were not similar to nvCJD or BSE (9).

Results from another study published by Dr. John Collinge and colleagues of Imperial College School of Medicine, London, United Kingdom, strongly support Bruce's results. Collinge's paper reports experimental transmission of BSE to transgenic mice expressing only human PrP (20).

The Health and Safety Executive in the United Kingdom now advises that BSE must be considered a biological agent (human pathogen) within the meaning of the Control of Substances Hazardous to Health Regulations 1994 (45).

FSIS BSE Rules:

On December 23, 2003, a BSE positive cow was identified in the state of Washington. As a result, FSIS issued several interim regulations Federal Register, January 12, 2004 (Volume 69, number 7, pages 1861-1892): to insure the American food supply was safe from potential BSE contamination. Two of the interim regulations were finalized in July 2007. You will learn more about these regulations in the BSE module in your PHV training. Some important features of the regulations are:

- Non-ambulatory disabled cattle presented for slaughter must be condemned.
- Air injection stunning is prohibited.
- Tissues identified as Specified risk materials (SMR's) are inedible and prohibited from use in human food. These include: brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the lumbar vertebrae and the wings of the sacrum) and dorsal root ganglia of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all ages of cattle.
- All federally inspected establishments that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their SSOPs or other prerequisite program.
- Advanced Meat Recovery (AMR) systems must not introduce central nervous system tissue into product labeled as "meat".

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Vesicular Stomatitis

Definition

Vesicular stomatitis (VS) is a viral disease characterized by fever, vesicles, and subsequent erosions in the mouth and epithelium on the teats and feet. Horses, cattle, and pigs are naturally susceptible; sheep and goats are rarely affected.

Etiology

The vesicular stomatitis virus is a *Vesiculovirus* in the family *Rhaboviridae*. The virion is a large bullet-shaped (65-185 nm) RNA virus. There are two serotypes of VSV: New Jersey and Indiana- 1. In the serotype Indiana 1, there are two subtypes: Indiana 2 (Cocal) and Indiana 3 (Alagoas). In addition to these two serotypes of VSV, there are other viruses within the genus *Vesiculovirus* that can experimentally cause vesicular lesions in domestic animals and infect humans; these are as follows:

Piry — first isolated from an opossum in Brazil.
Chandipura — first isolated from a person in India.
Isfahan — isolated from sandflies and humans in Iran.

Effective disinfectants are 2 percent, sodium carbonate - 4 percent, sodium hydroxide - 2 percent, iodophore disinfectants and chlorine dioxide disinfectants.

Host Range

The host range in decreasing order of severity of infection are horses, donkeys, mules, cattle, swine, and man. South American cameilids develop clinical infection. Sheep and goats are quite resistant and rarely become affected. Vesicular stomatitis virus has also been shown experimentally to infect a wide host range, including deer, raccoons, bobcats, and monkeys.

Geographic Distribution

Classical VS occurs only in North and Central America and the northern part of South America. Serotypes New Jersey and Indiana I occur in the United States and Central America. Serotypes New Jersey and Indiana 1, 2, and 3 occur in South America.

Transmission

The vesicular stomatitis virus has been shown to be transmitted by the sand fly (*Lutzomyia shannoni*) and the black fly (*Simuliidae*). Transovarial transmission has been shown to occur in both flies. The VS-NJ serotype was isolated from a variety of field-collected hematophagous insects such as *Culicoides* (biting midges), *Simuliidae* (black flies), *Aedes* (mosquitoes) and nonbiting insects such as *Chloropidae* (eye gnats), *Anthomyiidae*, and *Musca* (house flies) during the 1982 epizootic in the southwestern United States (1). Except for *Lutzomyia* and *Simulidae*, the role of these other insects in the transmission of VSV is unknown. Before the 1982 outbreak in the United States, people, on the basis of past experience, expected an outbreak to stop about 2 weeks after a killing frost. In the 1982 outbreak, cases and spread occurred through the winter. The winter spread of the disease is believed to have resulted from movement of infected animals and the resulting exposure of uninfected animals to contaminated waterers and feed bunks as well as contact with infected animals. It is known that VSV can be spread

by a contaminated milking machine. Overwintering did not occur in the 1995 outbreak in the United States.

Humans may be infected by contact and by aerosol.

Epidemiology

The disease occurs throughout the year in subtropical and tropical areas of the Americas. The disease occurs sporadically during the warm months in southern and western United States. Epidemics have occurred irregularly at 10 to 15 year intervals. The virus is spread by insect vectors, movement of infected animals, and contaminated objects. Researchers have shown transovarial transmission in the sand fly and black fly; this may be a way the virus can overwinter.

Incubation Period

A vesicle appears in about 24 hours after intradermal lingual inoculation of VSV. This similar to the incubation period for foot-and-mouth disease. In humans, the incubation period is 24 to 48 hours.

Clinical Signs

Animals develop a fever ranging to 104-106^{o} F (40-41^{o} C).

Horse

Vesicles in the mouth may cause the animal to chomp its jaws, drool, and rub its mouth on the manger or other objects. Lesions on the coronary band can cause lameness.

Cattle and pigs

See the clinical signs section in the FMD chapter. The signs are very similar.

Humans

In humans, VSV causes an influenza-like illness; there is fever, headache, muscular aches, and blisters in the mouth similar to those caused by herpes virus. The disease course is 4 to 7 days.

Morbidity and Mortality

Interesting data on the economic effect of VS in cattle were collected by Alderink during the 1982 outbreak of VS in Colorado. In 13 of the dairy herds studied, there were 2,404 cows and 378 cases of VS. Lesion distribution in these 378 was as follows:

Oral lesions only	263 animals (69.3%)
Teat lesions only	87 animals (23%)
Oral and teat lesions	22 animals (5.8%)
Foot lesions only	7 animals (1.9%)

Herds experiencing primarily oral lesions had an attack rate of 19.8 percent The attack rate in two of four herds with teat lesions was 55.8 percent and in the other two herds 1.6 percent. The clinical course in cases with oral lesions was 23.8 days. Mastitis complicated 72% of the cases with teat lesions.

The total cost to the 13 dairymen was $95,752, which came to an average cost of $253 per case. The approximate cost of a case with only oral lesions was $174 in contrast to an average cost of $568 for cases with teat lesions. Of the total $95,752 loss, 46 percent was for cows culled; 30 percent was for decreased production; 11 percent for deaths; and 11 percent for drugs, labor, weight loss, and veterinary charges.

Differences Between VS and FMD

The characteristics of VS are as follows:

Horses affected.

Sporadic incidence in the herd (see preceding section).

Distribution of lesions in an animal (small percentage of animals have lesions at more than one site of predilection; see preceding section).

No rumen lesions observed at necropsy.

No heart lesions observed at necropsy.

Vesicular stomatitis is less severe in young animals.

Stabled animals usually not affected.

In spite of these differences, do not attempt to make a final differential diagnosis in the field; get laboratory confirmation of the diagnosis.

Diagnosis

See FMD chapter.

Differential Diagnosis

Differential diagnosis for VS in cattle should include foot-and-mouth disease, foot rot, and chemical and thermal burns. In cattle, oral lesions caused by rinderpest, infectious bovine rhinopneumonitis, bovine virus diarrhea, malignant catarrhal fever, and bluetongue can be similar to the later lesions in FMD. In pigs, the differential diagnosis for VS should include foot-and-mouth disease, swine vesicular disease, vesicular exanthema of swine, foot rot, and chemical and thermal burns. In sheep, the differential diagnosis for VS lesions should include bluetongue, contagious ecthyma, lip and leg ulceration, and foot-rot.

Control and Eradication

Control movement of animals — no movement from an infected premise, except for slaughter, for 30 days after last lesion has healed.

Separate infected and healthy animals.

Stable animals if possible.

Disinfect milking machines between cows.

Milk infected cows last.

Control insects.

Commercial vaccines are available, but efficacy has not been field tested.

Public Health

Vesicular stomatitis (New Jersey and Indiana) infection frequently occurs in man and causes influenza-like symptoms but rarely results in vesicles. Other vesicular stomatitis viruses (Piry, Isfahan, and Chandipura) are much more infectious for man.

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APHIS Veterinary Services FAQ: Vesicular Stomatitis: Questions and Answers

Vesicular stomatitis (VS) is a viral disease that primarily affects horses, cattle, and swine and occasionally sheep, goats, llamas, and alpacas. Humans can also become infected with VS when handling affected animals, but this is a rare event. VS has been confirmed only in the Western Hemisphere. It is known to be an endemic disease in the warmer regions of North, Central, and South America, but outbreaks of the disease in temperate geographic parts of the Hemisphere occur sporadically.

Outbreaks in the Southwestern United States usually occur during warm months, often along waterways and in valleys. The Southwest experienced a VS outbreak from May 2004 through January 2005. Animals in Texas, New Mexico, and Colorado were involved. A total of 294 premises in 43 counties were affected in these three States. There could be another outbreak in 2005, and it is essential that veterinarians and livestock owners be on the alert for animals displaying clinical signs characteristic of VS.

Q. What are the clinical signs of VS?

A. In affected livestock, VS 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 or drink. If the hooves are affected, the animal may show signs of lameness. Severe weight loss usually follows, and in dairy cows, a severe drop in milk production commonly occurs. Some affected dairy cattle can appear to be clinically normal and will continue to eat about half of their normal feed intake. Lesions in horses may also be expressed as crusting scabs on the muzzle, lips, or ventral abdomen.

Q. How is the disease spread?

A. How VS spreads is not fully known; insect vectors, mechanical transmission, and movement of animals are all factors. Once VS is introduced into a herd, the disease may move from animal to animal by contact or exposure to saliva or fluid from ruptured lesions.

Q. Can humans contract VS?

A. Humans rarely contract VS when handling affected animals but can become infected. To avoid exposure to this disease, use protective measures when handling affected animals. In people, VS causes an acute influenza like illness with symptoms such as fever, muscle aches, headache, and malaise.

Q. Why is it so important to recognize animals with VS promptly?

A. VS is recognized internationally as a reportable disease. What this means is that there are serious economic and regulatory repercussions associated with the diagnosis, and once the disease is detected in the United States, many countries take action to block international trade of U.S. animals. Interstate movement of animals is also impacted. Premises containing affected animals are quarantined until 21 days after the lesions in the last affected animal have healed. These quarantine periods may be quite long.

While VS can cause economic losses to livestock producers, it is a particularly significant disease because its outward signs are similar to (although generally less severe than) those of foot–and–mouth disease, a foreign animal disease of cloven–hoofed animals that was eradicated from the United States in 1929. The clinical signs of VS are also similar to those of swine vesicular disease, another foreign animal disease. The only way to tell these diseases apart is through laboratory testing.

Q. What are clinical signs of VS? How does the disease progress in affected animals?

A. In affected livestock, the incubation period for VS ranges from 2 to 8 days. Often, excessive salivation is the first sign that an animal is affected. Body temperature may rise immediately before or at the same time lesions first appear. Initially, close examination of the mouth reveals blanched and raised vesicles. If there are no complications such as secondary infections, affected animals recover in about 2 weeks. VS does not generally cause animals to die.

Clinical signs of VS and other vesicular diseases include:

- Excessive salivation
- Swollen lips
- Blanched skin and raised or broken vesicles of various sizes around and in the mouth

Horses: Upper surface of the tongue, surface of the lips and around nostrils, corners of the mouth, and the gums.
Cattle: Tongue, lips, gums, hard palate, and sometimes the muzzle and the area around the nostrils.
Pigs: Snout.
• Lesions involving feet of horses and cattle are not commonly seen in the Southwestern United States. However, if lesions do occur, lameness may be noted as a clinical sign.

• Foot lesions and lameness are frequent in pigs.
• Teat lesions may occur in dairy herds. Loss of production and mastitis in dairy herds due to secondary infections may be a secondary complication.

Q. If there is another VS outbreak this year, what do I need to do if I plan to travel with my horse to another State or country?

A. During a VS outbreak, States and countries may put regulations into place restricting the movement of animals and requiring testing of animals prior to movement. Each State and country has different requirements for movement testing. It is important that the animal owner become familiar with the regulations and testing requirements associated with moving an animal.

Not all laboratories run the same antibody tests, so it is important to check with your laboratory to find out if they run the test you need to comply with regulations or movement restrictions. It is also important to contact the laboratory in advance to determine the samples needed submission procedures, and testing cost.

Not all VS tests are conducted on a daily basis, and during an outbreak of VS, there is an increased demand on laboratories for movement testing of animals. Therefore, it is important that a person submitting a sample to a lab for movement testing plan well in advance and have the sample at the lab at the earliest possible time based on the movement regulations.

For more information on testing, visit the APHIS Web site at http://www.aphis.usda.gov/vs/nvsl.

Q. What can we do to protect our animals?

A. There is no specific treatment or cure for VS. Owners can protect their animals from this disease by keeping their animals from congregating in the area where VS has occurred. Mild antiseptic mouthwashes may bring comfort and more rapid recovery to an affected animal. Good sanitation and quarantine practices on affected farms usually contain the infection until it dies out of its own accord. If you suspect that you have a horse with VS, do not allow it to come in contact with your other horses.

When a definite diagnosis of VS is made on a farm, the following procedures are recommended:

- Separate animals with lesions from healthy animals, preferably by stabling. Animals on pastures are at an increased risk of disease.
- As a precautionary measure, do not move animals from premises affected by VS, unless they are going directly to slaughter, for at last 21 days after the last lesion found has healed.
- Implement on-farm insect control programs that include the elimination or reduction of insect breeding areas and the use of approved insecticide sprays or insecticide-treated eartags on animals.

Additional Information

To see pictures of what lesions might look like, please visit the following Web site: http://www.aphis.usda.gov/vs/ep/fad_training/VESVOL7/page02_7.htm.

Additional information can be obtained from the following Web pages:

- http://www.quarterh.com/health3.htm
- http://www.oie.int/eng/maladies/fiches/A_A020.HTM
- http://www.vetmed.wisc.edu/pbs/zoonoses/vsv/vsvindex.html
- http://www.aphis.usda.gov/vs/ep/fad_training/VESVOL7/vesindex.htm

Foot and Mouth Disease

(Afta epizootica, Bek-en-klouseer, Fiebra aftosa, Fievre aphteuse, Maul-und-Klauenseuche**)**

Definition

Foot-and-mouth disease (FMD) is a highly contagious viral infection primarily of cloven-hoofed domestic animals (cattle, pigs, sheep, goats, and water buffalo) and cloven-hoofed wild animals. The disease is characterized by fever and vesicles with subsequent erosions in the mouth, nares, muzzle, feet, or teats.

Etiology

The FMD virus (FMDV) is a member of the genus *Aphthovirus* in the family Picornaviridae. There are seven serotypes of FMDV: A, O, C, Asia 1, and Southern African Territories (SAT) 1, 2 and 3. Within these serotypes, over 60 subtypes have been described, and new subtypes occasionally arise spontaneously. However, at a specific time, there are only a few subtypes causing disease throughout FMD endemic areas. The importance of subtypes is that a vaccine may have to be tailored to the subtype present in the area in which the vaccine is being used.

The FMD virus is pH sensitive; the virion is inactivated when exposed to pH below 6.5 or above 11. However, in milk and milk products, the virion is protected and can survive at 70^{o} C for 15 seconds and pH 4.6. Between pH 6.7 and 9, stability increases with decreasing temperature; the virus in cell culture medium will remain viable for a year at 4^{o} C. The virus in serum or other organic material will survive drying and can be carried on inanimate objects. In meat, the virus can survive for long periods in chilled or frozen bone marrow and lymph nodes.

Host Range

Cloven-footed domestic and wild animals are primarily affected. Examples of other susceptible species are hedgehogs, armadillos, nutrias, elephants, capybaras, rats, and mice.

Geographic Distribution

Foot-and-mouth disease, after World War II, was widely distributed throughout the world. In 1996, endemic areas were Asia, Africa, and parts of South America. In South America, Chile is free, and Uruguay and Argentina have not had an outbreak since April 1994. Most European countries have been recognized as free. Countries belonging to the European Union have stopped FMD vaccination. North and Central America, Australia, New Zealand, Japan, and the British Isles have been free of FMD for many years.

It is interesting how certain serotypes tend to be restricted to certain areas of the world.

Some examples are as follows:

Europe (historically)	A (5) O (1) C (1)
Asia	
Near East	A (22) O (1)

Middle East	A (22) O (1) C Asia (1)
Far East	A O (1) C Asia (1)
Africa	
Central East to West	A O
Northeast Central and South	SAT 1 and 2
South	SAT 3
Serotype C is uncommon in Africa	
South America	A (24), (27) O (1) C (3)

Transmission

The FMD virus can be introduced into a free area by the following means:

1. Direct or indirect contact with infected animals.

2. Spread of aerosol from infected animals (requires proper humidity and temperature). Aerosol from bulk milk trucks spread FMD in England. A person in contact with infected animals can have sufficient FMDV in his or her respiratory tract for 24 hours to serve as a source of infection for susceptible animals.

3. Feeding contaminated garbage (meat, milk, blood, glands, bones, cheese, etc.)

4. Contact with contaminated objects (hands, footwear, clothing).

5. Artificial insemination.

6. Contaminated biologicals such as hormones (extraction procedure may not inactivate the virus).

After an animal becomes infected by any means, the primary mode of spread is then via respiratory aerosols. Other important means of spread are direct and indirect contact. In an outbreak of FMD, the roles of the three primary hosts in transmission are as follows:

- Sheep act as maintenance hosts,
- Pigs act as amplifiers,
- Cattle act as indicators.

When sheep or goats become infected with FMDV, the disease may not be diagnosed for a considerable time because signs and lesions can be very mild. However, during this time, the animals will be producing infectious aerosols, contaminating fomites, and spreading the virus by contact.

Foot-and-mouth disease in pigs spreads very rapidly, for they produce 30 to 100 times more viruses in aerosols than sheep or cattle. An infected pig can produce a hundred million infectious doses per day.

When cattle are infected with FMDV, signs and lesions usually develop more rapidly and are more severe than in pigs, sheep, or goats. If cattle, sheep, and pigs are exposed

together, cattle will usually get sick first. This may result from increased exposure due to a greater pulmonary tidal volume.

Some animals can be carriers of FMDV. Most ruminant species can harbor the virus in their pharyngeal tissues for a long period. Recovered cattle or vaccinated cattle exposed to diseased animals can become healthy carriers for 6-24 months. Sheep can be carriers for 4-6 months. Although under experimental conditions it has been difficult to demonstrate transmission of FMD from carriers to susceptible livestock, there is strong circumstantial field evidence that carriers may have been the occasional cause of outbreaks. Also it has been shown that the virus was maintained for many years in a relatively small, isolated group of African buffaloes without the appearance of clinical signs.

Some strains of FMDV seem to have a predilection for certain species. There have been strains that affect pigs but not cattle. In South America, mature cattle have had clinical signs of FMD, when sheep in an adjacent pasture were normal.

Incubation Period

After experimental exposure, signs may develop as early as 12 hours. The usual interval is 24 to 48 hours.

When susceptible animals are in contact with clinically infected animals (peak time of transmission is generally when vesicles rupture), clinical signs usually develop in 3 to 5 days.

Pigs fed infected garbage usually develop signs in 1 to 3 days. Intact oral epithelium is resistant to infection, but during the process of ingesting food there may be injury, and the virus may also enter through the tonsils.

Clinical Signs

Cattle

Initial signs are fever of 103-105º F (39.4-40.6º C), dullness, anorexia, and fall in milk production. These signs are followed by excessive salivation; drooling, serous nasal discharge; shaking, kicking of the feet or lameness; and vesicle (blister) formation. Sites of predilection for vesicles are the tongue, dental pad, gums, soft palate, nostrils, muzzle, interdigital space, coronary band, and teats. Vesicles may be difficult to see. The animal may need to be tranquilized to facilitate a thorough examination.

After vesicle formation, drooling may be more marked, and nasal discharge, lameness or both may increase. Pregnant cows may abort, and young calves may die without developing any vesicle.

The course of an FMD infection is 2 to 3 weeks. Secondary infection may delay recovery. A lactating animal may not recover to preinfection production because of damage to the secretory tissue.

Sequelae to FMD in Cattle

Secondary infection — mouth, nose, feet
Hoof deformation
Low milk production

Mastitis
Unthriftiness — failure to gain weight
Breeding problems
Panting — associated with pituitary gland damage
Diabetes mellitus

Swine

Initial signs are fever of 104-105° F (40-40.6° C), anorexia, reluctance to move, and squeal when forced to move. These signs are followed by vesicles on the coronary band, vesicles on the heals, vesicles in the interdigital space (foot involvement is usually severe), and vesicles on the snout. Mouth lesions are not too common and when they occur are smaller and of shorter duration than in cattle and tend to be a "dry"-type lesion. There is no drooling. Sows may abort. Piglets may die without showing any clinical sign.

Sheep and Goats

Clinical signs, if they occur, tend to be very mild, and may include dullness; fever; and small vesicles or erosions on the dental pad, lips, gums, and tongue. Mild lameness may be the only sign. In lame animals there may be vesicles or erosion on the coronary band or in the interdigital space. Infected animals may abort. Nursing lambs may die without showing any clinical sign.

Gross Lesions

Cattle

The diagnostic lesions are single or multiple vesicles ranging from 2 mm to 10 cm. These can occur at all sites of predilection. Gross lesions on the tongue usually progress in the following manner:

1. A small blanched whitish area develops in the epithelium.

2. Fluid fills the area, and a vesicle (blister) is formed.

3. Vesicle enlarges and may coalesce with adjacent ones.

4. Vesicle ruptures.

5. Vesicular covering sloughs leaving an eroded (red) area.

6. Gray fibrinous coating forms over the eroded area.

7. Coating becomes yellow, brown or green.

8. Epithelium is restored, but line of demarcation remains; line then gradually fades.

Occasionally "dry" FMD lesions develop. Instead of forming a vesicle, the fluid is apparently lost as it forms and the upper layers of the epithelium become necrotic and discolored. The lesion therefore appears necrotic rather than vesicular.

Gross Lesions on the Feet:

The vesicle in the interdigital space is usually large because of the stress on the epithelium caused by movement and weight. The lesion at the coronary band at first appears blanched; then there is separation of the skin and horn. When healing occurs, new horn is formed, but a line resulting from the coronitis is seen on the wall of the hoof.

Gross Cardiac and Skeletal Lesions:

Animals that die may have grayish or yellowish streaking in the myocardium - degeneration and necrosis. These findings are known as "tiger heart". Skeletal muscle lesions occur but are rare.

Swine

Vesicles on the snout can be large and filled with clear or bloody fluid. Mouth lesions are usually the "dry" type and appear as necrotic epithelium. Feet lesions are usually severe, and the hoof can become detached. Animals that die may have grayish or yellowish streaking in the myocardium with degeneration and necrosis ("tiger heart").

Sheep

Lesions in the mouth and vesicles on the coronary band may be few, small, and difficult to find. Animals that die may have grayish or yellowish streaking in the myocardium with degeneration and necrosis ("tiger heart").

Morbidity and Mortality

The morbidity rate is essentially 100 percent in a susceptible population of domestic animals. Mortality is usually less than 1 percent, but in young animals and with certain isolates mortality can be high. In an FMD outbreak in Israel, there was a high mortality (at least 50 percent) in wild mountain gazelles. The same virus caused typical low mortality in cattle. In the gazelles, there was a severe viral pancreatitis that accounted for the high mortality.

Diagnosis

Field Diagnosis

In cattle, FMD should be considered whenever salivation and lameness occur simultaneously and a vesicular lesion is seen or suspected. Fever often precedes other clinical signs; therefore, febrile animals should be carefully examined. Early diagnostic lesions may be found before animals start to salivate, have a nasal discharge, or become lame. To avoid missing a diagnosis, examine the mouth of a lame animal and the feet of any animal with signs or lesions involving the mouth or nostrils. Typically, FMD spreads rapidly and there is a high clinical attack rate; however, this cannot be counted upon, for a relatively avirulent strain could appear, or more resistant animals (sheep) could be affected.

In pigs, sheep, and goats, FMD should be considered when animals have sore feet, vesicular lesion is suspected, or both.

Specimens for Laboratory Diagnosis

Because the various vesicular diseases have similar clinical signs, a laboratory diagnosis is mandatory. Oral, nasal, foot, or mammary lesions are good sources of specimens. The following should be collected from each of two or three animals:

1. Vesicular fluid (as much as possible).

2. Epithelium covering a vesicle.

3. Flaps of epithelial tissue still attached.

(For 2 and 3 above, try to collect about 0.5 gm.)

Old necrotic or fibrinous material that is difficult to remove is undesirable and often is highly contaminated with bacteria.

4. About 5 ml of blood with anticoagulant (viremia ends about 5 days after the onset of disease).

5. Esophageal—pharyngeal (OP) fluid from convalescent cattle, sheep, or goats.

This should immediately be diluted with an equal volume of cell culture fluid (e.g., Hanks balanced salt solution with lactalbumin hydolysate) and shaken vigorously for about 1 minute. If the solution turns yellow, the pH is low and the virus could be inactivated; discard and collect another sample.

6. Blood for serum (10 ml of serum).

7. From dead animals, collect samples of epithelial lesions, lymph nodes, thyroid, adrenal gland, kidney, and heart (about 10 gm).

8. Full set of tissues in formalin.

If the specimens can be delivered to a laboratory within 24 hours, they should be placed on ice. If delivery will take longer, quickfreeze the specimens, and do not allow them to thaw during transit. If dry ice is used, be sure that the vials are tightly sealed with stopper and tape so that no carbon dioxide enters the vial. The carbon dioxide will lower the pH and inactivate FMDV. Epithelium can also be placed in buffered glycerin and kept at 39º F (4º C) or -4º F (-20º C). Ratio of epithelium to glycerin should not exceed 1:10.

Laboratory Diagnosis

To confirm the initial case of FMD, the virus has to be isolated and identified. After confirmation of the initial case, diagnosis can be made by antigen or nucleic acid detection, or both.

Serological tests are available to detect antibody and differentiate infected and vaccinated animals.

Differential Diagnosis

Differential diagnosis for FMD should include vesicular stomatitis, swine vesicular disease, vesicular exanthema of swine, foot rot, and chemical and thermal burns. In cattle, oral lesions caused by rinderpest, infectious bovine rhinopneumonitis, bovine virus diarrhea, malignant catarrhal fever, and bluetongue can be similar to the later

lesions in FMD. In sheep, lesions caused by bluetongue, contagious ecthyma, and lip and leg ulceration can be similar to the later lesions of FMD.

Vaccination

Starting about 1951, FMD vaccine was produced by the Frenkel method. Normal tongue epithelium was removed, minced, placed in a nutrient broth, and inoculated with FMDV. After replication of FMDV, the virus was inactivated with formalin, and aluminum hydroxide was added as an adjuvant. This method as well as virus propagation in cell culture is being used today to produce FMD vaccine.

Outbreaks of FMD have been traced to use of formalin-inactivated vaccine. Apparently, in some cases, vaccine contained viable virus. Today (1996) the classical FMD vaccines are prepared using binary-ethyleneimine (BEI) inactivated virus and aluminum hydroxide-saponin or oil as an adjuvant. Double emulsion oil vaccines have been shown to produce an immunity of longer duration than aluminum hydroxide-saponin vaccine.

To date, molecular-engineered vaccines have not been as effective or as economical as the cell culture vaccines.

When vaccinating animals, it is important that the vaccine contain the same subtype of virus as is in the area. This necessitates frequent checking of the serotype and subtype during an outbreak because FMD virus frequently changes during natural passage through various species.

Protection induced by a good aluminum hydroxide vaccine decreases rapidly in 4-6 months. A double emulsion oil vaccine can protect for up to 1 year.

Vaccinated animals that are not completely protected can be a source of infection. The virus may replicate and be shed, but the animals may not show any clinical sign of infection.

Control and Eradication

The official attitude of a country regarding control of a disease depends on how seriously the disease affects the country, the financial and technical ability of the country, and what its neighbors are doing. The degree of control of FMD varies as follows:

1. Virtually no control in some Asian and African countries where FMD is enzootic.

2. Protection of valuable or accessible animals or vaccination along a border to provide a buffer zone. (May vaccinate cattle because of severity of the disease, but not sheep and goats.)

3. Large-scale vaccination and quarantine with or without slaughter of infected animals.

4. Regulatory measures to prevent entry of FMD virus and quarantine and implementation of an eradication program.

A country where FMD is endemic should be as concerned about introduction of FMD virus as a country that is free of FMD because the introduced virus may be a serotype to which the native animals have no immunity.

The following are the essential features of a control and eradication program:

1. Stop movement of animals and animal products in the area affected.

2. Slaughter infected animals (and known contact animals).

3. Destroy carcasses.

4. Disinfect vehicles leaving the infected area.

5. Perform vaccination.

If eradication by slaughter fails, vaccination may be used to control the outbreak. There are experimental results indicating that potent vaccine may induce significant immunity in 4 days to protect exposed cattle to FMD.

6. Inform and educate the community.

Most developed countries have detailed plans to deal with an outbreak of FMD.

Public Health

In a review of the zoonotic aspects of FMD by K. Bauer in 1997, he reported that, since 1921, FMD virus has been isolated and typed from slightly over 40 human cases (4). The cases occurred on three continents: Europe, Africa, and South America. Type O predominated, followed by C, and rarely A. Because infection is uncommon, FMD is not considered to be a public health problem.

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Swine Vesicular Disease

Definition

Swine vesicular disease (SVD) is an acute, contagious viral disease of swine caused by an enterovirus and characterized by fever and vesicles with subsequent erosions in the mouth and on the snout, feet, and teats.

Etiology

Swine vesicular disease virus is in the enterovirus group of picornaviruses and is closely related to the human enterovirus Coxsackie B-5 and unrelated to known porcine enteroviruses. Some researchers believe this is a case where a human pathogen transferred to pigs through the eating of human feces. The virion is a roughly spherical 28 nm single-stranded RNA virus. This pathogen is resistant over a wide pH range (2.5-12), relatively resistant to heat (inactivated at 157° F [69° C]), and persists for a long time (up to 2 years) in salted, dried, and smoked meat products.

Host Range

Pigs are the only natural host. Baby mice can be experimentally infected, and there has been accidental laboratory infection of humans.

Geographic Distribution

Swine vesicular disease first occurred in Italy and was subsequently recognized in Hong Kong, England, Scotland, Wales, Japan, Malta, Austria, Belgium, France, the Netherlands, Germany, Poland, Switzerland, Greece, and Spain. Outbreaks in the 1990's were reported in Italy, Spain, and Portugal.

Transmission

The disease can be introduced into a herd by feeding garbage containing infected meat scraps, by introducing infected animals, or by contacting infected feces (e.g., an improperly cleaned truck).

Recent outbreaks in Europe appeared after the introduction of animals that had no clinical sign of SVD, which indicates that there is a subclinical form of the disease. After the initial infection, the disease spreads through contact of susceptible pigs with infected pigs and infected feces.

Incubation Period

Signs of SVD develop in 2 to 3 days after eating contaminated feed and in 2 to 7 days after contact with infected pigs.

Clinical Signs

Clinical signs are very similar to those of foot-and-mouth disease and other vesicular diseases. There is a fever, vesicles in the mouth and on the snout and feet, and lameness, all of which are grossly indistinguishable from FMD. More suggestive of SVD

is an unsteady gait, shivering, and chorea — (jerking) — type leg movements due to an encephalitis.

Gross Lesions

Vesicles are indistinguishable from those of foot-and-mouth disease, vesicular stomatitis, and vesicular exanthema of swine. See the foot-and-mouth disease chapter.

Morbidity and Mortality

Morbidity in SVD is lower, and lesions are less severe, than in foot-and-mouth disease. There is essentially no mortality in SVD.

Diagnosis

See chapter on foot-and-mouth disease.

Serology is complicated by cross reactions with other undefined porcine enteroviruses.

Differential Diagnosis

Differential diagnosis for SVD should include foot-and-mouth disease, vesicular stomatitis, vesicular exanthema of swine, and chemical and thermal burns.

Vaccination

There is no vaccine.

Control and Eradication

Prevention measures are similar to those for FMD: control of animals imported from infected areas, and sanitary disposal of garbage from international aircraft and ships

Eradication measures consist of quarantining infected farms and areas, slaughtering and disposing of infected and contact pigs, and cleaning and disinfecting infected premises.

Public Health

Human infection has been reported in laboratory personnel working with the virus. Caution should be taken when working with infected material.

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Classical Swine Fever (Hog Cholera)

(Note: The preferred term for this disease is now classical swine fever.)

(Classical swine fever, peste du porc, colera porcina, Virusschweinepest)

Definition

Classical Swine Fever (CSF), formerly known as Hog cholera (HC) is a highly contagious viral disease of swine that occurs in an acute, a subacute, a chronic, or a persistent form. In the acute form, the disease is characterized by high fever, severe depression, multiple superficial and internal hemorrhages, and high morbidity and mortality. In the chronic form, the signs of depression, anorexia, and fever are less severe than in the acute form, and recovery is occasionally seen in mature animals. Transplacental infection with viral strains of low virulence often results in persistently infected piglets, which constitute a major cause of virus dissemination to noninfected farms.

Etiology

Although minor antigenic variants of CSF virus have been reported, there is only one serotype. CSF virus is a lipid-enveloped pathogen belonging to the family Flaviviridae, genus *Pestivirus*. The organism has a close antigenic relationship with the bovine viral diarrhea virus (BVDV) and the border disease virus (BDV), as demonstrated in the immunodiffusion and immunofluorescence tests. The serum neutralization test can, however, differentiate between HCV and BVDV. In a protein-rich environment, HCV is very stable and can survive for months in refrigerated meat and for years in frozen meat. The virus is sensitive to drying (desiccation) and is rapidly inactivated by a pH of less than 3 and greater than 11.

Host Range

The hosts of HCV are the pig and wild boar.

Geographic Distribution

According to the FAO—WHO—OIE Animal Health Yearbook 1989, HC (CSF) is recognized in 36 countries and is suspected of being present in another 2. The disease has been eradicated in Australia, Canada, and the United States. Constant progress toward eradication has been made in the countries of the European Economic Community since the guidelines for CSF control in individual member states were accepted in 1980.

Transmission

The pig is the only natural reservoir of CSF virus. Blood, tissues, secretions and excretions from an infected animal contain CSF virus. Transmission occurs mostly by the oral route, though infection can occur through the conjunctiva, mucous membrane, skin abrasion, insemination, and percutaneous blood transfer (e.g., common needle, contaminated instruments). Airborne transmission is not thought to be important in the epizootiology of CSF, but such transmission could occur between mechanically ventilated units within close proximity to each other.

Introduction of infected pigs is the principal source of infection in CSF-free herds. Farming activities such as auction sales, livestock shows, visits by feed dealers, and rendering trucks are also potential sources of contagion. Feeding of raw or insufficiently cooked garbage is a potent source of CSF virus. During the warm season, CSF virus may be carried mechanically by insect vectors that are common to the farm environment. There is no evidence, however, that CSF virus replicates in invertebrate vectors. Husbandry methods also play an important role in CSF transmission. Large breeding units (100 sows) have a higher risk of recycling infection than small herds. In large breeding units where continuous farrowing is practiced, strains of low virulence may be perpetuated indefinitely until the cycle is interrupted by stamping-out procedures and a thorough cleaning and disinfection are carried out.

Incubation Period

The incubation period is usually 3 to 4 days but can range from 2 to 14 days.

Clinical Signs

The clinical signs of CSF are determined by the virulence of the strain and the susceptibility of the host pigs. Virulent strains cause the acute form of the disease, whereas strains of low virulence induce a relatively high proportion of chronic infections that may be inapparent or atypical. These strains are also responsible for the "carrier-sow" syndrome from which persistently infected piglets are produced.

Acute Classical Swine Fever

In acute CSF, the pigs look and act sick. Their disease progresses to death within 10 to 15 days, and remissions are rare. In an affected herd, some pigs will become drowsy and inactive and will stand with arched backs. Other pigs will stand with drooping heads and straight tails. Some pigs may vomit a yellow fluid containing bile. The sick pigs will huddle and pile up on each other in the warmest corner of the enclosure and will rise only if prompted vigorously. Anorexia and constipation will accompany a high fever that may reach 108° F (42.2° C) with an average of 106° F (41.1° C). Pigs may continue to drink and may have diarrhea toward the end of the disease process. Conjunctivitis is frequent and is manifested by encrustation of the eyelids and the presence of dirty streaks below the eyes caused by the accumulation of dust and feed particles. Sick pigs become gaunt and have a weak, staggering gait related to posterior weakness. In terminal stages, pigs will become recumbent, and convulsions may occur shortly before death. In the terminal stage, a purplish discoloration of the skin may be seen; if present, the lesions are most numerous on the abdomen and the inner aspects of the thighs.

Chronic Classical Swine Fever

Chronic CSF is characterized by prolonged and intermittent disease periods with anorexia, fever, alternating diarrhea and constipation, and alopecia. A chronically infected pig may have a disproportionately large head relative to the small trunk. These runt pigs may stand with arched backs and their hind legs placed under the body. Eventually, all chronically infected pigs will die.

Congenital Classical Swine Fever

Congenital CSF virus infection by virulent strains will likely result in abortions or in the birth of diseased pigs that will die shortly after birth. Transplacental transmission with

low-virulence strains may result in mummification, stillbirth, or the birth of weak and "shaker" pigs. Malformation of the visceral organs and of the central nervous system occurs frequently. Some pigs may be born virtually healthy but persistently infected with CSF virus. Such infection usually follows exposure of fetuses to CSF virus of low virulence in the first trimester of fetal life. Pigs thus infected do not produce neutralizing antibodies to CSF and have a lifelong viremia. The pigs may be virtually free of disease for several months before developing mild anorexia, depression, conjunctivitis, dermatitis, diarrhea, runting, and locomotive disturbance leading to paresis and death. In breeding herds affected with low virulence strains of CSF virus, poor reproductive performance may be the only sign of disease.

Gross Lesions

Acute Classical Swine Fever

The most common lesion observed in pigs dying of acute CSF is hemorrhage. Externally, a purplish discoloration of the skin is the first observation. There may be necrotic foci in the tonsils. Internally, the submandibular and pharyngeal lymph nodes are the first to be affected and become swollen owing to edema and hemorrhage. Because of the structure of the pig lymph node, hemorrhages are located at the periphery of the node. As the disease progresses, the hemorrhage and edema will spread to other lymph nodes. The surface of the spleen, and particularly the edge of the organ, may have raised, dark wedge-shaped areas. These are called splenic infarcts. Infarcts are frequently observed in pigs infected experimentally with older strains of CSF virus but are less commonly seen with the contemporary strains.

Pinpoint to ecchymotic hemorrhages on the surface of the kidney are very common in CSF. Such lesions are easier to see in the decapsulated kidney. Hemorrhages are also found on the surface of the small and large intestine, the larynx, the heart, the epiglottis, and the fascialata of the back muscles. All serous and mucosal surfaces may have petechial or ecchymotic hemorrhages.

Accumulation of straw-colored fluids in the peritoneal and thoracic cavities and in the pericardial sac may be present.

The lungs are congested and hemorrhagic and have zones of bronchopneumonia.

Chronic Classical Swine Fever

In chronic CSF, the lesions are less severe and are often complicated by secondary bacterial infections. In the large intestine, button ulcers are an expression of such a secondary bacterial infection. In growing pigs surviving for more than 30 days, lesions may be seen at the costo-chondral junction of the ribs and at the growth plates of long bones.

Congenital Classical Swine Fever

In pigs infected transplacentally with CSF virus strains of low virulence, the most commonly seen lesions are hypoplasia of the cerebellum, thymus atrophy, ascites, and deformities of the head and of the limbs. Edema and petechial hemorrhages of the skin and of the internal organs are seen at the terminal stage of the disease.

Morbidity and Mortality

In acute CSF, the morbidity and mortality are high.

Diagnosis

Field Diagnosis

Septicemic conditions in which pigs have high fever should be investigated carefully. A thorough history from the herd owner should be obtained to determine if raw garbage was fed, if unusual biological products were used, or if recent additions were made to the herd. Careful observation of the clinical signs and of the necropsy lesions should be recorded. In acute CSF, it is helpful to necropsy four or five pigs to increase the probability of observing the representative lesions.

A marked leukopenia is detectable at the time of initial rise in body temperature and persists throughout the course of the acute and chronic disease. This feature was once widely used in the field diagnosis of CSF. Nowadays, with the development of more specific laboratory diagnostic methods, which are aimed at demonstrating the virus or its structural antigens in tissues or at detecting specific antibodies in the serum, the white blood count is not as widely used. In endemic areas it could be helpful.

Specimens for Laboratory

For virus isolation and antigen detection, the tonsils are considered essential. In addition, submandibular and mesenteric lymph nodes, spleen, kidneys, and the distal part of the ileum should be collected. In live pigs, tonsil biopsies and whole blood collected with anticoagulants are useful to diagnose CSF. Sample collection should be targeted to pigs having fever or showing other signs of the disease. Each sample of tissue should be placed in a separate plastic bag and identified. The samples should not be frozen (interference with fluorescent antibody tissue section test) but kept at refrigeration temperature. The material should be transported and stored in leak-proof containers in accordance with national regulations for transportation of diagnostic biologic samples.

Serum samples for antibody detection should be collected from animals that have recovered from suspected infection or from sows known to have been in contact with infected or suspected cases. A sufficient number of samples should be collected to ensure a high probability of detecting infection.

A complete set of tissues, including the whole brain, should be submitted in 10 percent buffered formalin.

Laboratory Diagnosis

Any clinical diagnosis of CSF must be confirmed by the submission of specimens to a specialized diagnostic laboratory that should also have the capability to distinguish between CSF and African swine fever.

The laboratory diagnostic procedures for CSF have evolved in parallel with the emergence of new technologies. Until the 1960's, laboratory diagnosis was restricted to recognition of gross lesions and confirmation by histopathology. Inoculation of susceptible pigs was often used as final confirmatory test and to determine the virulence

of the viruses. Numerous laboratory techniques have been described to diagnose CSF, but only a few have gained international acceptance and have been integrated into national CSF control programs. Only these will be discussed in this presentation.

In the fluorescent antibody tissue section test (FATST), direct fluorescent antibody technique is applied to detect CSF viral antigens in frozen tissues of organs from dead pigs, in biopsy material, or in impression smears. Theoretically, a diagnosis can be confirmed within hours from the reception of the specimen. In countries where the disease has been eradicated, the diagnosis of the "index case" by the FATST alone may be difficult, and confirmation in cell culture may be needed. The FATST may not differentiate CSF from BVDV infection; an accurate distinction between the two viruses has to be made before releasing a final diagnosis. Differentiation between CSFV and BVDV can readily be made with the immunoperoxidase test using monoclonal antibodies or the serum neutralization test.

The isolation of CSFV in cell culture and the identification using fluorescein-labeled hog cholera antibody (fluorescent antibody cell culture test) can provide confirmation in cases where the results of investigation of frozen tissue sections are inconclusive.

As control measures for CSF are implemented in a country, virulent strains of CSFV will be reduced, and there will be a relative increase of low-virulence strains. As the proportion of subclinical cases in a national herd increases, it will become increasingly difficult to recognize the disease. The antigen detection systems previously described become less effective; thus, serological tests are essential for a successful control and eventual eradication program.

Approximately 75 percent of pigs infected with acute CSF have microscopic lesions of encephalitis characterized by perivascular cuffing, endothelial proliferation, and microgliosis. This feature is easily recognized in a nonspecialized diagnostic laboratory and may constitute the most important single factor that will cause the pathologist to suspect CSF.

Differential Diagnosis

Differential diagnosis of CSF should include African swine fever, erysipelas, salmonellosis, eperythrozoonosis, and salt poisoning.

Vaccination

Over the years, numerous regimens of vaccination have been advocated with a variable degree of success. In the past two decades, modified live vaccines (MLV) with no residual virulence for pigs have become available. The lapinized Chinese (C) strain, the Japanese guinea pig cell culture-adapted strain, and the French Thiverval strain have been widely used. All three strains are considered innocuous for pregnant sows and piglets over 2 weeks old.

Control and Eradication

In countries where CSF is enzootic, a systematic vaccination program is effective in preventing losses. Experience in the United States and in some countries of the European Union has proven that a strict regimen of vaccination will reduce the number of outbreaks to a level at which complete eradication by sanitary measure alone will be feasible. At that point, vaccination must be stopped. A successful eradication program

requires a massive input of funds from a central government and cooperation from the government, the swine industry, and the veterinary profession. Eradication measures will be assisted by strictly enforcing the garbage cooking laws, having an effective swine identification system, and using serological surveys targeted primarily to breeding sows to detect subclinical infections.

In countries where CSF has been eradicated and in which the threat of reintroduction is significant, it is essential to initiate an effective serological monitoring system. Sampling may be limited to strategic locations such as the border of an infected neighbor country or be intensified to target populations such as the garbage-fed herds. Such a system has been in effect in the United States since successful eradication in 1976; several thousand samples have been accessed annually.

Public Health

Human beings are not susceptible to CSFV infection.

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African Swine Fever

(Peste porcine Africaine, fiebre porcina Africana, maladie de Montgomery)

Definition

African swine fever (ASF) is a tickborne and contagious, febrile, systemic viral disease of swine

Etiology

The ASF virus is a large (about 200 nm) lipoprotein-enveloped, icosahedral, double-stranded DNA virus. For many years the agent was classified as an iridovirus (3), but in recent years it was found to have many characteristics of poxvirus; thus, researchers have suggested establishment of a new family for ASF virus (ASFV) (19).

This virus is quite stable and will survive over a wide range of pH. In serum-free medium, ASFV is inactivated at pH 3.9 or lower and at pH 11.5 or higher. In the presence of 25 percent serum, ASFV will remain viable for 7 days at pH 13.4 (17). The virus will survive for 15 weeks in putrefied blood, 3 hours at 50° C, 70 days in blood on wooden boards, 11 days in feces held at room temperature, 18 months in pig blood held at 4° C, 150 days in boned meat held at 39° F, and 140 days in salted dried hams (8A).

Over the years, ASFV isolates with lower virulence have emerged — particularly in the Iberian peninsula. Virulence of isolates varies from highly virulent (essentially 10 percent mortality in 7-10 days after exposure), to moderately virulent (acute illness in which a high percentage of the pigs survive) , to low virulence (only seroconversion occurs).

Host Range

Initially, domestic and wild pigs (Africa: warthog, bush pig, and giant forest hog; Europe: feral pig) were thought to be the only hosts of ASFV (1,16). In 1963, Spanish workers isolated ASFV from the soft tick *Ornithodoros erraticus* collected from ASF-infected farms (13). Subsequently, researchers showed that ASFV replicates in the tick and that there is transstadial, transovarial, and sexual transmission in *Ornithodoros* ticks. *O. moubata* collected from warthog burrows in Africa were shown to be infected with ASFV (5). African swine fever in wild pigs in Africa is now believed to cycle between soft ticks living in warthog burrows and newborn warthogs (18). *Ornithodoros* ticks collected from Haiti, the Dominican Republic, and southern California have been shown to be capable vectors of ASFV (4,5), but in contrast to the African ticks, many of the ticks from California died after being infected with ASFV. Many researchers believe that ASFV is really a tick virus and the pig is an accidental host (11).

Because ASFV-infected ticks can infect pigs, ASFV is the only DNA virus that can qualify as an arbovirus.

Geographic Distribution

African swine fever is present in several African countries and on the island of Sardinia.

Transmission

Even though the soft tick has been shown to be a vector (and in Africa probably the reservoir of ASFV), the primary method of spread from country to country has been through the feeding of uncooked garbage containing ASFV-infected pork scraps to pigs. Once a pig becomes infected, ASFV spreads by direct contact, and contaminated people, equipment, vehicles, and feed. The role of carrier pigs has been difficult to prove experimentally, but circumstantial evidence from the field incriminates carrier pigs. An outbreak of ASF in a contained swine operation in Africa was traced to workers feeding the entrails of guinea fowl to pigs. It was shown that the guinea fowl feed on soft ticks; thus, ASFV was present in the guinea fowl intestines fed to the pigs.

The amount of ASFV needed to infect a pig depends on the route of exposure. Experimentally, a pig can be infected by intramuscular or intravenous inoculation with a 0.13 hemadsorbing dose (HAD_{50}); intranasal-oral inoculation required 18,200 HAD_{50}.

In an ASF endemic area where there are soft ticks, ticks can be the source of infection. However, in these areas in Africa, pigs can be very successfully raised in confinement with double fencing, proper isolation, and sanitary procedures. In Africa, the production system with the highest risk of ASF is the village pig, for these pigs roam. The owners do not practice isolation procedures when the pigs are confined.

In other areas, the disease has to be introduced by infected live pigs or by feeding uncooked garbage containing ASFV-infected pork. Once the disease is introduced into a herd, it spreads by direct and indirect contact with secretions and excretions from infected pigs. Aerosol transmission is not important in the spread of ASF. Because ASFV does not replicate in epithelial cells, the amount of virus shed by an ASF-infected pig is much less than the amount of virus shed by a hog-cholera-infected pig. The blood of a recently infected pig contains a very high ASFV titer: $10^{5.3}$ to $10^{9.3}$ HAD_{50} per milliliter (7). Therefore, if pigs fight, an infected pig develops bloody diarrhea, or an infected pig is necropsied, blood is shed, and there is massive environmental contamination.

Piglets born of ASF-convalescent dams are free of ASFV and ASF antibody at birth but seroconvert after ingesting colostrum (14,15). When piglets from noninfected (control) and ASF-convalescent dams were challenge-inoculated when 7 weeks old, the control piglets developed an average viremia of $10^{7.6}$ and died, whereas the piglets from convalescent gilts developed an average viremia of $10^{4.9}$ and survived. However, because of persistent infection by ASFV, reestablishing a herd using pigs from convalescent animals will not result in an ASFV- free herd. When farmers in Cameroon repopulated their herds using ASF-convalescent animals, the herds experienced recurring periods of high mortality due to ASF.

Incubation Period

After intranasal-oral exposure, pigs usually develop fever and leukopenia in 48 to 72 hours.

Clinical Signs

Highly and Moderately Virulent ASF Isolates

The clinical signs of ASF are influenced by the virulence of the virus and the physiological state (age and pregnancy) of the pig. After inoculation of feeder pigs with

either a highly virulent or moderately virulent isolate, the clinical course for both isolates is similar for the first 4-6 days post infection. About 2 DPI, the pigs will develop a fever of 105-107° F (40.5-41.7° C) and white pigs will have a reddened skin, moderate anorexia, and leukopenia. When disturbed the pigs will get up and move about but if left alone will after a short time lie down.

After 4-6 DPI, a difference between the pigs inoculated with the different isolates will become apparent.

Highly Virulent Isolate

The pigs become progressively sicker (eat and move less), and most die between 7 and 10 DPI. It is not unusual to see a pig walking and a short time later to find it dead.

Moderately Virulent Isolate

Pigs infected by moderately virulent ASFV usually have a high fever for 10-12 DPI. Some mortality usually occurs at this time. After 12-14 DPI, temperatures and leukocyte counts start to return to normal levels. It is not unusual to have one or more pigs die as early as 7-8 DPI, but when these pigs are necropsied, the cause of death is frequently hemorrhage into the stomach; the underlying mechanism of death was that ASFV infection caused a thrombocytopenia, resulting in a prolonged bleeding time and hemorrhage from a preexisting gastric ulcer (2). Very young pigs may have a high mortality and have lesions similar to infection by highly virulent virus.

Pigs affected with either isolate, in addition to the reddened skin, may develop dark red to purple discoloration of the skin on the ears, tail, extremities of the legs, or skin on the hams. This is a nonspecific sign also seen in other diseases. Some groups of pigs will develop diarrhea; this is probably due to disturbed gut physiology and flora rather than a direct effect of the virus because the virus does not replicate in epithelium. In contrast to Classical Swine Fever (hog cholera), ASFV-infected pigs do not develop a conjunctivitis or encephalitis, and, despite the high fever, the ASFV- infected pigs stay in good condition, whereas classical swine fever -infected pigs quickly lose much weight.

Pregnant animals infected with a high-, moderate-, or low-virulence ASF isolate abort.

Low Virulence Isolates

Non-pregnant animals infected by certain low-virulence ASFV may only seroconvert; pregnant animals will abort.

Other low-virulence ASFV isolates will cause a low fever for 2-3 weeks and then reddened areas 1 cm^2 to many centimeters in size may develop in the skin. These areas then become raised and necrotic. These pigs may also have painless enlargements of joints—particularly the carpal and tarsal joints. This form is referred to as chronic ASF (10). Many of these pigs will have recurring episodes of a more acute disease and eventually die during an acute episode.

Gross Lesions

Highly Virulent ASFV Infection

Pigs that die peracutely from an infection with a highly virulent ASFV may have poorly developed lesions. Animals that die 7 or more DPI have more classic lesions. Three lesions most consistently found and highly suggestive of ASF infection are as follows:

- Greatly enlarged dark red to black friable spleen
- Very enlarged hemorrhagic gastrohepatic lymph nodes
- Very enlarged hemorrhagic renal lymph nodes.

Other lesions described for ASF are more variable and are as follows:

- Dark red to purple areas of skin on ears, feet, and tail
- Petechial hemorrhages on serosal surfaces
- Petechial to ecchymotic hemorrhages in the renal cortex
- Perirenal edema
- Edema of the gall bladder
- Swollen liver
- Edema of the lung.

In pigs infected orally, the submandibular lymph node may be enlarged and have some hemorrhage. Other peripheral lymph nodes may have only edema.

Moderately Virulent Virus

The gross lesions 8-12 DPI in pigs infected with a moderately virulent ASFV are similar to those infected by a highly virulent ASFV. The main difference in the lesions between these two types of isolates is that in infections by a moderately virulent ASFV, the spleen although enlarged, has a more normal color and is not friable.

Low Virulent Virus

The most common lesions in chronic ASF are necrotic skin lesions, consolidated lobules in the lung, generalized lymphadenopathy, swollen joints, and pericarditis.

Aborted fetuses may be anasarcous, and there may be petechial hemorrhages in the placenta, skin, and myocardium, and a mottled liver.

Morbidity and Mortality

The warthog and bush pig develop a viremia but have a very mild or subclinical disease, whereas ASF infection in domestic pigs and European feral pigs can cause a high mortality.

Morbidity in a previously unexposed herd will usually be 100 percent in pigs that have contact with each other. Mortality varies with the virulence of the isolate. Highly virulent isolates will cause about a 100 percent mortality. Infection by lesser virulent isolates can cause mortality that varies from a low percentage to 60-70 percent. Factors that can increase mortality in infections by the lesser virulent isolates are concurrent disease, a young age, and pregnancy.

Diagnosis

Field Diagnosis

The highly virulent form of ASF will be easiest to diagnose because essentially 100 percent of the pigs will die. African swine fever caused by the lesser virulent isolates will be more difficult to diagnose but should always be suspected when there are febrile pigs and necropsy findings include the following:

Greatly enlarged dark red to black spleen
Very enlarged hemorrhagic gastrohepatic lymph nodes
Very enlarged hemorrhagic renal lymph nodes.

African swine fever has frequently been misdiagnosed as classical swine fever . In contrast to classical swine fever , ASFV-infected pigs do not develop a conjunctivitis or encephalitis, and despite the high fever, the ASFV-infected pigs stay in good condition. In contrast, classical swine fever -infected pigs are severely depressed and quickly lose much weight; moreover, they usually have a foul smelling diarrhea.

Specimens for Laboratory

The ASFV is present in the blood starting about 2 DPI. In infections by lesser virulent isolates, ASFV can usually be isolated from the blood for 25 or more DPI. Specimens for laboratory diagnosis are as follows:

- Heparinized blood
- Clotted blood or serum
- Submandibular lymph node
- Inguinal lymph node
- Tonsil
- Spleen
- Gastrohepatic lymph node
- Lung
- Liver
- Kidney

Bone marrow should be submitted if there are considerable postmortem changes.

The specimens should be shipped refrigerated or frozen. Pieces of the tissues listed above, the brain, and any other gross lesion should be submitted in 10 percent buffered formalin.

Aborted fetuses are usually free of virus; therefore, it is necessary to submit a blood sample from the dam.

Laboratory Diagnosis

The initial diagnosis of ASF in a free area requires isolation and identification of the virus. After the initial diagnosis, confirmation of a diagnosis can be made by demonstrating ASF antigen in tissue or ASF antibody.

Differential Diagnosis

Differential diagnoses for ASF should include classical swine fever, erysipelas, salmonellosis, and eperythrozoonoisis.

Vaccination

There is no vaccine.

Control and Eradication

Prevention

Introduction of the disease into free areas can be prevented by cooking all garbage fed to pigs (this applies to commercial and backyard pigs and pets [potbellied pigs]) and importing only ASF-disease free pigs.

Eradication

Control and eradication of ASF in developed countries can be accomplished by slaughter and disposal of all acutely infected pigs, widespread testing and elimination of all seropostive animals, and good herd isolation and sanitary practices.

Today (1996), ASF is not as great a threat to the United States as it was several years ago. The major pork-exporting countries have eradicated the disease in domestic pigs.

Public Health

Human beings are not susceptible to ASFV infection.

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Contagious bovine pleuropneumonia

Definition

Contagious bovine pleuropneumonia (CBPP) is a highly infectious acute, subacute, or chronic disease, primarily of cattle, affecting the lungs and occasionally the joints, and caused by *Mycoplasma mycoides mycoides*.

Etiology

Contagious bovine pleuropneumonia is caused by *M. mycoides mycoides* small colony type (SC type). *M. mycoides mycoides* large colony type is pathogenic for sheep and goats but not for cattle. *M. mycoides mycoides* (SC type) survives well only in vivo and is quickly inactivated when exposed to normal external environmental conditions. *M. mycoides mycoides* does not survive in meat or meat products and does not survive outside of the animal in nature for more than a few days. Many of the routinely used disinfectants will effectively inactivate the organism.

Host Range

Contagious bovine pleuropneumonia is predominantly a disease of the genus *Bos*; both bovine and zebu cattle are naturally infected. There are many reported breed differences with respect to susceptibility. In general, European breeds tend to be more susceptible than indigenous African breeds (8). There does seem to be some age resistance, for animals less than 3 years of age are less resistant to experimental challenge (5). In zoos the infection has been recorded in bison and yak. Although it has been reported that the domestic buffalo (Bubalus bubalis) is susceptible, the disease is difficult to produce experimentally in this species (7).

Geographic Distribution

Contagious bovine pleuropneumoia is endemic in most of Africa. It is a problem in parts of Asia, especially India and China. Periodically, CBPP occurs in Europe, and other outbreaks within the last decade have occurred in Spain, Portugal and Italy. Contagious bovine pleuropneumonia was eradicated from the US in the nineteenth century. It is of historical interest that the Bureau of Animal Industries, which was a forerunner of USDA's APHIS was formed in 1884 specifically to eradicate CBPP. The United States was declared free of CBPP only 9 years later in 1893. Currently CBPP is not present in the Western Hemisphere.

Transmission

Contagious bovine pleuropneumonia is spread by inhalation of droplets from an infected, coughing animal. Consequently, relatively close contact is required for transmission to occur. Outbreaks usually begin as the result of movement of an infected animal into a naïve herd. It is widely believed that recovered animals harboring infectious organisms within a pulmonary sequestrum may become active shedders when stressed. Although this may be a factor in some outbreaks, it has not been substantiated experimentally (9). There are limited anecdotal reports of fomite transmission, but this means of transmission is not generally thought to be a problem.

Incubation Period

The time from natural exposure to overt signs of disease is variable but generally quite long. It has been shown that healthy animals placed in a CBPP-infected herd may begin showing signs of disease 20-123 days later (7). Experimentally, subsequent to instillation of large quantities of infective material at the tracheal bifurcation, the incubation period was 2-3 weeks.

Clinical Signs

Usually the first abnormality noticed is a depressed, inappentent animal with fever. Coughing may be the next sign followed by evidence of thoracic pain and an increased respiratory rate. As pneumonia progresses and animals become increasingly dyspenic, animals are inclined to stand with elbows abducted in an attempt to decrease thoracic pain and increase chest capacity. Auscultation of the lungs reveals any of a wide variety of sounds, depending on how severely the pulmonary parenchyma is affected. Crepitations, rales, and pleuritic friction rubs are all possible. Percussion over affected areas reveals dullness. When pulmonary involvement is extensive and severe, there will be very labored respiration and sometimes open mouthed breathing. Occasionally in calves, pneumonia may be accompanied by a polyarthritis. Animals affected in this manner may be very reluctant to move and stand stiffly with an arched back. Getting up and down may cause obvious discomfort. Large joints may be distended and warm on palpation. If joint pain is severe, animals may be so reluctant to bend the joints that they lie in lateral recumbency with legs outstretched. Contagious bovine pleuropneumonia often evolves into a chronic disease. This form, characterized by ill thrift and recurrent low-grade fever, may be difficult to recognize as pneumonia. Forced exercise may precipitate coughing.

Gross Lesions

The gross pathologic features of CBPP are quite characteristic (3). If the animal dies, there is usually extensive and marked inflammation of the lung and associated pleura. In severe cases there can be abundant fluid in the thoracic cavity. The inflammation is not uncommonly unilateral. The initial focus can be in any part of the lung, and in fatal cases, usually has spread locally and extensively to include a sizeable segment. The affected pulmonary parenchyma is odorless and often has all stages of lesions with both acute and chronic pulmonary changes adjacent to one another. The predominant gross change is consolidation, or thickening, of individual lobes which become encased in markedly widened interlobular septa, resulting in very characteristic marbled appearance. Interlobular septa become distended first by edema, then by fibrin, and finally by fibrosis. The overlying pleura may be very thickened by an irregular layering of yellow fibrin which, with time, becomes fibrosed, often resulting in adhesions between parietal and visceral pleurae. Not uncommonly, within an affected lung will be found a sequestrum - a focus that has undergone coagulative necrosis, and is effectively sealed off from the rest of the lung. Such sequestra may even be found in recovered animals. It has been shown that *M. mycoides mycoides* (SC-type) can survive within these sequestra for months or possibly longer.

Morbidity and Morality

The attack rate with CBPP is variable. It is not thought to be a highly contagious disease. With increased confinement of animals, morbidity rises. The mortality rate with CBPP is quite varied and ranges from 10-70 percent in various outbreaks. As with many subacute and chronic infectious diseases, mortality may depend on other intercurrent factors such as plane of nutrition, level of parasitism, and general body condition.

Diagnosis

Field Diagnosis

Clinical diagnosis of CBPP is difficult. At postmortem the gross lesions of CBPP are somewhat distinct. Often there is extensive deposition of fibrin and a large quantity of straw colored fluid in the thoracic cavity with prominent marbling of pulmonary parenchyma. Generally, all stages of pathologic changes from acute through to chronic are present in one animal. In some chronic cases the nodules of inflammation may not be readily apparent from the pleural surface but can be palpated within the parenchyma. Unlike many other pneumonia CBPP is often unilateral.

Specimens for Laboratory

From a live animal, nasal swabs, transtracheal washes, or pleural fluid obtained by thoracic puncture all provide good samples for isolation attempts. From a dead animal that has had severe clinical disease, the best specimens to submit are affected lung, swabs of the major bronchi, tracheo-bronchial or mediastinal lymph nodes, and joint fluid from those animals with arthritis. All samples should be collected aseptically and, if possible, placed in transport medium (heart infusion broth, 20 percent serum, 10 percent yeast extract, benzylpenicillin at 250 to 1000 IU/ml). Samples should be kept cool and shipped on wet ice as soon as possible. If transport to the laboratory is delayed (more than a few days), samples may be frozen (1). Blood should be collected for serum.

Laboratory Diagnosis

A definitive diagnosis is made by isolating and identifying the organism. Serology is helpful in the diagnosis of CBPP. Because CBPP is a subacute or chronic disease, most animals will have developed antibodies by the time of clinical disease.

Differential Diagnosis

Clinically, CBPP may be confused with other pneumonic conditions, especially bovine pasteurellosis. However, bovine pasteurellosis would likely spread much more rapidly and consequently the epidemiologist picture would be distinct.

Treatment

Mycoplasma mycoides mycoides (SC-type) is susceptible to a variety of antimicrobials, including streptomycin, oxytetracycline and chloramphenical. However, antimicrobial therapy[y may only serve to slow the progression of the disease or may even in some

cases favor the formation of sequestra. In the case of chronically affected animals, or subclinically affected carriers, the organisms may be in an inaccessible location with an area of coagulative necrosis, which by definition is not served by a blood supply.

Vaccination

A modified live virus vaccine is available for use in enzootic areas. A major drawback of this vaccine is that it generates an unpredictable local reaction. For this reason it is often given in the tail tip, which may become necrotic and slough. Immunity subsequent to vaccination is generally good and lasts at least 12 months. The CBPP vaccine is often given in combination with the vaccine for rinderpest.

Prevention

Because CBPP is a chronic disease that may exist subclinically in carrier animals, it is important to maintain sufficient regulatory restrictions to prevent its introduction in apparently healthy animals. Serologic testing of susceptible animals for importation is a recommended safeguard.

Control and Eradication

Successful control of the spread of CBPP rests on removing susceptible animals from any possible contact with CBPP-infected animals whether they are clinically affected or subclinical carriers only. On-farm quarantine of suspicious and contact animals would be very advantageous in stemming the spread of disease. In an outbreak situation, testing, slaughter, and quarantine would be methods of choice.

Public Health Aspects

There is no evidence to indicate that humans are susceptible to this disease.

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Rinderpest

Definition

Rinderpest is a contagious viral disease of cattle, domestic buffalo, and some species of wildlife. It is characterized by fever, oral erosions, diarrhea, lymphoid necrosis, and high mortality.

Etiology

Rinderpest virus (RPV) is a single-stranded RNA virus in the family Paramyxoviridae, genus Morbillivirus. It is immunologically related to canine distemper virus, human measles virus, peste des petits ruminants virus, and marine mammal morbilliviruses. There is only one serotype of rinderpest virus, but field strains vary widely in virulence, ease of transmission, and host affinity.

Rinderpest virus is a relatively fragile virus. Sunlight is lethal and the vaccine must therefore be kept in a brown bottle and protected from light; virus in a thin layer of blood is inactivated in 2 hours. Moderate relative humidity inactivated the virus more quickly than wither high or low humidity. The virus is very sensitive to heat and both lypholized and reconstituted virus should therefore be kept cold; lypholized virus stored at -20° C is viable for years. Vaccine reconstituted in pure water quickly loses potency. Vaccine is more stable in a saline solution; reconstitution in a molar concentration of sulfate ions greatly increases resistance to heat.

Rinderpest virus is rapidly inactivated at pH 2 and 12 (10 minutes); optimal for survival is pH 65.-7. The virus is inactivated by glycerol and lipid solvents.

Host Range

Most wild and domestic cloven footed animals can be infected.

Geographic Distribution

Rinderpest is present in the Indian subcontinent, Near East and sub-Saharan Africa.

Transmission

Rinderpest was established as an infectious disease in 1754 when susceptible animals were infected by placing bits of material previously dipped in morbid discharge into an incision made in the dewlap. In 1899, cattle were infected with a bacteria-free infiltrate.

Secretions and excretions, particularly nasal-ocular discharges and feces, 1 to 2 days before clinical signs to 8 to 9 days after onset of clinical signs contain large quantities of virus. Spread of RP is by direct and indirect (contaminated ground, waters, equipment,

clothing) contact with infected animals; aerosol transmission s not a significant means of transmission (it occurs only in a confined area and over a short distance). A major reason RP spreads in Africa is that herds are nomadic. Cattle follow the grass and thus move great distances, and during the dry season, many herds will use the same well or watering area, thus there is ample opportunity for cross-infection. It is said that a good fence will control RP.

There is only one serotype of RPV: recovered or properly vaccinated animals are immune for life, and there is no vertical transmission, arthropod vector, or carrier state. For these reasons, RPV is an ideal virus to be targeted for eradication.

Highly virulent strains of RPV are responsible for epizootics in susceptible animals and tend to die out. Milder strains tend to persist in an area, and the disease is not recognized as RP unless serology is performed.

The roles the various hosts can play in the disease are as follows:

- Cattle and domestic buffalo - highly susceptible
- Sheep and goats in Africa - subclinical infection and seroconversion, but there is no transmission to other animals
- Sheep and goats in India - when infected by low-passage goat RP vaccine will transmit to domestic buffalo
- Pigs - Swayback pigs in Thailand and the Malay Peninsula can be naturally infected and may die. European pigs can be infected by ingestion of RPV-infected meat and will transmit to cattle and other pigs.
- Wild ungulates - African buffalo, wildebeest, kudu, eland, giraffe, and wart hog are highly susceptible; Thompson gazelle, hippopotamus are fairly susceptible. Wild ungulates are infected by contact with cattle and can transmit to cattle. IN the absence of RP in cattle, the disease dies out in wildlife.

Incubation Period

The incubation period varies with the strain of virus, dosage, and route of exposure. Following natural exposure, the incubation period ranges from 3 to 15 days but is usually 4 to 5 days.

Clinical Signs

Depending on the strain of virus, resistance of the animal affected, and the concurrent infection, RP can appear as a peracute, acute or mild infection.

Peracute form

This form is seen in highly susceptible and young animals. The only signs of illness are fever of 104° to 107° F (40-41.7°C), congested mucous membranes, and death within 2-3 days after the onset of fever.

Acute or Classic form

This form of disease progresses as follows:

- Small amounts of virus may be in nasal and ocular secretions before the onset of fever
- Fever of 104-106°F (40-41.1°C)
- Serous to mucopurulent ocular discharge
- Serous to mucopurulent nasal discharge
- Leukopenia
- Depression
- Anorexia
- Constipation
- Oral erosions - salivation may be abundant and frothy
- Fever decreases and viral titer drops
- Diarrhea - may be very watery and hemorrhagic or both
- Dehydration, emaciation
- Prostration and death in 6-12 days after onset of illness.

Gross Lesions

Oral lesions are variable; some isolates cause good oral lesions and with others there is no oral lesion. Oral lesions start as small grey foci that may coalesce. The grey (necrotic) epithelium then sloughs off and leaves a red erosion.

- Mouth - lesions occur on the gums, lips, hard and soft palate, cheeks, and base of tongue. Early lesions are grey, necrotic, pinhead-sized areas that later coalesce and erode and leave red areas.
- Esophagus - Brownish necrotic or eroded areas
- Rumen and reticulum - lesions are rare
- Omasum - erosions and hemorrhage are rare
- Abomasum - congestion and edema
- Small intestine-necrosis or erosion of Peyer's patches in the jejunum; necrosis or erosions over the lymphoid area in the ileum (ingesta adhering to the intestinal mucosa indicates areas of necrotic epithelium)
- Cecum and colon - the wall may be edematous, and there may be blood in the lumen and blood clots on the mucosa. Lesions are usually more severe in the upper colon (edema of the wall, erosions in the mucosa, and congestion). The lesions may be accentuated at the cecocolic junction. Further down the colon, the colonic ridges may be congested; this is referred to as "tiger striping". Tiger striping can occur in other diarrhea and probably results tenesmus.
- Severity of intestinal lesions varies between isolates.
- Lymph nodes - Generally swollen and edematous.
- Liver- There may be petechial to ecchymotic hemorrhages in the gall bladder.
- Lung -there may be emphysema, congestion, and areas of pneumonia.

Diagnosis

Field Diagnosis

Rinderpest should be considered in all ages of cattle whenever there is a rapidly spreading acute febrile disease accompanied by the preceding clinical signs and lesions of RP. The all ages stipulation is important because this will be one of the major differences between bovine virus diarrhea-mucosal, which predominantly affects animals between 4 and 24 months of age.

Specimens for Laboratory

Because the viral titer drops when the fever falls and diarrhea starts, specimens could preferably be collected from animals with high fever and oral lesions. The following samples should be collected from live animals:

Blood in EDTA or heparin
Blood for serum
Swabs containing lacrimal fluid
Necrotic tissue from the oral cavity
Aspiration biopsies of superficial lymph nodes

For the best specimens, a febrile animal should be slaughtered and specimens collected. If this cannot be done, then collect specimens from moribund animals. Collect the blood samples listed above and sections of spleen, lymph nodes, and tonsil.

The preceding samples should be transported to the laboratory on wet ice - -NOT FROZEN. A complete set of tissues, including sections of all lesions, should be collected in 10 percent formalin.

Laboratory Diagnosis

To confirm the initial diagnosis in a free area, the virus has to isolated and identified.

Differential Diagnosis

The differential diagnosis for RP should include bovine rhinotracheitis, malignant catarrhal fever, foot and mouth disease, vesicular stomatitis, salmonellosis, paratuberculosis and arsenic poisoning.

Vaccination

The following types of RP vaccine have been used:

1. Lapinized in China and Korea
2. Avianized-lapinized in Korea
3. Goat-adapted in India
4. Cell-culture adapted in Africa, Middle Eats, and India.

An experimental vaccine-vectored vaccine containing the F and H genes of RPV has protected against a challenge inoculation of virulent virus.

The two most commonly used vaccines in 1996 were the goat-adapted and cell-culture adapted vaccines. The goat adapted vaccine is only partially attenuated; it will cause disease in animals with low innate resistance or concurrent latent disease and kills sheep and goats. The cell-culture attenuated vaccine was developed by Plowright in Kenya in the 1960's. This is a safe vaccine for many species and produces life long immunity in cattle (animals challenge-innoculated 7 years after vaccination were protected). In endemic areas where cattle have been vaccinated, colostral immunity will interfere with the vaccination of calves up to 11-12 months of age. Because the duration of colostral immunity is variable, the recommendation is to vaccinate calves annually for 3 years.

One of the biggest problems with the cell-culture adapted vaccine has been stability. The lypholized virus has to be kept cold (cold chain) until used. The combination of maintenance of the cold chain and remoteness of vaccination sites made RP vaccination very expensive. Because of the uncertainty that the vaccine being used was viable, the areas in Africa it is and was the policy to vaccinate animals every year in the hope that one of the vaccinations would immunize the animal. Researchers at Plum Island in the early 1990's greatly increased the stability of the lypholized vaccine by modifying the stabilizers and lyophilization process. This change in production is now being used in some production facilities in Africa.

Experimentally, the vaccine-vectored RP vaccine protected cattle against challenge inoculation with RPV. This vaccine is undergoing field testing. This vaccine could be particularly useful in an eradication program because vaccine-vectored RP vaccine immunized animals can be differentiated serologically from animals having antibody induced by the live virus. The vaccine-vectored vaccine would enable a country toward the end of an eradication program to maintain herd immunity to RP without using a live RP virus.

Control and Eradication

Countries and areas free of RP should prohibit unrestricted movement of RP-susceptible animals and uncooked meat products from areas infected by RP or practicing RP vaccination.

Because recovered animals are not carriers, and there are good serological techniques, zoological ruminants and swine can be imported with proper quarantine and testing. If an outbreak occurs, the area should be quarantined, infected and exposed animals slaughtered and buried or burned; and ring vaccination considered.

Experimentally it has been shown that RPV will not be transmitted by bovine embryo transfer if the embryos have been processed by the technique recommended by the International Embryo Transfer Society and the OIE.

High risk countries (those trading with, or geographically close to, infected countries) can protect themselves by having all susceptible animals vaccinated before they enter the country or vaccinating the national herd, or both. If an outbreak occurs, the area should be quarantined and ring vaccinated.

Endemic countries should vaccinate the national herd. Owing to the uncertainty of vaccine potency, the recommendation is to vaccinate annually for at least 4 years,

followed by annual vaccination of calves. Foci of infection should be quarantined and stamped out. Wildlife, sheep and goats should be monitored serologically. Serological monitoring of sheep and goats could be complicated by using RP vaccine to protect against pest des petits ruminants.

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Heartwater

General

Heartwater is an infectious, noncontagious, tick-borne disease of domestic and wild ruminants, including cattle, sheep, goats, antelope, and buffalo. The disease is caused by an intracellular rickettsial parasite, Ehrlichia ruminantium, and is transmitted by a number of species of ticks in the genus Amblyomma.

Heartwater is usually an acute disease and is commonly fatal within a week of onset of clinical signs. The disease is widespread in most of Africa and on several islands in the West Indies. With increased trade and movement of animals in today's global market, Heartwater may present a significant threat to the domestic livestock industry in the United States.

Livestock owners should monitor their animals for exotic ticks and for clinical signs of the disease. If Heartwater is suspected, owners should immediately report these findings to a veterinarian or to a State or Federal animal health official.

History

Heartwater was first identified in sheep in South Africa in the 1830s. By 1898, it was shown to be a transmittable disease, and in 1900, the tropical bont tick was identified as a vector. In 1980, Heartwater was reported for the first time in the Western Hemisphere on the Caribbean island of Guadeloupe, although the vector tick was probably introduced from Africa much earlier. The disease is also present on the Caribbean islands of Marie Galante and Antigua.

The tropical bont tick has spread to several other islands in the Caribbean, although a definitive diagnosis of Heartwater has not been made to date on those islands.

Signs

The acute form of heartwater is the most commonly observed presentation of the disease. A sudden high fever (107° F) is followed by loss of appetite, depression, and respiratory problems. Animals may initially have an increased respiratory rate, followed within a few days by severe respiratory distress. Nervous disorders often follow the respiratory signs and can include a variety of abnormal behaviors such as excessive chewing movements, incoordination, head tilting upward, overly rigid posture, and walking with a high-stepping gait.

Some animals may undergo convulsions or be unable to rise. These nervous signs usually last for no more than 24 to 48 hours, followed by the animal's death. In some cases, the nervous signs may not be noticed prior to death.

A mild form of the disease, known as Heartwater fever, is present in some affected regions among indigenous breeds with a natural or acquired resistance to Heartwater. The only clinical sign of the mild form of the disease is a transient fever, and animals with this form usually recover.

Postmortem Lesions

Heartwater derives its name from a common postmortem finding of excessive fluid in the sac surrounding the heart. More commonly, the fluid accumulates within the lungs, thus the lungs appear "wet" and heavy. The fluid may also accumulate within the chest cavity itself, outside the lungs.

A definitive diagnosis of heartwater is made by microscopic examination and observation of the causative rickettsia in a brain tissue smear.

How It Spreads

Heartwater is transmitted only by ticks of the genus Amblyomma, with the tropical bont tick as one of the most important vectors. This tick is widely distributed throughout Africa, Yemen, the Cape Verde islands, and several islands in the Caribbean.

The life cycle of Amblyomma ticks may take from 1 to 4 years. Thus, the infection may persist, inside the tick for a long time. In its immature stages, the tick will feed on a wide variety of livestock, wild ungulates, ground birds, small mammals, reptiles, and amphibians.

Rapid spread of the tropical bont tick in the West Indies has occurred since the 1960s. Movement of tick-infested livestock was incriminated in some cases, but overall, the cause of the spread of these ticks has not been determined.

Cattle egrets became established in the region in the 1950s and have been implicated in much of the recent spread of heartwater. Small numbers of tick-infested cattle egrets have been shown to move among islands in the region, but these birds are not considered to be efficient disseminators of the tick.

Susceptible Species

Animals susceptible to heartwater include cattle, sheep, goats, and buffalo. Some breeds of cattle (e.g., Jerseys and Brahmas) may be more susceptible than others. Exotic ruminants can also contract the disease.

In laboratory tests in the United States, the white-tailed deer (*Odocoileus virginianus*) has been shown experimentally to be highly susceptible to heartwater. Amblyomma maculatum, another potential vector, is a common parasite of white-tailed deer in the Southern United States. However, there is no evidence that heartwater is present in wildlife in this country.

Prevention and Control

Preventive measures by livestock owners should include implementation of an effective tick-control program, including regular inspection of animals and pastures for ticks and elimination of the vector through the use of acaricides.

To prevent introduction of heartwater or any other foreign animal disease, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) tests imported animals for heartwater and other diseases and ensures that all animals are free of ticks or other potential insect vectors before entry into the United States is permitted.

Sheep and Goat Pox

Definition

Sheep and goat pox (SGP) is an acute to chronic disease of sheep and goats characterized by generalized pox lesions throughout the skin and mucous membranes, a persistent fever, lymphadenitis, and often a focal viral pneumonia with lesions distributed uniformly throughout the lungs. Subclinical cases may occur.

Etiology

The virus that causes SGP is a capripoxvirus, one of the largest viruses (170-260nm by 300-450nm) (10). It is closely related to the virus that causes lumpy skin disease; SGP Virus and lumpy skin disease virus cannot be distinguished serologically. There is only one serotype of SGP virus (SGPV). Various strains of SGPV cause disease only in sheep, others only in goats and some in both sheep and goats (2,3,9). The SGPV is very resistant to physical and chemical agents.

Host Range

Sheep and goat pox virus causes clinical disease in sheep and goats. The virus replicates in cattle but does not cause clinical disease. The disease has not been detected in wild ungulate populations.

Geographic Distribution

The disease is endemic in Africa, the Middle East, the Indian subcontinent, and much of Asia.

A goat pox like disease was reported in the western United States (15), but no attempt was made to identify the agent with reference serum against SGPV. Serum samples from animals representing the affected group of goats were submitted to the Foreign Animal Disease Diagnostic Laboratory (FADDL) at Plum Island, NY, and tested for antibody to SGPV; no antibodies were found against SGPV. The serums were not tested for antibodies to bovid herpesvirus 2 or contagious ecthyma at the FADDL. Unfortunately, the viral isolate was not available for study. It is conclusive that what was reported in the literature was not goat pox.

Transmission

Contact is the main means of transmission of SGPV. Inhalation of aerosols from acutely affected animals, aerosols generated from dust contaminated from pox scabs in barns and night holding areas, and contact through skin abrasions either by fomites or by direct contact are the natural means of transmitting SGPV. Insect transmission is possible. The virus can cause infection experimentally by intravenous, intradermal, intranasal, or subcutaneous inoculation.

Incubation Period

Under field conditions, the incubation of SGP is between 4 and 8 days. Experimentally, the first sign (fever) may appear within 3 to 5 days after inoculation. The course of the disease is 4 to 6 weeks with various stages of pox lesions present at the same time. Full recovery may take up to 3 months.

Clinical Signs

Sheep and goat pox virus may cause subclinical infection; clinical cases vary from mild to severe (3). The course of the disease in sheep and goats is similar. The first signs may include fever, depression, conjunctivitis, lacrimation, and rhinitis. Within a few days of the prodromal signs, pox lesions develop in the skin. These are more easily observed on the wool-free or hair-free parts of the body such as the perineum, inguinal area, scrotum, udder, axilla, and muzzle. Lesions do occur in wooled or haired skin. Generally more severe (extensive) skin lesions correlate with more severe illness. The skin lesions first appear as an erythematous area (macula). The lesions progress to a raised, slightly blanched lesion that presents erythema with edema in the central part of the lesion (papule). Pox lesions with a transudate, representing the vesicular stage of the lesion, may be noted, but rarely is there any gross vesicle in the skin. The center of the lesion then becomes depressed and gray (necrotic) and is surrounded by an area of hyperemia. Late in the course of the disease (2 to 4 weeks after the first signs, the lesion becomes dry and a scab forms. A characteristic feature of a pox lesion is that lesions involve the entire epidermis and dermis and penetrate into the subcutaneous tissue; it feels like a nodule. Depending on the severity of the skin lesion, there may be a scar, an area devoid of wool or hair, after the lesion heals. Secondary bacterial infection may complicate the healing process. The muzzle may be swollen, and the nares and oral mucosa may have extensive lesions. IN many cases, pneumonia may occur with labored breathing and a respiratory rate approaching 90 per minute. Depression, anorexia, and emaciation are common and may persist. Nervous signs may occur, but how these are related to the SGPV infection is not clear.

Lambs and kids under 1 month of age may suffer a very severe generalized form of SGP. The signs described above for older animals are exaggerated, and there is an increased mortality.

Gross Lesions

At necropsy, skin lesions have congestion, hemorrhage, edema, vasculitis and necrosis and will be seen to involve all layers of the epidermis, dermis, and in severe cases, extend into the adjacent musculature. Lymph nodes draining affected areas are enlarged up to eight times their normal size owing to extensive lymphoid proliferation, edema, congestion and hemorrhage.

Mucous membranes of the eye, mouth, and nose have pox lesions that, in severe cases, may coalesce. In severe cases of SGP, the eyelids may be so seriously affected that the proliferative lesions and inflammation cause the eyes to close. Lesions on the muzzle and mares may coalesce, and proliferative changes and inflammation may be

extensive. Pox lesions may occur in the pharynx, epiglottis, and trachea. These usually appear as rounded blanched areas surrounded by an area of hyperemia. Occasionally there may be lesions in the epithelium of the rumen and Omasum.

Pox lesions in the lungs may be severe and extensive; the lesions are focal and uniformly distributed throughout the lungs as the result of hematogenous infection. Early lesions are congested areas; these progress to discreet areas of congestion and edema and finally to white nodules. Areas distal to the pox lesions have lobular atelectasis. Mediastinal lymph nodes are often enlarged up to five times their normal size and may be congested, hemorrhagic, and edematous.

Pox lesions also may be present on the vulva, prepuce, testicles udder, and teats.

Morbidity and Mortality

The severity of SGP varies depending on the strain of the virus and the age and breed of the animals affected (5). In adult sheep and goats, morbidity may range from 70-90 percent with some subclinical infections. Mortality can approach 50 percent. In endemic areas, mortality rates range from 5-10 percent, but it can approach 100 percent in imported animals (OIE). In susceptible lambs and kids under 1 month of age, morbidity may approach 100 percent, and mortality may be as high as 95 percent. Factors that may complicate the course of the disease and increase the mortality are poor nutrition, heavy parasitism, and severe climatic conditions.

Diagnosis

Field Diagnosis

A tentative diagnosis of SGP can be made on the basis of clinical signs consisting of skin lesions, which on palpation involve the whole thickness of the skin, a persistent fever, lymphadenitis, and often pneumonia; mortality may approach 50 percent in adults and 95 percent in lambs and kids under 1 month of age.

Specimens for Laboratory

For laboratory diagnosis of SGP, skin biopsies of early lesions can be used for virus isolation and histopathologic and electron microscopic studies. Samples aspirated from enlarged lymph nodes can be used for virus isolation. Necropsy samples should include a full set of tissues, but samples of the lungs, trachea, and rumen containing gross lesions are especially valuable for histopathology. Samples for virus isolation should be shipped under wet ice if they will arrive within 2 days and shipped under dry ice if delivery will take longer (send in screw capped vials with the caps secured with electrical tape). Samples for histopathology should be preserved in 10 percent buffered formalin (DO NOT FREZE). Serum samples should be taken from acute and chronic cases. Follow-up serum samples from acute cases may be taken 2 to 3 weeks after the first sample.

Laboratory Diagnosis

The laboratory procedures for the diagnosis of SGP include identification of the agent by cell inoculation and identification by immunofluorescence staining of intracytoplasmic inclusion bodies, inhibition of the cytopathic effect using positive serum, and antigen detection ELISA. Serological tests include agar gel immunodiffusion, ELISA, detection of antibody by virus neutralization, the indirect fluorescent antibody test (4) or both; in combination with characteristic histopathologic lesions (3).

Differential Diagnosis

Following are several diseases to consider in the differential diagnosis for SGP:

- Bluetongue - Animals are depressed and have a non-purulent conjunctivitis. The muzzle is swollen, congested, and edematous, and there may be a coronitis. Deformed aborted fetuses and deformed newborn sheep and goats may be encountered.
- Peste des Petits Ruminants - Conjunctivitis, rhinitis, and oral lesions that are white, raised, and necrotic are common. Pneumonia, diarrhea, and mortality approaching 90 percent in lambs and kids under 1 month of age are characteristic signs.
- Contagious ecthyma (contagious pustular dermatitis, ORF) - this disease is most severe in lambs and kids. The proliferative pox disease is most severe in lambs and kids. The proliferative pox lesions are common on the muzzle ad eyes of affected neonates; mortality may approach 50 percent. Nursing females may have proliferative pox lesions on the teats and muzzle. This is a zoonotic disease; lesions in attendants are not uncommon.
- Photosensitization - dry, flakey, inflamed areas are confined to the non-pigmented parts of the skins.
- Insect Bites - the trauma from insect bites may cause local inflammation, edema, and pruritis. Insects seldom bite mucous membranes.
- Parasitic pneumonia - severe signs of respiratory distress may occur with extensive parasitic lesions; in these cases, there is no pox lesion in the skin.
- Caseous lymphadenitis - focal, raised lesions ion the skin represent caseous abscesses; abscesses are not seen in SGP.
- Streptothricosis (*dermatophilus congolensi* infection) - lesions are superficial and often moist. Lesions are common in the skin of the neck, axillary region, inguinal region, and perineum. The organism may be demonstrated by Geisma staining.
- Mange - scab-like skin lesions are seen with psoroptic mange. Itching and scratching are not seen in SGP.

Vaccination

In endemic areas, vaccination is an effective means of controlling losses from SGP. Killed vaccines have not proven to be practical under field conditions because they do not provide solid, long lasting immunity. Several modified live virus vaccines have been used for protection against SGP. The most widely used employed vaccine is probably the Romanian strain that has been used effectively for many years (14, 16). The Kenya O 180 strain (6) is possibly the vaccine with the best safety and efficacy.

Control and Eradication

Prevention

The most likely manner for SGP to enter a new area is by introduction of infected animals. Restrictions on the movement of animal and animal byproducts (meat, hair, wool, and hides) are essential to prevent introduction of SGP. Wool, hair, and hides must be subjected to suitable decontamination procedures before entry into non-endemic areas.

Control

If a new case is confirmed in a new area before extensive spread occurs, the area should be quarantined, infected and exposed animals should be slaughtered, and the premises cleaned and disinfected. Vaccination of susceptible animals on premises surrounding the infected flock(s) should be considered.

If the disease has spread over a large area, the most effective means of controlled losses from SGP is vaccination; however, consideration should be given to eliminating infected and exposed flocks by slaughter; properly disposing of animals and contaminated material; and cleaning and disinfecting contaminated premises, equipment, and facilities.

Eradication

A carrier state has not been shown for SGPV. However, the virus may persist for many months on contaminated premises. The imposition of quarantines on areas and premises containing infected or exposed animals is required to prevent disease spread. Depopulation of infected and exposed flocks should be used if limited spread has occurred. If the disease has spread extensively, massive vaccination followed by cessation of vaccination and control of animal movements from the area represent a strong strategy to control and then eradicate SGP.

Public Health

There is no conclusive evidence that SGPV infects humans. A report from India (17) that implied that goat pox caused human infection was merely based on clinical signs. There was no attempt to isolate the causative virus or perform serology on the convalescent serums of three patients to differentiate the infection from contagious ecthyma, which is a known zoonotic agent that occurs worldwide. A report from Sweden (1) indicated that human infection occurred during an outbreak of goat pox. Although serological studies seemed to indicate that the apparent causative agent of the outbreak was not vaccine or contagious ecthyma, no virus was isolated. Therefore it cannot be said that goat pox caused human infection.

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Scrapie

Scrapie is a fatal, degenerative disease affecting the central nervous system of sheep and goats. It is among a number of diseases classified as transmissible spongiform encephalopathies (TSE). Infected flocks that contain a high percentage of susceptible animals can experience significant production losses. Over a period of several years the number of infected animals increases, and the age at onset of clinical signs decreases making these flocks economically unviable. Female animals sold from infected flocks spread scrapie to other flocks. The presence of scrapie in the United States also prevents the export of breeding stock, semen, and embryos to many other countries. TSEs are the subject of increased attention and concern because of the discovery of bovine spongiform encephalopathy (BSE) in cattle, the link between BSE and variant Creutzfeldt-Jakob disease (vCJD) in people, and feline spongiform encephalopathy (FSE) in cats in Europe. This increased concern has led to the following:

- Packers and producers have had difficulty finding options for disposal of sheep offal and dead sheep causing packers and producers to incur significant increases in disposal costs,
- Other countries have expressed concerns and have indicated that they may prohibit or restrict certain ruminant products because the United States has scrapie, and
- Domestic and international markets for U.S. sheep–derived meat and bone meal have been adversely affected.

The combination of all of these factors has led to the decision to develop a strong scrapie eradication program in the United States.

Epidemiology and Transmission

The agent responsible for scrapie and other TSEs is smaller than the smallest known virus and has not been completely characterized. There are three main theories on the nature of the scrapie agent: (1) the agent is a prion, which is an abnormal form of a normal cellular protein, 2)the agent is a virus with unusual characteristics, and (3) the agent is a virino, a very small piece of DNA that acts like a virus. The scrapie agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any detectable immune response or inflammatory reaction in sheep and goats.

The scrapie agent is thought to be spread most commonly from the ewe to her offspring and to other lambs through contact with the placenta and placental fluids. Signs or effects of the disease usually appear 2 to 5 years after the animal is infected but may not appear until much later. Sheep may live 1 to 6 months or longer after the onset of clinical signs, but death is inevitable. The genetics of the sheep affects their susceptibility to scrapie.

In the laboratory, the scrapie agent has been transmitted to hamsters, mice, rats, voles, gerbils, mink, cattle, and some species of monkeys by inoculation. There is no scientific evidence to indicate that scrapie poses a risk to human health. There is no epidemiologic evidence that scrapie of sheep and goats is transmitted to humans, such as through contact on the farm, at slaughter establishments, or butcher shops.

Clinical Signs

Signs of scrapie vary widely among individual animals and develop very slowly. Due to damage to nerve cells, affected animals usually show behavioral changes, tremor (especially of head and neck), rubbing, and locomotor incoordination that progresses to recumbency and death.

Early signs include subtle changes in behavior or temperament. These changes may be followed by scratching and rubbing against fixed objects, apparently to relieve itching. Other signs are loss of coordination, weakness, weight loss despite retention of appetite, biting of feet and limbs, lip smacking, and gait abnormalities, including high–stepping of the forelegs, hopping like a rabbit, and swaying of the back end.

An infected animal may appear normal if left undisturbed at rest. However, when stimulated by a sudden noise, excessive movement, or the stress of handling, the animal may tremble or fall down in a convulsive–like state.

Several other problems can cause clinical signs similar to scrapie in sheep, including the diseases ovine progressive pneumonia, listeriosis, and rabies; the presence of external parasites (lice and mites); pregnancy toxemia; and toxins.

On the farm, veterinarians diagnose scrapie based on the appearance of its signs combined with knowledge of the animal's history. Scrapie can be diagnosed in the live animal by biopsy of the lymphoid tissues on the inside of the third eyelid. This test is used by the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) to determine whether exposed flocks are infected. Scrapie is most often diagnosed by microscopic examinations of brain tissue at necropsy or by procedures that detect the presence of the abnormal prion protein in brain tissue.

Research

Scrapie research efforts are currently focused on developing more practical live–animal tests to diagnose infected sheep before they show signs, investigating transmissibility of the agent, identifying the scrapie agent and its different strains, identifying genes that influence scrapie infection and evaluating genetic selection as a tool for scrapie eradication. Substantial evidence has accrued to show that the risk of scrapie transmission by embryo’s is negligible provided that the embryos are properly handled between collection and transfer, but additional experimental data are needed to support existing evidence.

Related Diseases

The TSE family of diseases includes BSE: transmissible mink encephalopathy; FSE; chronic wasting disease of deer and elk; kuru; both classical and variant Creutzfeldt-Jakob disease; Gerstmann–Straussler-Scheinker syndrome; and fatal familial insomnia. TSEs have also been reported in Europe in captive wild ruminants in the bovid family, cats, and monkeys. The occurrence of TSEs in captive wild animals is believed to h
Eradication Program
USDA has initiated an accelerated scrapie eradication program. The program is based on the following key concepts:

- Identification of preclinical infected sheep through live animal testing and active slaughter surveil lance,

- Effective tracing of infected animals to their flock/herd of origin made possible as a result of the identification requirements, and

- Providing effective genetic based flock cleanup strategies that will allow producers to stay in business, preserve breeding stock, and remain economically viable. APHIS provides the following to exposed and infected flocks/herds that participate in cleanup or monitoring plans:

    1. Indemnity for high–risk, suspect, and scrapie positive sheep and goats, which owners agree to destroy,
    2. Scrapie live-animal testing,
    3. Genetic testing, and
    4. Testing of exposed animals that have been sold out of infected and source flocks/herds. Operating an effective program to deal with this insidious disease requires cooperation among producer organizations, allied industries, and governmental agencies.

History

First recognized as a disease of sheep in Great Britain and other countries of Western Europe more than 250 years ago, scrapie has been reported throughout the world. Only two countries are recognized by the United States as being free of scrapie: Australia and New Zealand.

The first case of scrapie in the United States was diagnosed in 1947 in a Michigan flock. The flock owner had imported sheep of British origin through Canada for several years. APHIS conducted a slaughter surveillance study from April 1, 2002, to March 31, 2003, which determined the prevalence of scrapie in mature U.S. cull sheep to be 0.2 percent or one positive out of 500 cull sheep.

In the United States, scrapie has primarily been reported in the Suffolk breed. It also has been diagnosed in a Border Leicester, Cheviots, Corriedales, a Cotswold, Dorsets, Finn sheep, Hampshires, Merinos, Montadales, Rambouillets, Shropshires, Southdowns, and a number of crossbreeds. Through October 2003, approximately 2,350 cases in sheep and 12 cases in goats have been reported.

IV. Reporting Procedures

If, while conducting routine ante mortem or postmortem inspection of animals, identify a condition that you feel is suspicious of a reportable or foreign animal disease, you are to notify the District Office immediately. The DO will contact the State Animal Health Official and/or the APHIS Veterinary Services Area Veterinarian In Charge (AVIC) immediately. Veterinary Services is obligated to respond to your concern immediately, and will be there to assist you with diagnosis of this condition. Your importance in this role cannot be overemphasized: FSIS employees many more veterinarians than does Veterinary Services, and we look at many more animals through routine slaughter procedures. Therefore, we have a unique opportunity to identify reportable and foreign animal diseases, and can play a critical role in disease control and eradication, and in prevention of potential bioterrorist activities. A complete list of AVIC's and State Veterinarians is in sections VI and VII of these materials for your reference.

V. MOU

MEMORANDUM OF UNDERSTANDING
BETWEEN
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
AND
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Relative to
Cooperation with Respect to Surveillance Programs

The parties to this Memorandum of Understanding are the United States Department of Agriculture, Food Safety and Inspection Service, hereinafter called FSIS, and the United States Department of Agriculture, Animal and Plant Health Inspection Service, hereinafter called APHIS.

WHEREAS, the parties to this Memorandum of Understanding agree to cooperate in meeting their responsibilities relative to information exchange regarding animal and public health disease surveillance, diagnostic testing, investigations, trace backs, recalls, animal welfare, and animal and public health concerns and of providing a safe, secure, wholesome, and economical food supply; and

WHEREAS, FSIS has qualified personnel available to inspect, observe, and report evidence of communicable diseases at the time of slaughter; and

WHEREAS, APHIS has laboratory expertise, facilities, and personnel available to conduct tests on blood samples and tissue specimens, conduct sample collection for surveillance purposes, conduct epidemiological traces of animals and animal products, respond to disease outbreaks and animal welfare concerns; and

WHEREAS, both parties have responsibilities in these areas, are willing to enter into a mutually beneficial reimbursable agreement for certain services, and are committed to developing further plans for implementation of said agreement; and

WHEREAS both parties are committed to utilizing this agreement to build stronger and mutually supportive working relationships to better protect human and animal health,

NOW, THEREFORE, in consideration of the agreements and mutual covenants herein contained, the parties hereto do mutually agree:

FSIS Agrees:

1) Upon notification of a potential concern related to the administration of veterinary biologics, to notify APHIS, Veterinary Services (VS), and the FSIS Technical Services Center when evidence is found at slaughter that abnormal findings may have resulted from the administration of veterinary biologics.

    - To cooperate with APHIS-VS on routine inspection of restricted meats imported

into the United States, including sampling and laboratory examination as required for certain products, produced in specific establishments, which are suspected of being undercooked. (Refer to Appendix 1.)

- To cooperate with APHIS-VS in the breaking of official seals applied to shipments of restricted livestock and poultry arriving at slaughter and to continue to provide APHIS with information concerning violations of animal health or animal welfare regulations relative to movement of livestock and poultry observed by FSIS inspectors.

- To notify APHIS-VS of animals suspicious for screwworm infection, scrapie, and other animal diseases of interest to APHIS.

- To cooperate with APHIS on bovine spongiform encephalopathy (BSE) surveillance. (Refer to Appendix 9.)

- To collect and submit for laboratory testing blood samples from test eligible adult cattle and swine and to collect suspected tuberculosis lesions from cattle and suspected tuberculosis thoracic lesions from swine disclosed at slaughter, and to collect all manmade identification devices from all cattle and swine from which blood samples or lesions are collected. (Refer to Appendices 3 and 4.)

2. Where APHIS has contracts for blood collection to ensure that all manmade animal identification devices are collected.

    - To collect all manmade identification devices and report to APHIS all known, identified, or permitted brucellosis or tuberculosis reactors slaughtered.

    - To collect tissues from animals upon special request for *Brucella* culturing. (Refer to Appendices 3 and 4.)

    - To promptly notify APHIS-VS when signs and/or lesions of foreign animal diseases are noted in livestock or poultry during antemortem and/or postmortem inspection(s). FSIS will inform the appropriate APHIS-VS official prior to processing animals suspected of a foreign animal disease and will follow existing FSIS regulatory procedures. (Refer to Appendix 6.)

    - To cooperate with the collection and submission of tissue samples that may be suspected of tuberculosis (mycobacteria). (Refer to Appendix 4.)

    - To provide APHIS with read only access to the data obtained from the electronic Animal Disposition Reporting System (eADRS) slaughter data as per the MOU signed November 2004. (Refer to Appendix 7.)

    - To provide APHIS with read only access to the data obtained from the eADRS slaughter data for animal disease surveillance programs. (Refer to Appendix 10.)

3. When livestock presented for slaughter are to be released for a purpose other than slaughter, the operator of the official establishment or the owner of the livestock shall first

obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction as per Title 9, *Code of Federal Regulations* (9CFR), section 309.2(p).

- To notify APHIS-VS of imported meat, poultry, or egg products suspected of being tampered or containing toxic industrial chemicals, foreign animal disease agents, or other potential biological or chemical contamination.

- To promptly notify APHIS-VS when agents of biological or chemical warfare/terrorism are suspected in animal-based food product.

- To perform food security verification procedures at certain threat levels that includes coordinating security concerns on live animals with APHIS-VS officials.

- To cooperate with APHIS-VS on the Brucellosis Eradication Program through blood sample collection at slaughter under a quarterly reimbursable agreement. FSIS will provide APHIS-VS with a report of the number of samples collected by FSIS personnel quarterly by establishment.

B. APHIS Agrees:

1. To notify FSIS when administration of certain veterinary biologics may be related to abnormal reactions or that certain animals slaughtered have been exposed to a biologic of interest to APHIS.

2. To arrange and coordinate with State authorities for the collection and submission of specimens from animals potentially infected with diseases of interest to APHIS for diagnosis and to provide FSIS with current lists of diseases of interest to APHIS and guidelines to report such diseases.

3. To, in consultation with FSIS, provide clearance for new adjuvants or other ingredients of biologics where the safety of meat of animals or poultry for human consumption following their use may be questionable, and to establish withholding periods for biological products which produce temporary residues in animals and poultry.

4. To conduct field investigations and to advise FSIS of outbreaks of diseases that affect the health of animals including those of public health significance such as brucellosis, tuberculosis, ornithosis, anthrax, rabies, BSE, or other zoonotic or potentially zoonotic diseases or syndromes of interest to APHIS and to report progress in eradicating these diseases.

5. To conduct field investigations and to advise FSIS in a timely manner of outbreaks of vesicular or other reportable or exotic diseases of foreign origin.

6. To provide, upon request, assistance in the inspection of swine or other animals at slaughter when vesicular or other reportable or exotic diseases of foreign origin are suspected.

7. To provide information relative to traceback of animals to points of origin as requested by FSIS inspectors and to conduct field investigations for those incidences that are of mutual interest to both parties.

8. To provide FSIS inspectors, via telephone, fax, or e-mail, timely laboratory results on tissue specimens submitted to the National Veterinary Services Laboratories for examination for tuberculosis on retained carcasses or other public health diseases that result in retention of carcasses.

9. To provide FSIS, upon request, reports on the number of blood samples received by APHIS laboratories for analysis from their respective areas.

10. To notify FSIS inspectors when known tuberculosis reactors are shipped to slaughter plants and to assist FSIS inspectors upon their request in the collection of laboratory samples from tuberculosis reactors.

11. To provide the FSIS inspector feedback regarding any actions and/or findings that result from inspector contributions to investigations of communicable diseases.

12. To notify appropriate FSIS officials of any findings of residue or chemical substances in livestock or poultry, or in the tissues or products thereof, which may indicate the potential for adulteration of the meat or poultry supply, including specific available information as to the origin or location of livestock or poultry associated with such findings.

13. To arrange for the Permit for Movement of Restricted Animals or Materials (VS Form 1-27) when applicable animals need to be moved from the slaughterhouse to alternate locations.

14. To provide FSIS training slots in each applicable class to attend the Foreign Animal Disease Diagnostician Course held at Plum Island, New York, at FSIS expense.

15. To notify appropriate FSIS officials of any findings suggestive of biologic or chemical warfare or terrorist actions against livestock or poultry.

16. To provide FSIS with recommended on-farm, market, and transportation biosecurity measures.

17. To notify FSIS of any live imported food animal suspected of having been exposed to potential terrorist/warfare agents.

18. To cooperate when requested on the tracing of recalled products should there be an animal, public health, or food security emergency.

19. To notify FSIS in a timely manner when samples of imported meat, poultry, or egg products are required because they may not meet APHIS regulatory requirements.

20. To assist FSIS when notified of serious livestock animal welfare concerns and

when inhumane transportation is observed, especially if it concerns imported animals shipped under an APHIS seal.

21. To provide certificate forms to certify inedible byproducts for export when APHIS/VS personnel are not available and has prearranged the certification with FSIS.

22. To reimburse FSIS quarterly for blood samples collected by FSIS personnel.

23. To make available, upon request, electronic copies of reports and to consult with FSIS prior to publicly releasing data derived from the eADRS as per Appendix 7.

C. It is Mutually Understood and Agreed:

1. That the details of this cooperative undertaking shall be jointly planned through an APHIS-FSIS Implementation Working Group and executed by the cooperating parties.

2. This Memorandum of Understanding is to define in general terms the basis on which parties concerned will cooperate and does not constitute a financial obligation to serve as a basis for expenditures. Each party will acquire and expend its own funds. Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the Memorandum of Understanding must be in accord with Department rules and regulations and in each instance based upon appropriate financial procedures. Expenditures made by either party will be in accord with its particular rules and regulations. Reimbursable agreements will be developed to provide for the exchange of funds between agencies as required.

3. Either party shall be free to furnish such equipment as may be needed without cost to the other party. Any such equipment furnished shall remain the property of the providing party and subject to its disposition.

4. The responsibilities assumed by each of the parties hereto are contingent upon funds being available from which expenditures legally may be met.

5. Both parties will share training resources involving subjects of mutual interest; tuberculosis postmortem training by FSIS (refer to Appendix 8) and foreign animal disease diagnostician training by APHIS.

6. The results of the work herein may be published jointly by the parties hereto or by either party separately, but manuscripts prepared for publication by either shall be submitted to the other party for suggestions and approval prior to publication. In the event of disagreement, either party may publish results about its own responsibility, giving proper acknowledgment to the other cooperator. Both parties shall share with each other proposed policies or procedures related to this MOU that may directly impact the other prior to the public release with sufficient time for the other to respond appropriately prior to publication.

7. This Memorandum of Understanding supersedes previous FSIS-VS Memoranda of Understanding, including #MU 12-37-MU-334.

8. The provisions of this Memorandum of Understanding shall be reviewed annually.

9. This Memorandum of Understanding shall become effective upon the date of final signature and shall continue indefinitely but may be modified or discontinued at the request of either party. Each party shall provide in writing 60 days notice in advance of the effective date desired for termination of this agreement or any major modification.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

_____

Date Administrator

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

_____

Date Administrator

Appendix 1

Food Safety and Inspection Service (FSIS)
Animal Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Inspect, collect and examine imported cooked meats for underprocessing.

Cooked meats are allowed to be imported from certain countries where exotic animal diseases occur only when these meats are thoroughly cooked. FSIS has qualified import inspection personnel assigned to the ports of entry (POE) that are available to inspect and report evidence of meat products that are suspected of being insufficiently cooked during processing in the country of origin. Because APHIS-VS has a regulatory responsibility to prevent the distribution of underprocessed meat products from these countries, both parties agree as follows:

A. FSIS Agrees:

1. To immediately notify APHIS-VS via telephone or fax, followed up by e-Mail, of any suspect lots and findings; and retain/detain suspect lots when available. FSIS will retain or control any related lots of products that APHIS-VS considers necessary. Suspect lots include, but are not limited to, those displaying evidence of inadequate processing, such as bones and undercooking.

2. To assist APHIS-VS in the examination of suspect lots and collect samples as directed by APHIS-VS.

3. As directed by APHIS-VS or the Department of Homeland Security to refuse entry of any lot not meeting APHIS-VS requirements during import inspection and to impose restrictions on future lots.

4. To provide, when appropriate, representatives from various FSIS staffs to serve on emergency situation teams.

B. APHIS Agrees:

1. To accept responsibility when a suspect lot is in violation of its import requirements and that APHIS-VS is the final authority for the disposition of suspect lots.

2. To provide FSIS as quickly as possible with oral and written instructions on sampling plans and action requested such as depth of recall, retention or detention of suspect lots, and final disposition of product.

3. To determine and inform FSIS of any additional information required to ensure complete enforcement of APHIS-VS standards and import requirements.

4. To notify the foreign government, the brokers/importers, and the appropriate FSIS office of the findings and actions being taken by APHIS-VS as a result of violations of regulatory requirements.

5. To provide representatives to work with FSIS emergency response teams.

C. It is Mutually Understood and Agreed:

1. That APHIS-VS and FSIS will cooperate in accordance with applicable laws and regulations to allow resolution of each incident.

2. FSIS will coordinate action in cases where the product has not completed FSIS import reinspection.

Appendix 1: Attachment A

Standard Procedures for Handling Imported Cooked Meat Products in Which Pink Juices are found at an approved FSIS Import Establishment.

A. The Food Safety and Inspection Service (FSIS) will retain, if available, the entire shipment, including the sample, and notify the local Department of Homeland Security, Customs and Border Protection, as well as the Animal and Plant Health Inspection Service (APHIS), Protection and Quarantine (PPQ), Veterinary Regulatory Support (VRS), Animal Quarantine Inspection Veterinarian (AQIV), or the VRS headquarters office by telephone, fax, or e-Mail and the FSIS Office of International Affairs and provide the following information:

    1. Production code (complete tube and carton identification).

    2. Country of origin and establishment number.

    3. Type and amount of product.

B. Location of retained product

C. Any specific decontamination procedures related to intentional or un-intentional contamination issues.

D. Department of Homeland Security-Customs and Border Control (DHS-CBP) and/or APHIS-PPQ-VRS-AQIV at the local port office will immediately notify the APHIS-PPQ-VRS headquarters office, the Director, Animal Products, National Center for Import-Export (NCIE), Animals and Products Staff, Veterinary Services (VS), Riverdale, Maryland, and provide the same data listed under A (above) by telephone.

E. The APHIS Director of the NCIE will:

    1. Establish communication with the following;

        a. U.S. representative of the foreign establishment or the U.S. importer.

        b. The appropriate FSIS office.

    2. Notify appropriate government officials in the country of origin through the Agricultural Attaché.

    ~~3.~~ Investigate the extent of the problem by determining if other shipments are involved.

    4. Initiate appropriate action to:

        a. Refuse entry in accordance with APHIS regulations and policy.

        b. Coordinate with direct assistance of APHIS-PPQ-VRS headquarters, with local APHIS, PPQ Office of International Affairs to ensure that satisfactory

disposition of product is made as per VS policy and to ensure that all appropriate PPQ, VS, and FSIS personnel are notified as is appropriate.

c. Coordinate appropriate actions with regional and local VS offices when pink juices are found in commerce; i.e., in U.S. establishments or wholesale warehouses (after passing port-of-arrival inspection).

F. APHIS-VS field personnel shall not take action to dispose of product without first obtaining instructions through channels from VS, NCIE.

APHIS will consider any contamination hazards and coordinate with FSIS on specific procedures related to potential food security contamination issues.

Appendix 1: Attachment B

Standard Procedures for Handling Perishable Cooked Pork Products from Restricted Countries as indicated in 9 CFR, Part 94.

A. When Food Safety and Inspection Service (FSIS) laboratory results indicate the cooked pork product was undercooked (155 degrees F. or less), the laboratory shall immediately notify the appropriate FSIS office which will immediately notify the Animal and Plant Health Inspection Service (APHIS), National Center for Import/Export (NCIE). The laboratory should report the production codes, specific type of product, and any other pertinent information.

B. APHIS, NCIE,-(note-spell out please, and the FSIS officials managing recalls will coordinate to retain/detain all of the available products in the lot and to recall products that have been shipped from the import establishment.

C. The Director of NCIE will:

    1. Immediately contact the U.S. representative of the foreign establishment or importer.

    2. Notify appropriate government officials in the country of origin through the Agricultural Attaché.

    3. Request information (records) for location, etc., of identified production code product.

    4. Coordinate with appropriate FSIS or APHIS, Plant Protection and Quarantine (PPQ), Veterinary Regulatory Support (VRS), headquarters office any action to control recall, destroy, or export product.

    5. Involve APHIS-Veterinary Services (VS), APHIS-PPQ-VRS- Animal Quarantine Inspection Veterinarian, and Department of Homeland Security-Customs and Border Control field personnel in tracing product, if necessary.

D. The movement and/or destruction of the product will be under APHIS-VS or APHIS-PPQ-VRS supervision.

Appendix 2

Food Safety and Inspection Service (FSIS)
Office of International Affairs (OIA)

Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Activities by FSIS and APHIS-VS to ensure that meat and poultry products imported from foreign countries into the United States meet applicable animal health and inspection control standards.

FSIS and APHIS-VS have separate but closely related statutory responsibilities regarding the eligibility for import into the United States of meat and poultry products from foreign countries. Both agencies maintain separate staffs of experts to ensure that these important requirements are met on a continuous basis. To maximize efficiency and effectiveness, the following statements are agreed to by the parties:

A. FSIS and APHIS-VS will exchange information on plants certified and approved to export to the United States and provide updates of the plant listings.

B. Regular monthly telephone conferences will be scheduled between APHIS' National Center for Import and Export, Technical Trade Services, Plant Protection and Quarantine, and FSIS.

C. APHIS-VS will provide FSIS with copies of product restriction information when this information is not contained in Title 9, *Code of Federal Regulations*, part 94, or when more detailed information is available.

D. APHIS-VS and FSIS will inform each other of changes in foreign country disease status and export eligibility status.

E. APHIS-VS and FSIS will exchange addresses of program officials stationed in foreign countries. Notification of changes will be made in a timely manner.

F. APHIS-VS will inform FSIS of acceptable interpretations of regulations affecting product production in restricted countries. This information will be updated on a periodic basis when FSIS personnel are attending area meetings or when there are significant changes in policy. FSIS, through its regular reviews, will gather information and notify APHIS-VS of any deviations from acceptable practices.

G. APHIS-VS and FSIS will exchange information regarding the disease status of countries exporting to the United States and information on their respective audit plans. FSIS will notify APHIS-VS of any information learned relative to animal health concerns found during the course of review activities.

H. APHIS-VS and FSIS will exchange travel plans for foreign country visits on a quarterly basis. When possible, travel will be coordinated to avoid taxing resources of any foreign country.

I. APHIS-VS will conduct reviews of foreign plants to determine the adequacy of proposed procedures for processing product to mitigate risk due to animal disease. APHIS-VS will provide to FSIS detailed interpretations of requirements and how they must be met in the establishments. When requested by APHIS-VS, FSIS will collect information regarding animal disease issues and in-plant processes during regularly scheduled audits and will report relevant information to APHIS.

J. APHIS-VS and FSIS agree to brief their respective foreign program personnel on the various facets of each other's program.

There will be no reimbursement for these activities.

Appendix 3

Food Safety and Inspection Service (FSIS)
Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Brucellosis Eradication: Title 9, *Code of Federal Regulations*, part 78: Collection of samples for *Brucella* isolation.

FSIS collects all manmade identification devices and reports to APHIS all known brucellosis or tuberculosis reactors slaughtered, and collects tissues from animals upon special request for culturing *Brucella*.

APHIS-VS documents animal movements from brucellosis infected and/or suspect herds on VS Form 1-27. In order to confirm or prove the existence of *Brucella* organisms in the herd or herds of origin, FSIS is requested to collect tissue samples from such animals when specifically identified and agreed upon with VS. In most instances, VS personnel will participate in or conduct the collections.

FSIS Agrees:

1. To submit tissue samples to the National Veterinary Services Laboratories (NVSL) for *Brucella* isolation in accordance with established procedures, provided sufficient personnel are available or if personnel are not available to notify VS immediately.
    - To make no charges to VS for collecting and submitting subject tissue samples.
    - To utilize the most current VS sampling procedures and official forms.

APHIS-VS Agrees:

1. To process samples submitted for *Brucella* isolation as promptly as possible.
2. To furnish shipping containers and preservatives for submitting specimens to NVSL.
3. To notify FSIS in advance of the arrival of animals to be sampled.
4. To provide FSIS with the most current sampling procedures and forms.

It is Mutually Understood and Agreed:

1. FSIS and VS will cooperate to minimize the work of collecting, submitting, and reporting laboratory results on specimens identified for *Brucella* culturing.
2. That both VS and FSIS, insofar as possible, will inform the other of impending changes in procedure that are likely to affect the submission or handling of specimens.

Appendix 4

Food Safety and Inspection Service (FSIS)

Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Tuberculosis Eradication: Title 9, *Code of Federal Regulations*, part 77: Collect and submit suspected tuberculosis lesions or thoracic granulomas found in cattle carcasses along with all accompanying manmade identification devices.

The goal of national tuberculosis surveillance is to collect and submit a minimum of one suspicious lesion per 2,000 adult cattle slaughtered to the National Veterinary Services Laboratories (NVSL), Ames, Iowa, or to another laboratory officially approved by VS for detailed inspection.

FSIS Agrees:

1. To submit specimens (plus all manmade non-FSIS identification devices) to NVSL to be examined for tuberculosis from carcasses where lesions resembling tuberculosis or thoracic granulomas are found; in nonreactor cattle at a rate of at least one lesion per 2,000 adult cattle slaughtered and from reactor cattle as mutually agreed upon.

2. To make no charge to VS for collecting and submitting specimens resembling tuberculosis and thoracic granulomas.

3. To submit: (a) completed VS Form 6-35 for each nonreactor animal from which specimens are submitted, and (b) completed VS Form 10-4 (or FSIS Form 6000-1) with specimens from reactors sent to NVSL.

APHIS-VS Agrees:

1. To provide adequate personnel in plants where it is mutually agreed that assistance is required to meet program goals.

2. To examine specimens submitted by FSIS as promptly as possible for tuberculosis.

3. To report laboratory findings to FSIS by telephone, fax, or e-mail within 3 working days of receipt of specimens from carcasses retained for disposition because of suspected tuberculosis or thoracic granulomas; such telephone call, fax, or e-mail to be followed by a written summary of the histopathologic findings on VS Form 10-17 and mycobacteriologic results on VS Form 10-2.

4. To send slides from selected specimens as mutually agreed upon to the FSIS Field Service Laboratories in Athens, Georgia, or to other FSIS laboratories upon request.

5. To furnish shipping containers and preservative for submitting specimens to NVSL.

It is Mutually Understood and Agreed:

1. To work together to minimize the work of collecting, identifying, submitting, and reporting laboratory results on specimens resembling tuberculosis and thoracic granulomas.

2. That both VS and FSIS, insofar as possible, will inform the other of impending changes in procedure that are likely to affect the submission or handling of specimens.

3. That personnel from both Agencies will exchange visits to the laboratory and facilities of the other agency for professional interchange and uniformity.

4. That the two Agencies will collaborate in furnishing summaries to appropriate personnel of results obtained in this operation of mutual benefit.

Appendix 5

Food Safety and Inspection Service (FSIS)

Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Identification of Mycobacterium Isolates

FSIS has qualified personnel available to analyze, and report evidence of mycobacterium in postmortem pathologic samples of domestic animals.

APHIS has laboratory expertise, facilities, and personnel available to identify several varieties of mycobacterium isolates and has an interest in these microorganisms due to their invasiveness for both animals and humans.

In that both parties have responsibilities is these areas, the parties agree with each other as follows:

FSIS Agrees:

- To coordinate efforts with APHIS-National Veterinary Services Laboratories (NVSL) to provide access to necessary pathology samples and related electronic data to promote the surveillance and eradication of tuberculosis.

- To cooperate with APHIS on routine inspection of meat and poultry including sampling and laboratory examination by APHIS-NVSL as required to isolate and identify mycobacteria.

- To collect and submit to APHIS-NVSL postmortem samples for microbiological identification of approximately 100 mycobacteria cultures per year during routine and special meat and poultry mycobacteria surveillance program activities.

APHIS-VS Agrees:

1. To advise FSIS of significant increases or decreases in mycobacteria infections or mortalities in domesticated animals.

2. To provide FSIS with monthly reports on cultures received from FSIS by APHIS.

3. To cooperate with FSIS to establish improved ways to share information gained via pathology samples to promote the eradication of tuberculosis.

It is Mutually Understood and Agreed:

1. That the details of this cooperative understanding shall be jointly planned and executed by the cooperating parties.

Appendix 6

Food Safety and Inspection Service (FSIS)

Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Foreign Animal Diseases and Reportable Diseases: Notification to VS when vesicular or other reportable conditions and/or lesions of foreign animal diseases are suspected in livestock or poultry during antemortem and/or postmortem inspection.

When vesicular or other reportable diseases or exotic diseases of foreign origin are suspected in a packing plant/slaughter establishment during antemortem or postmortem inspection, the Area Veterinarian in Charge (AVIC) for VS shall immediately be notified. Upon receipt of such a report, the following procedures are to be implemented by VS:

1. The AVIC immediately requests an investigation by the nearest trained foreign animal disease diagnostician (FADD).

2. The FADD will immediately respond to the request according to established APHIS protocols.

3. The FADD will do a thorough investigation, including areas such as case evaluation, possible traceout and premises of origin evaluation, and sample collection, as indicated.

4. All samples collected will be submitted to the Foreign Animal Disease Diagnostic Laboratory on Plum Island or the National Veterinary Services Laboratories at Ames, Iowa, depending upon the results of the investigation.

5. Serology test results will be available within 24 hours of receipt of the samples at the laboratory. Other tests, such as cell culture or animal inoculation, will take longer. However, in most cases, serology results or polymerase chain reaction should be sufficient for correct disposition of the carcasses and/or live animals.

6. VS will execute prompt response to FSIS plant personnel notifying them of the test results of submitted samples.

7. VS, upon request, will provide assistance in the inspection of livestock and poultry at slaughter when vesicular or other reportable or exotic disease of foreign origin are suspected

Appendix 7

APHIS Agreement No. 05-9208-0141-MOU
MEMORANDUM OF UNDERSTANDING
BETWEEN
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE (FSIS)
And
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

ARTICLE 1 - PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to document the requirements of the collaborative effort between APHIS AND FSIS through the sharing of the FSIS eADRS database system used to permit APHIS to access data for BSE Surveillance work.

ARTICLE 2 - BACKGROUND

The USDA BSE Surveillance program is reliant on data collected on-farm, and at slaughter plants and other sample collection facilities. Data for the program is primarily entered into the USDA BSE Surveillance system however; slaughter data is also entered daily by FSIS personnel into the electronic Animal Disease Reporting System.

ARTICLE 3 - AUTHORITIES

Under the Farm Security and Rural Investment Act of 2002, P.L. 107-171, Subtitle E, Animal Health Protection, Section 10401-10418, the Secretary of Agriculture, in order to protect the agriculture, environment, economy, and health and welfare of the people of the United States by preventing, detecting, controlling, and eradicating diseases and pests of animals, is authorized to cooperate with foreign countries, States, and other jurisdictions, or other persons, to prevent and eliminate burdens on interstate commerce and foreign commerce, and to regulate effectively interstate commerce and foreign commerce.

ARTICLE 4 - OBJECTIVE

APHIS has requested FSIS provide direct electronic access to the eADRS database to:

1. Validate information concerning animals sampled as a result of the BSE Surveillance program.
2. Assure comparability between data recorded on eADRS and the BSE Surveillance Information System
3. Reference data as needed for other surveillance programs and emerging animal health issues identification.

ARTICLE 5 – MUTUAL AGREEMENT

APHIS and FSIS jointly agree to assist in promptly troubleshooting access to eADRS problems incurred by APHIS and resolving the system conflicts identified as a result.

ARTICLE 6 - FSIS RESPONSIBILITIES

FSIS will provide APHIS with read only access to the data obtained from the electronic Animal Disease Reporting System (eADRS) database. Provide electronic access capability including network authorization, and system and application user ID's/passwords to two APHIS/VS/CEAH personnel.

Assist in promptly troubleshooting access problems and resolving system conflicts identified.

Initial contact:

Steve Weber
USDA:APHIS:VS:CEAH
2150 Centre Ave, Building B
Fort Collins, CO 80526
Telephone (970) 494-7271
Fax (970) 472- 494-7269____
Internet: steve.weber@aphis.usda.gov

ARTICLE 7 – APHIS: VS: CEAH RESPONSIBILITIES

APHIS will use the data to:

1. Validate information concerning animals sampled as a result of the BSE Surveillance program.
2. Assure comparability between data recorded on eADRS and the BSE Surveillance Information System
3. Reference data as needed for other surveillance programs and emerging animal health issues identification.

APHIS (CEAH) agrees to protect the confidentiality and sensitivity of the data being provided to the extent required by Federal regulations and FOIA. Furthermore, USDA APHIS will not release, publish, or publicly report any proprietary information originating from the eADRS, and will consult with FSIS prior to proposing policy or program direction based on the data obtained. USDA APHIS will make available to FSIS, upon request, electronic copies of internal reports derived from eADRS data.

- Limit electronic data access only to two authorized personnel.
- Access system only for retrieval or analysis of identified information and log off eADRS system promptly after retrieving necessary data.
- Utilize data retrieved from eADRS only for purposes identified above.

ARTICLE 8 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this MOU does not constitute a financial obligation on the part of APHIS or FSIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU.

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Food Safety

Food Safety and Inspection Service

Washington, DC 20250

ARTICLE 9 - LIMITATION OF COMMITMENT

This MOU and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this MOU shall be expended in accordance with its terms and in the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

ARTICLE 10 - CONGRESSIONAL RESTRICTIONS

Not applicable.

ARTICLE 11 - AMENDMENTS

This MOU may be amended at any time by mutual agreement of the parties in writing.

ARTICLE 12 - TERMINATION

This MOU may be terminated at any time by mutual agreement of the parties in writing, or by one party within 30 days notice in writing of the other party.

ARTICLE 13 - EFFECTIVE DATA AND DURATION

This MOU will be in effect upon final signature and will continue until December 31, 2005

NAME: Kenneth Petersen
TITLE: Acting Deputy Assistant Administrator
USDA:FSIS:OFO
CITY, STATE Washington, DC

/s/ Kenneth Petersen _____ 11/23/04
Signature Date

NAME: Dr. John Clifford
TITLE: Deputy Administrator
USDA:APHIS Veterinary Services
Washington DC

/s/ John R.Clifford _____ 11/19/04
Signature Date

Appendix 8

VETERINARY SERVICES AND OFFICE OF FIELD OPERATIONS
MEMORANDUM NO. 552.7

Subject: Post Mortem Techniques for Tuberculosis Reactors and Suspects

To: VS Management Team
Area Veterinarians in Charge, VS
State Veterinarians
FSIS Office of Field Operations Headquarters Executive Team
FSIS District Office Managers
OPPD Assistant Administrator

I. PURPOSE

This memorandum establishes a training program with the Food Safety and Inspection Service (FSIS), Office of Field Operations that will provide Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), veterinarians an opportunity to become skilled in the proper techniques of conducting post mortem examinations of tuberculin test reactors and suspects.

II. CANCELLATION

This memorandum replaces and cancels Animal Health Division Memorandum 552.7, dated February 20, 1970.

III. GENERAL

VS remains committed to the longstanding practice that FSIS provides specialized training to selected VS veterinarians in proper post mortem techniques for tuberculosis reactors and suspects.

When tuberculosis reactors or suspects are slaughtered in federally or State inspected slaughtering establishments, the VS Area Veterinarian in Charge (AVIC) is responsible for confirming that thorough post mortem examinations and proper disposition or disposal of tuberculin reactor cattle were conducted according to official procedures. These procedures are of mutual benefit to FSIS and VS and are prerequisites to the payment of Federal indemnity.

In order to provide the thorough and high quality post mortem examinations necessary, VS veterinarians must receive appropriate instruction and be provided opportunities for practical experience. To achieve this, FSIS will provide in-plant training without cost to VS, and VS will pay the travel, per diem, and similar costs for VS personnel participating in the training.

This training will provide FSIS with professional assistance, particularly when large numbers of reactors or suspects are slaughtered at an establishment. As needed, VS veterinarians would be available to assist with the post mortem examination of tuberculosis reactors or suspects being slaughtered at federally inspected slaughter establishments. The appropriate AVIC will inform the appropriate FSIS District Managers and State and local meat inspection managers that VS veterinarians are available to assist with post mortem examinations.

IV. TRAINING PROGRAM

A. FSIS agrees to assist in classroom training at the National Bovine Tuberculosis Epidemiology Training Course in Ames, Iowa.

VS periodically conducts the National Bovine Tuberculosis Epidemiology Training Course for VS veterinarians and State veterinarians at the National Veterinary Services Laboratories (NVSL), Ames, Iowa. Instruction is provided by tuberculosis epidemiologists; FSIS veterinarians experienced in tuberculosis slaughter surveillance; university professors involved with the pathology, immunology, and epidemiology of tuberculosis; and tuberculosis laboratory experts from NVSL. This 1 week course has limited hands-on post mortem training activity. APHIS will pay for travel and per diem expenses for FSIS instructors participating in this course.

B. APHIS agrees to coordinate field training with FSIS.

The AVICs will submit nominations for post mortem training to the National Tuberculosis Program Coordinator, National Center for Animal Health Programs (NCAHP), Eradication and Surveillance Team, VS, who will arrange for the training with the FSIS Center for Learning (CFL) in College Station, Texas. Notification of training dates will be provided well in advance.

After the formal training at NVSL, selected VS veterinarians (in groups of two or three) will be detailed to official establishments for training. FSIS will determine and schedule the training dates. The training period may require approximately 1 week (3 days training and 2 days travel). If more or less time is required, the FSIS veterinary field mentor may determine the time required to achieve the necessary results. APHIS will pay all travel costs for the trainees. FSIS will issue a copy of the most current guidelines to each VS trainee upon arrival at the designated establishment.

VS veterinarians will spend time on the line in the slaughterhouse working with and learning from FSIS veterinarians skilled in post mortem techniques. VS veterinarians should be able to observe a significant amount of pathology and learn from their FSIS colleagues how to locate and evaluate the appropriate lymph nodes and proper procedures to collect, prepare, and ship various laboratory specimens. VS veterinarians will be able to appreciate the multitude of activities occurring in slaughterhouses and learn how to interact effectively with FSIS and industry in the slaughterhouse environment. FSIS veterinarians and food inspectors will receive additional information regarding the importance of their role in the Cooperative State-Federal Tuberculosis Eradication Program and will be exposed to epidemiological tracing, tuberculosis testing, prevalence and incidence of bovine tuberculosis, etc.

V. EQUIPMENT

APHIS will supply the appropriate equipment and clothing, such as scabbard, knife, stone, steel, hook, white smocks or coveralls, helmet, and rubber boots, to the trainee well in advance of the scheduled training.

VI. CERTIFICATE OF TRAINING

FSIS, CFL, will collaborate with VS to appropriately certify the VS trainees. The training report signed by the FSIS mentor and the SF-182 (Request, Authorization, Agreement, and Certification of Training) will document the training. The title of the course is to be shown as "Post Mortem Techniques for Tuberculosis Reactors or Suspects." The CFL will track training completion in the training database.

1/21/04 /s/ Ron DeHaven	1/21/04 /s/ William Smith
W. Ron DeHaven	William Smith
Deputy Administrator	Assistant Administrator
Veterinary Services	Office of Field Operations
Animal and Plant Health Inspection Service	Food Safety and Inspection Service

Appendix 9

MEMORANDUM OF UNDERSTANDING
BETWEEN
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INSPECTION SERVICE
AND
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Relative to Bovine Spongiform Encephalopathy (BSE) Sampling of Cattle Condemned on Ante mortem Inspection

The parties to this Memorandum of Understanding are the United States Department of Agriculture, Food Safety and Inspection Service, hereinafter called FSIS, and the United States Department of Agriculture, Animal and Plant Health Inspection Service, hereinafter called APHIS.

WHEREAS, BSE is a reportable animal disease in the United States,

WHEREAS, FSIS has qualified personnel available to inspect, condemn, and obtain samples from condemned animals; and

WHEREAS, APHIS has laboratory expertise, facilities, and personnel available to conduct tests on cattle brains for BSE; and

WHEREAS, both parties have responsibilities in these areas,

NOW, THEREFORE, in order to ensure that all cattle condemned on ante mortem inspection are sampled for BSE, the parties hereto do mutually agree to the following:

A. The FSIS agrees:

1. To collect brain samples from all cattle that are condemned by FSIS upon ante mortem inspection at federally inspected establishments. Veal calves condemned for reason other than CNS disorders are exempt from this collection.
2. To provide training for FSIS Public Health Veterinarians designated to carry out such sampling.
3. To provide for shipping of theses samples to an APHIS laboratory designated by APHIS for the purpose of BSE testing.

B. The APHIS agrees:

1. To obtain samples from animals at locations other than federally inspected establishments, including animals that are dead on arrival-but not offloaded-through their routine sampling and agreements with dead-stock facilities, renderers, and other animal disposal facilities.

2. To coordinate with the FSIS State Liaison Directors, through memoranda of understanding or other such agreements, to ensure sample collection from State-inspected facilities.

3. In cases where APHIS has provided funding for a technician to remain on the premises and take samples at federally inspected establishments, that technician when conducting BSE sampling is under the supervisory oversight of the FSIS inspector-in-charge. The FSIS inspector–in-charge will have the authority to direct the APHIS technician to select samples for BSE submission.

4. To provide FSIS with the following equipment and supplies:
   a. special sample boxes, pre-addressed shipping labels, and shipping instructions,
   b. equipment needed to harvest samples, and
   c. protective equipment for FSIS personnel who will be taking samples.

5. To test samples collected by FSIS at the National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another APHIS-designated laboratory.

6. To promptly report the results of testing in accordance with the BSE communications plan.

7. To provide FSIS with access to the APHIS database containing sample results and associated information.

8. To reimburse FSIS for the following costs:
   a. $40 per sample for samples collected by FSIS personnel for FY 2004. In subsequent fiscal years, this amount will be adjusted for inflation and increases in pay and benefits.
   b. Up to $75,000 in FY 2004 to provide initial training for its Public Health Veterinarians to carry out the sample collection.
   c. Up to $1.6 million initially and up to $100,000 annually thereafter for rabies vaccination of Public Health Veterinarians who request such vaccination.
   d. Transfer $2.0 million in FY 2004 to provide FSIS inspection personnel with the necessary telecommunications and hardware for the electronic transfer of data to APHIS. FSIS will use these funds to provide for electronic transfer of data in Federal establishments that slaughter 50 or more cattle per month.
   e. Transfer up to $1.0 million per year, beginning in FY 2005 for the annual telecommunication service costs associated with the electronic transfer of data. This annual funding will continue for the duration of FSIS participation in BSE surveillance testing.

C. <u>It is Mutually Understood and Agreed:</u>

1. That the details of this cooperative undertaking shall be jointly planned and executed by the cooperating parties.

2. Expenditures made by either party will be in accord with its particular rules and regulations.

3. The results of the work herein shall be shared between parties, and any manuscripts prepared for publication by wither shall be submitted to the other party for suggestions and approval prior to publication.

4. The provisions of the Memorandum of Understanding shall be reviewed annually.

5. By mutual agreement, this Memorandum of Understanding shall become effective upon the date of final signature and shall continue indefinitely but may be modified or discontinued at the request of either party. Requests for termination or any major modification shall be submitted to the other party in writing for consideration not less than 60 days in advance of the effective date desired.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INSPECTION SERVICE

2/12/02 /s/ Barbara J. Masters
Date Acting Administrator

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

7/15/04 /s/ Kevin Shea
Date Acting Administrator

Appendix 10

Food Safety and Inspection Service (FSIS)

Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)

Electronic reporting of slaughter data (eADRS) to APHIS

Statistics concerning the number and class of animals slaughtered and estimated prevalence of disease in these animals are collected by FSIS personnel in slaughter plants. These statistics are compiled and entered into the FSIS database. These slaughter surveillance data are critical for VS to establish animal disease program status, evaluate the effectiveness of animal identification and blood sample collection, and to measure program targets and goals.

In addition, condemnation data is important to VS to identify disease trends and risk areas that VS needs to investigate as possible foreign animal disease incursions or emerging disease outbreaks/issues.

FSIS Agrees:

FSIS agrees to provide APHIS with read only electronic access to the data obtained from the eADRS database including network authorization, and system and application user ID's/passwords to two APHIS/VS/NCAHP personnel.

APHIS agrees use the data to:

1. Validate information concerning animals sampled as a result of animal disease and surveillance programs.
2. Protect the confidentiality and sensitivity of the data being provided to the extent required by Federal regulations and the Freedom of Information Act. Furthermore, APHIS will not release, publish, or publicly report any proprietary information originating from the eADRS and will consult with FSIS prior to proposing policy or program direction based on the data obtained. APHIS will make available to FSIS, upon request, electronic copies of internal reports derived from eADRS data.
3. Limit electronic data access only to two authorized personnel.
4. Access system only for retrieval or analysis of identified information and log off eADRS system promptly after retrieving necessary data.
5. Utilize data retrieved from eADRS only for purposes identified above.

APHIS and FSIS jointly agree to assist in promptly troubleshooting access to eADRS problems incurred by APHIS and resolving the system conflicts identified as a result.

V. BOVINE TUBERCULOSIS ERADICATION AWARDS PROGRAM

January 24, 2001
VETERINARY SERVICES MEMORANDUM NO. 540.6

Subject: Bovine Tuberculosis Eradication Performance Awards Program
To: Directors, VS Regions Area Veterinarians in Charge, VS

I. PURPOSE

A. Revise and update the special performance awards program for bovine tuberculosis eradication.

B. Authorize issuance of awards to Food Safety and Inspection Service (FSIS) Food Inspectors and Public Health Veterinarians (PHV's) assigned to Federally inspected cattle, bison, and cervid slaughtering establishments for their significant contributions to the eradication of tuberculosis in cattle, bison, and cervids.

C. Provide policies and procedures for nominating, selecting, and rewarding such employees under this program.

D. Describe the types of awards to be given.

II. BACKGROUND

Instructions for the Bovine Tuberculosis Eradication Performance Awards Program were previously outlined in the Animal and Plant Health Inspection Service (APHIS) Directive 540.6, June 18, 1996. Recommendation for a cash award under the Bovine Tuberculosis Eradication Program is a part of the Comprehensive Strategic Plan for the Eradication of Bovine Tuberculosis, dated October 2000.

III. GOAL

The goal of this awards program is to reward timely detection of bovine tuberculosis and increase the quality and number of laboratory specimens submitted by FSIS personnel.

IV. COVERAGE AND AREA OF CONSIDERATION

This award recognizes FSIS employees for their superior contributions in support of the Bovine Tuberculosis Eradication Program. Food Inspectors (grades GS-7 through GS-9) and PHV's (grades GS-9 through GS-13) are eligible**.**

V. TYPE OF AWARD

FSIS Food Inspectors and PHV's will be considered for:

A. A cash award of $100 for steers and $500 for adult animals to be shared equally each time Mycobacteriosis is reported on histopathology by the National Veterinary Services Laboratories (NVSL). If the specimen is positive for *Mycobacterium tuberculosis (complex)* on Polymerase Chain Reaction (PCR) test, or *M. bovis* is isolated, the cash award will be increased to a total of $200 for steers and fed heifers and $1,000 for adult animals. Tissues submitted only to FSIS field service laboratories or to other approved, diagnostic laboratories that are indicative of tuberculosis shall be forwarded to NVSL for reconfirmation in order to qualify for an award.

B. A second cash award of $6,000 to be shared equally when an infected herd located in the United States is initially found as a result of the information provided to Veterinary Services (VS) regarding the identification of the lesioned animal.

Note: Each award is to be shared with the Food Inspector or Inspectors responsible for retaining the affected carcass and the PHV initiating the VS 6-35 report. In the event of multiple cases in the same slaughter lot, awards will be granted for as much as three cases from such a lot. Specimens from animals sent to slaughter under permit because of tuberculosis (reactors, suspects, animals from quarantined herds, exposed animals being depopulated, and exposed animals traced to new herds) will not qualify as a basis for an award.

C. A team award of **$**300 per team member will be awarded annually to high submitting FSIS slaughter inspection groups irrespective of histopathology results. High submitting establishments will qualify, at the end of each 12-month period (Fiscal Year), when the plant is credited with one or more suspicious tuberculosis lesions or thoracic granulomas submitted per 1,000 cattle killed.

The accounting will be kept according to the following procedure: Each time a VS Form 6-35 is completed, the recording official (initiating PHV) and Food Inspector will place their signatures and print legibly their names on the form. VS will keep an account of names by submission and establishment. For each establishment attaining the goal of one submission per 1,000 cattle killed, all participants in that achievement group will be considered team members warranting the team award. An individual inspector is eligible for no more than one team award per year.
Dollar amounts of the team award are expected to remain at **$**300 per member, but may change periodically, up or down, according to available budgetary allowances. FSIS District Managers may participate in determining the team makeup.

The monetary provisions of these awards are effective on the issuance date of this memorandum.

Note: There is a direct correlation between successful tracebacks and the accuracy of systems correlating identification devices with the correct carcass. In the experience

of VS, “countback” systems of recovering ID have resulted in about 50 percent unsuccessful tracebacks to the correct herd of origin. More positive carcass/ID correlation systems are highly recommended.

Note: Submitting specimens (and ID) from cattle, bison, and cervidae condemned for granulomatous conditions would contribute to numbers of submissions needed to fulfill team awards criteria.

VI. CRITERIA FOR NOMINATION

To be eligible for consideration for an award:

A. The Food Inspector must:

1. Detect lesions of possible tuberculosis in a regular kill animal and hold for further examination by the PHV; and
2. Collect identification devices and coordinate identification with the affected carcass.

B. The Public Health Veterinarian must:

1. Make the determination that the lesions may be tuberculosis and should be submitted for examination;
2. Collect and submit the specimens to NVSL, Ames, Iowa, for histopathologic and mycobacteriologic examination;
3. Collect all identification devices (such as ear tag, back tag, sale tag) with any supporting information (slaughter permit, brands, herd of origin) and submit them with the specimens to NVSL; and
4. Complete VS Form 6-35, “Report of Tuberculosis Lesions or Thoracic Granulomas in Regular Kill Animals.” All identification collected (see paragraph VI.B.3 above) should be noted in the report.

All identification devices should be placed in a shipping container with the specimens. The better the quality of specimens submitted, the greater likelihood of mycobacterial confirmation (paragraph V.A). The more complete and accurate the identification of the animal, the greater likelihood of finding the infected herd of origin (paragraph V.B).

VII. ADMINISTRATIVE PROCEDURES

A. Animal Health Programs Staff (AHPS), VS, will prepare the appropriate documents for award consideration when an FSIS employee meets the requirements outlined in section VI.

B. Senior Staff Veterinarian for Tuberculosis Eradication will review the award recommendation to ensure all criteria have been met, and forward documentation to Marketing and Regulatory Programs-Business Services (MRP-BS), Minneapolis Business Site (MBS), Personnel Services, Processing Team, Minneapolis, Minnesota.

C. MBS, Personnel, Processing Team, by authority outlined in a Reimbursable Agreement, will input this data into their payroll system and electronically transmit the data to the National Finance Center (NFC), New Orleans, Louisiana, for issuance of the check. NFC will forward the check to the appropriate VS Area Office.

D. Area Offices will:

1. Prepare a letter of appreciation for signature by the Area Veterinarian in Charge (AVIC);
2. Forward a copy of the letter of appreciation to MBS, Minneapolis, Minnesota, for the employee's official personnel folder; and
3. Arrange for an appropriate presentation. The AVIC will personally present the award to the employees when possible.

VIII. PUBLICIZING AWARDS

The Animal Health Programs Staff, VS, will provide information to the Administrators of APHIS and FSIS for publicizing the awards within each Agency. They will also provide information to the National Association of Federal Veterinarians for publicizing the awards in their monthly newsletter. Local newspaper coverage is also encouraged.

IX. EFFECT ON OTHER AWARDS

No previous TB incentive award should in any way jeopardize or enhance subsequent incentive awards or any other performance award for which the employee may be eligible.

/s/Chester A. Gipson for
Alfonso Torres
Deputy Administrator
Veterinary Services

VI.Paper: "Surveillance of Zoonotic Diseases"

Background:

Legal Authority/Statutory Directive:

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Act") (PL 107-188) was signed into law on June 12,2002. The Act instructs the Secretary of Health and Human Services, through the Commissioner of FDA and the Director of CDC, and the Secretary of the U. S. Department of Agriculture to coordinate surveillance of zoonotic diseases. This terminology appears in Title III of the Act, Subtitle A, "Protection of the Food Supply," Section 313.

The Act provides little guiding language to define the scope of Congressional intent in this section. In its broadest terms, "zoonotic diseases" includes all infections, toxico-infections, and intoxications related to microorganisms that may cause disease in humans and are transmitted either directly or indirectly from animals. Inasmuch as Section 313 emerges in Title III, "Protecting Safety and Security of Food and Drug Supply," there is a natural extension of the definition to include infectious diseases of animals that would threaten our food sources (e.g., exotic animal diseases) and human nutrition, even if these additional diseases are not caused by human pathogens. Therefore, the most robust response by HHS and USDA to Section 313 will address all of the diseases caused by bacteria, parasites, viruses, and prions that are shared by humans and other animals (domestic and wild), plus those diseases of domestic animals that pose a substantial risk of large epidemics in our livestock and poultry populations or have characteristics that make them likely (but unrecognized) agents of human disease. The latter category of potential zoonotic agents will be useful sources of hypotheses when syndromic surveillance of human illnesses identifies clusters without known etiologic agents. While a little further afield, natural toxins, such as mycotoxins and marine biotoxins, fit well within the counter-terrorism context of zoonoses, and could be included as well.

Discussion:

Summary of Proposed Action:

Passive surveillance of certain zoonotic diseases in humans and other animals, and microbiologic monitoring for commonly encountered zoonotic agents in foods, feeds, cosmetics, biologics, and medical devices already occurs to some extent for communicable disease control and regulatory purposes. In the U. S. many zoonotic diseases are of low incidence, and the programs related to them tend to be under-resourced, uncoordinated, and unattended by decision-makers at the highest levels. In addition to known zoonotic agents, there exists, probably in low frequency, infectious agents of xenogeneic origin that may become pathogenic in humans under certain circumstances. Ratcheting up the current FDA programs to counter-terrorism levels and coordinating them for maximum public health benefit will require additional human and other resources, and an expanded scope. Broadly speaking, the surveillance interest

and expertise in this range of zoonoses is distributed among agencies in HHS and USDA as follows:

- CDC/NCID: Human diseases caused by all zoonotic pathogens, regardless of route of transmission, and clinical isolates of the agents.
- USDA/APHIS: Diseases of domestic animals caused by zoonotic pathogens or by agents that threaten to cause large epidemics in livestock and poultry populations, and clinical isolates of agents in both categories.
- FDA/ORA:
- FDA/CFSAN: Foodborne zoonotic agents isolated from food, dietary supplements, special nutritionals, and cosmetics.
- FDA/CVM: Feed isolates of agents that are transmissible to humans or that can cause epidemic disease in animals; surveillance of antimicrobial resistance.
- USDA/FSIS: Meat, poultry and egg product isolates of agents that are transmissible to humans or that can cause epidemic disease in animals.
- FDA/CBER: Xenogeneic infectious agents that can contaminate non-human origin cell cultures or tissue cultures used in vaccine production, or transmit from biologic-producing or xenotransplantation products to a human recipient. This includes, in addition to known zoonotic agents, xenogeneic agents that might not otherwise be pathogenic in humans or have the opportunity to infect humans.
- FDA/CDRH: Zoonotic agents that can contaminate non-human origin xenotransplantation products and be transmitted to human recipients.
- FDA/CDER: Zoonotic agents that contaminate non-human drug ingredients.

Broad interpretation of Section 313 will result in an interagency program that incorporates a number of different surveillance approaches and priorities, with each activity informing and enhancing the effectiveness of the others (a ZooNet, perhaps?). The combined data from all of these related surveillance systems will create a baseline to characterize “normal” so unusual events can be rapidly identified, characterized, and contained. Developing such a program requires a number of activities, including the following:

- Prioritizing agents to allow for the rational development of surveillance programs.
- Prioritizing products likely to be terrorist targets for the high priority agents.
- Development of sensitive, specific, cost-effective and practical diagnostic tools.
- Validation of diagnostic tools and training in their use.
- Development of survey instruments and systems for data management and analysis.
- Implementation into surveillance programs.
- Coordination of data management, sharing, and use by interagency collaborators.

Within this mix of surveillance activities, CFSAN’s initial response to Section 313 will be to develop guidance to the FDA field staff related to procedures to be followed for microbiologic surveillance of zoonotic agents in foods, dietary supplements, special nutritionals, and cosmetics regulated by FDA. Further development of this concept to incorporate a broader perspective (CBER, CDRH, CVM, CDER, CDC) and inter-departmental (HHS and USDA) approach will be achieved through participation in drafting the concept paper by representatives of other Centers and agencies. Developing this guidance will include risk ranking for agents and agent/product

combinations, assessing current methods capabilities, implementing current methods and a sampling plan in the field, developing laboratory methods as needed and employing these new methods in the field, and establishing procedures for collating, analyzing, communicating, and responding to the results.

The guidance from CFSAN will be considered together with related guidance from the other Centers to establish FDA surveillance priorities and a work plan for inspections and sample analyses. FDA priorities and work plans will be coordinated with those of CDC, APHIS, and FSIS. Clinical, product, and environmental isolates derived from microbiologic surveillance systems can be pooled in interagency strain sets (for subtyping, GIS, and other collaborative analyses).

Time line: **[Note: This time line relates only to the CFSAN related issues].**

Event	Due Date
1. Develop concept paper	October 18, 2002
2. Clear concept paper through FDA	November 4, 2002
3. Develop risk ranking	November 29, 2002
4. Determine current methods capabilities	December 13, 2002
5. Implement current methods in the field, with appropriate sampling plan	March 2003
6. Develop procedures for collating, analyzing, communicating, and responding to the results.	June 2003
7. Develop and validate first round of new methods (those at the top of the risk ranking)	September 2003
8. Implement new methods in the field with appropriate testing program.	December 2003
9. Develop and validate second round of new methods	September 2004
10. Implement new methods in the field with appropriate testing program.	December 2004

Preliminary Cost/Benefit Analysis: Initial evaluation suggests that economic analysis is not necessary for implementing Section 313.

Small Entity Analysis: Not applicable.

Stakeholder Interest: Section 313 imposes no new regulatory or record-keeping requirements on industry, and this will limit the immediate impact and level of interest. However, zoonotic agents have media appeal and cause public concern, so enhanced detection of these agents and their association with products in commerce will create at least a moderately high level of stakeholder interest. More active and coordinated interagency surveillance programs will improve control of zoonoses in humans and other animals generally, decrease the response time to intentional and unintentional health emergencies involving zoonoses, and increase the likelihood that infections and epidemics can be predicted and prevented.

IX. Internet Resources:

World trade organization Implementation of the agreement on the association of sanitary and phytosanitary measures

http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

Codex Alimentarius for Food Safety Health Concerns:

http://www.codexalimentarius.net

Organization International des Epizooties for Animal Health Concerns:

http://www.oie.int/

Terrestrial Animal Health Code: recommended rules for agricultural commerce:

http://www.oie.int/eng/normes/mcode/en_sommaire.

Manual of Standards for Diagnostic Tests and Vaccines:

http://www.oie.int/eng/normes/mmanual/A_summry.htm

International Aquatic Animal Health Code and Diagnostic Manual for Aquatic Animal Diseases:

http://www.oie.int/eng/normes/en_acode.htm

Regulations base for import and export – Title 9 Code of Federal Regulations:

http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfrv1_07.html

Communicates international requirements:

http://www.aphis.usda.gov/regulations/vs/iregs/animals/

FSIS import-export:

http://www.fsis.usda.gov/Regulations_&_Policies/Export_Information/index.asp

Regionalization in APHIS:

http://www.aphis.usda.gov/import_export/animals/reg_request.shtml

Andean Community:

http://www.comunidadandina.org/

http://www.comunidadandina.org/normativa/RES/R449.HTM

OIRSA – Regional Organization for Agricultural Health

http://ns1.oirsa.org.sv/

Mercosur – Common Market of South America

http://www.mercosur.org/english/default.htm

North American Free Trade Agreement

http://www.sice.oas.org/trade/nafta/naftatce.asp

RESIDUE DETECTION PROGRAM

OBJECTIVES

After completing this module, you will be able to:

1. List the names of the three federal agencies that are involved with residues in food animals.
2. Explain your role as a PHV in residue detection in the establishment
3. Describe the monitoring and receipt of laboratory results through LIMS-Direct.
4. Perform and accurately read KIS™ test.
5. Evaluate conditions which would lead to a decision by the PHV to perform an in-plant residue test.

Resource Materials

FSIS Directive 7355.1 Use of Sample Seals for Laboratory Samples and Other Applications

FSIS Directive 10,100.1 FSIS Sampling for the National Antimicrobial Resistance Monitoring System (NARMS)

FSIS Directive 10,200.1 Accessing Laboratory Sample Information via LEARN

FSIS Directive 10,800.1 Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program for Meat and Poultry Products

FSIS Directive 13,000.2 Performing Sampling Tasks in Official Establishments Using the Public Health Information System

FSIS Notice 03-15 Sampling Project Codes for the Fiscal Year 2015 National Residue Program

FSIS Notice 60-14 FSIS Sampling Data Reporting Through LIMS-Direct

Best available preventive practices are discussed in the Federal Register titled: Residue Control in a HACCP Environment dated November 28, 2000 (Vol. 65, No 229).

FSIS National Residue Program

The Food Safety and Inspection Service (FSIS) works with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to accomplish the responsibilities under the National Residue Program. FSIS's primary mission under the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat, poultry, and egg products. The NRP also provides for the collection of national data on the occurrence of residues to support risk assessment, enforcement, and educational

activities. The United States has a complex residue control system, with rigorous processes for approval, sampling and testing, and enforcement.

Three principal agencies are involved in the control of residues in meat, poultry, and egg products: FSIS, FDA, and EPA. FDA and EPA establish tolerances (maximum permissible levels) for chemical residues in foods, and FSIS enforces these tolerances through its various residue control programs.

FDA establishes tolerances for veterinary drugs and food additives under the statutory authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). These tolerances are published in Title 21 of the Code of Federal Regulations (21 CFR). EPA establishes tolerances for registered pesticides under the statutory authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by the Food Quality Protection Act (FQPA). These are published in 40 CFR. Maximum permissible levels have also been established for residues that are the result of environmental contamination, such as cancelled pesticides that are no longer approved for use but persist in the environment (e.g., DDT), industrial chemicals (e.g., PCBs), and heavy metals. Tolerances for industrial chemicals and heavy metals are established by FDA and published in 21 CFR. For cancelled pesticides, action levels (similar to tolerances, but less formal) are established by FDA or FSIS, based on recommendations that EPA has published in the Federal Register.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act ™™(PPIA), and the Egg Products Inspection Act (EPIA), FSIS acts to ensure that USDA-inspected meat, poultry and egg products do not contain illegal levels of chemical residues. The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products. The FSIS NRP, which has been in effect since 1967, provides a variety of sampling plans to prevent residues from entering the food supply, and develops national data on the occurrence of chemical residues to support risk assessment, enforcement and educational activities.

The range of chemical compounds evaluated for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry, and egg products and that may pose a potential human health hazard.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues, and (4) collection, statistical analysis, and reporting of the results of these activities.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer and other parties involved in offering these animals for sale. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to voluntary recall and/or other actions. In addition, FDA and cooperating state agencies may make on-site visits to these firms.

The purpose of the residue program is to maintain vigilance for non-permitted residues in food animals. The National Residue Program is the corner stone of FSIS residue prevention activities. The regulatory system that enforces U.S. food safety laws has been evolving since 1906.

There are three major aspects of the NRP:

1. the prevention of illegal chemical residues,
2. an analytical systematic testing program for the residues in domestic and imported products, and
3. verification that establishments are fulfilling their responsibilities under HACCP for preventing violative residues. This is discussed more under "Residue in a HACCP environment".

An essential aspect of food safety in meat, poultry and egg products is the **control** of residues that may result from the use of animal drugs and pesticides, or from incidents involving environmental contaminants. The NRP is an example of interagency cooperation and teamwork between Food and Drug Administration, the Environmental Protection Agency and FSIS. Within FSIS there is extensive teamwork among the following offices and personnel, Office of Public Health and Science, Policy Development Staff, National Information Technology Center, District Offices, Laboratory support (Eastern Lab, Western Lab and Midwestern Lab), and most importantly, the FSIS in-plant personnel who review animals everyday, collect and submit the samples. This teamwork is what makes the National Residue Program a success.

To have a better understanding of the role you will fulfill as an in-plant Public Health Veterinarian (PHV) it is important to understand the four basic components of the NRP:

1. monitoring,
2. special projects,
3. surveillance,
4. and enforcement.

The monitoring plan covers both domestic and imported product. There is a "special project" component which encompasses projects such as the testing of show animals for Clenbuterol. This information is also in FSIS Directive 10,800.1. Surveillance sampling is a scheduled sampling designed to investigates and control the occurrence of residue violations in targeted animal populations. The fourth component is the enforcement testing. This is the testing for residue in animals or lots that appear suspicious to FSIS in-plant inspectors, based on herd history or antemortem /postmortem inspection.

Import residue sampling is part of the NRP and this program is where FSIS randomly samples meat, poultry and egg products for residues at the U.S. port-of-entry. However, as a PHV, the main components of the NRP that you will be concerned with are the monitoring plan and enforcement testing.

There are some basic differences between the plans. For example, monitoring samples are ***directed samples***. You will receive direction and forms from OPHS (Office of Public Health Science), in Washington D.C., letting you know when to collect a sample and what sample to collect. The method of animal selection is also different. Monitoring samples are randomly chosen from all animals that have passed ante-mortem inspection

without regard to whether the animal may or may not pass postmortem inspection and been permitted entry into the food supply.

Enforcement testing is initiated by the in-plant FSIS personnel based on their judgment that an animal (or lot) may contain drug or chemical residues. This judgment can be based on ante-mortem findings, post-mortem findings and herd history. Herd history means that due to previous residue violations by a producer you may decide that in-plant screening for enforcement testing should be performed. The other reason to test is to verify the establishment's HACCP system. This is inspector-generated sampling.

Regulatory Authority and Residue in a HACCP Environment

Because you are joining a public health regulatory agency it is beneficial to know the regulatory authority under which we operate. Regulatory residue authority for FSIS is in the US code Title 21 chapters 10 and 12, the Poultry Product Inspection Act and the Federal Meat Inspection Act. Under the FMIA, PPIA and EPIA, FSIS acts to ensure that USDA inspected meat, poultry and egg products do not contain illegal levels of chemical residues.

There are multiple regulations in the CFR 9 that give guidance on residue. These are parts 309, 310, 311, 318, 320, 381, and 417. Production classes for which FSIS has regulatory authority include: horses, bulls, beef cows, dairy cows, heifers, steers, bob veal calves, formula-fed veal calves, non formula-fed calves, heavy calves, sheep, lambs, goats, market hogs, boars, sows, young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, rabbits, and egg products (liquefied eggs and dried eggs).

Contained in the regulations above, that cover livestock and poultry, there are parts that should be clarified due to changes in practice. CFR 9 Part 310.21 specifically pertains to calves. You will notice that the regulation is written with CAST as the testing used. CAST is no longer used for federal establishments (we now use the Kidney Inhibition Swab® (KIS™) for all bovine); however we still use the regulation as a guideline. You may disregard the definition of "certified calves" as that classification is no longer used. CFR 9 part 310.5 refers to carcasses or parts found to be adulterated; under FSIS definition (301.2 - adulterated), could mean with residues. The information regarding the increased testing that happens in calves when positive test results occur is still followed even though we use KIS™ instead of CAST.

The development and implementation of PR/HACCP introduced a new evolution to the residue control and avoidance responsibilities of the government and industry. Residue in a HACCP environment introduced the thinking that the establishment has a responsibility to address residue within their food safety system. It is made clear in 9 CFR 417.2 (a) (3) that violative residues present food safety hazards that may arise from chemical contamination, pesticides and drug residues. Using the principles of HACCP, each establishment must perform a hazard analysis and determine if residue is a hazard that is reasonably likely to occur in that establishment.

The FDA and EPA set tolerance limits of drugs, chemicals and pesticides.. A result is violative when this tolerance level is exceeded. When a violative result is reported to you by the Policy Development Division, you need to determine if the establishment addresses residue in a HACCP environment. FSIS has told establishments that if their

HACCP plans include residue controls that constitute the best available preventive practices, supply FSIS with information about violators, and follow appropriate corrective actions, then the Agency will not treat violative residue findings as a noncompliance (see CFR 9 part 417.3(a)). We will also follow these guidelines on FSIS monitoring and enforcement sample results.

However, when a residue result is violative and the establishment does not fully address residue in a HACCP environment a noncompliance record (NR) is generated under the Slaughter HACCP Verification task. Also, if the establishment does fully address residue in a HACCP environment, but they have failed to follow their plan, a noncompliance record should be generated.

Best available preventive practices are discussed in the Federal Register titled: Residue control in a HACCP environment dated November 28, 2000 (Vol. 65, No 229). Several things happen with best available preventive practices. The establishment must ensure all animals are identified for successful trace back to the owner of origin. Our concern is to prevent repeat violators from continually sending residue animals to slaughter. To do this we need to have the correct owner name and address. The establishment needs to notify producers in writing of the residue findings and the company's future expectations of the producer. Future expectations may include the company's business practice of refusing to purchase more animals from a producer after several repeated violative results are confirmed by the FSIS labs. A company may have a policy where they send a representative to visit with the producer to make sure they understand residue avoidance.

Additional practices mentioned in the federal register discuss how some states may have a state-certified voluntary residue avoidance program. If this exists the establishment may be able to add to their purchase specifications a requirement that suppliers participate in the program and supply certification to that effect. The establishment could explore live animal testing as a rapid and convenient verification tool. If the establishment institutes the named best available preventive practices, when a violative residue occurs - they may not receive an NR (in general) as long as appropriate corrective actions are followed. Having said this, the Agency may take additional enforcement action against establishments that repeatedly purchase and slaughter animals with violative residue levels from the same source supplier. See the section headed "Multiple FSIS Laboratory Confirmed Residue Violations from the Same Source" on page 9 of this handout.

Residue Terminology

These are the basic "understood" definitions of violator and repeat violator.

- Violator: a person or organization that presents an animal for slaughter for food purposes (not including pre-clearance testing) which contains a violative tissue residue concentration of a drug, pesticide or other chemical.

- Repeat violator: a violator who has had two or more violative tissue residues within the twelve months following issuance of an FSIS violation notification letter. (same thing as "residue notification letter")

- AMDUCA: Animal Medicinal Drug Use Clarification Act - The AMDUCA establishes conditions for extra label use or intended extra label use in animals by or on the orders of licensed veterinarians of FDA approved new animal drugs and approved new human drugs.

  -There are a list of drugs that are prohibited for extra label use; Chloramphenicol, Clenbuterol, Diethylstilbestrol (DES), Dimetridazole, Ipronidazole, Other Nitroimidazoles, Furazolidone, Nitrofurazone, other Nitrofurans Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine) Fluoroquinolones Glycopeptides (example: vancomycin) Phenybutazone in female dairy cattle 20 months of age or older

Residue responsibilities for the Public Health Veterinarian

Public Health Veterinarians/Inspectors-in-Charge (PHV/IIC):

1. Identifies animals as suspect for residue testing at ante-mortem.
PHVs are to handle animals for slaughter with known violative residue levels in accordance with 9 CFR 309.16.

2. Understands how the establishment addresses residue control in its HACCP system.

3. Manages the duty station to ensure that it has proper equipment needed for the effective collection of samples and performance of in-plant tests and maintains the adequate control of supplies, incubators, and other equipment.

4. Verifies that Consumer Safety Inspectors (CSIs) have been trained in residue testing sample submission procedures and in the appropriate identification of carcasses or products suspect for violative residues on post-mortem inspection.

5. Accurately completes FSIS Residue Sample Forms 10,000.2 and 10,210.3 in PHIS and records the carcass owner's name, address, and other identifying information on the forms and in PHIS.

6. Selects carcasses or products for testing and ensures proper handling, labeling, processing, sealing, and shipping of the samples to avoid discard of any samples.

7. Tracks the status of the sample and determines carcass/part disposition by reviewing LIMS-Direct.

8. Documents noncompliance.

Frontline Supervisors/Multi In-Plant Performance System Assignment:

1. Evaluates and assesses in-plant residue control performance of PHV or inspection program personnel.

2. Evaluates and assesses in-plant staffing needs, sets priorities to ensure that an adequate residue control system is in place, and provides feedback to the PHV.

3. Maintains current information on the NRP and apprises inspection program personnel of any program changes in a timely manner.

4. Operates in conjunction with the DO to ensure uniform and consistent implementation of the NRP.

District Office:

1. Receives notification of residue violations and violators from LIMS-Direct and the PDS through the Residue Violator Information System (RVIS).

2. Coordinates residue related activities and disseminates residue information to field personnel on an as-needed basis and operates in conjunction with the PDS when special sampling situations arise.

3. Cooperates with residue violation investigations that may involve FSIS, FDA, and EPA.

4. Cooperates with and aids the PDS in trace-back activities that may require contacting auction houses, brokers, establishments or PHVs in order to obtain information that the PDS needs for residue management efforts.

5. Ensures that OFO staff and inspection program personnel enroll in appropriate training necessary to carry out NRP responsibilities.

6. Evaluates the performance of field personnel to ensure uniform and consistent implementation of the NRP.

7. Verifies, through management information systems, the degree and level of application of various residue-related activities conducted at the in-plant level by interpreting and analyzing operational reports, data and other information to effect corrective actions in situations where the program failed.

8. May receive information from the PDS and OFO Headquarters relating to field residue violations that require increased in-plant testing by the PHV.

OPPD, PDS Role in Residue Detection

The Policy Development Division coordinates residue violator activities and the dissemination of residue-related information among FSIS, FDA and EPA in accordance with the existing Memorandum of Understanding (MOU). The PDS uses RVIS to manage violation cases. Case management includes communication with FSIS field personnel, FSIS District Offices, FDA Districts, State officials, and the owners and establishment officials responsible for violations. The PDS also provides correlation as requested by OFO on residue results reported in LIMS-Direct, inclusive of carcass or part disposition.

Residue Violation Cases

All violative residue reports result in a residue notification letter being sent to the owner identified on the residue lab form. The PDS will send the original letter to the owner, and copies will be sent to FDA for their investigation efforts, and to the District Office of where the owner lives. There may be two District Offices informed of one case. For example when the PDS first receives the lab fax, the form with the written residue carcass disposition will then be faxed to the DO of where the establishment is located. This provides the IIC and that DO the information that a violation occurred. When the residue notification letter is completed a copy of it is sent to the DO of the residence of the identified owner. A case file is built at the PDS for each violator.

FDA, EPA and FSIS work in conjunction on the National Residue Program. An MOU spells out the information on violators that FSIS is required to provide to the other Agencies. In the spirit of teamwork and cooperation, FDA also provides FSIS with a final report (Called Attachment C) of their case investigation. The PDS reviews the final reports for any changes that should be made to the Residue Violation Information System.

Residue Follow Up Cases

There are different situations where you may be asked to increase your in-plant testing on a specific producer's animals. If you have knowledge that there have been previous violations by the owner, you may want to increase testing of those animals when they arrive. This is a judgment call on your part; you can find additional guidance on when to increase testing in FSIS Directive 10,800.1. If you have concerns, you should discuss them with the PDS Staff Officers. The FDA or the State may call the PDS who will in turn contact you in cases where increased scrutiny is requested. If there is a producer from that list bringing animals into your facility, you may also want to increase scrutiny and testing.

The PDS, in conjunction with the labs and OPHS, review residue results for trends and unusual findings. In cases where an illegal drug, or a result of ten times over the tolerance or when a new drug shows up we will notify and work with FDA and EPA to determine the risks involved and if additional action is needed.

Multiple FSIS Laboratory Confirmed Residue Violation from the Same Source

When you are notified that your duty station has one or more FSIS laboratory – confirmed residue violations from animals purchased from the same source supplier, discuss this finding with the establishment at the next weekly meeting. Also, let them know that FSIS is implementing a more focused approach on the same source suppliers to ensure the establishment is notified of the residue history or its suppliers. Recommend that the establishment adopts corrective and preventive measures for chemical residues. Document the meeting in weekly meeting MOI and distribute copies to the establishment, FLS and District Office.

Review the establishment's residue control program, which may be addressed in the HACCP plan, Sanitation SOP or other prerequisite program. If the HACCP system is in

compliance, do not document a NR. If the establishment has a residue control program but has failed to take corrective actions, or the corrective actions are ineffective, issue a NR (for a prerequisite program, use 9 CFR 417.5(a)(1); for a Sanitation SOP, use 9 CFR 416.15; for a HACCP plan, use 9 CFR 417.3(a). If the establishment has not incorporated residue control into any of these programs, use 9 CFR 417.3(b) for a unforeseen hazard.

Increase testing of the animals the establishment receives from this same source supplier subsequent to the initial violative finding. Test two or more animals each time the establishment receives animals from the supplier, up to 100% testing of animals from that supplier to ensure animals with violative residues don't enter the human food supply. Continue with this level of testing until tests for four consecutive, separate shipments from that supplier are negative.

After the initial violative finding, if there is another FSIS laboratory-confirmed residue violation from the same source supplier, issue a NR as described above and another NR citing 9 CFR 318.20, documenting the establishment's failure to prevent animals with violative residues from entering slaughter.

If there are multiple or recurring noncompliances, you may determine that the HACCP system is inadequate under 9 CFR 417.6 and further enforcement is warranted. Contact your supervisor and the District Office to discuss your assessment and determine if a NOIE should be issued.

Review FSIS Directive 10,800.1 for complete information on addressing repetitive residue violations from the same source supplier. The directive appendices include flow charts on enforcement actions.

Residue Violation Information System (RVIS)

Frequent communication between Agencies (FSIS, FDA, EPA, and states) and divisions of FSIS is vital to the NRP. The RVIS database is a nationwide, interagency computer information system designed to share pertinent data for regulatory enforcement on an open and regular basis. The system operates 24 hours a day to provide information on residue violations in livestock and poultry slaughtered in the USA. The RVIS has proven to be an excellent tool for supporting residue control measure in meat and poultry because it allows exchange of information among participating agencies regarding regulatory enforcement.

RVIS is a unique system and a successful example of interagency cooperation and teamwork. It was implemented in 1987, and since that time improvements have been made to increase the capabilities for its use. The goal continues to be to provide reliable, consistent, current and accessible source of information on residue violations.

Tracking the status of Residue Samples via LIMS-DIRECT

A. The Laboratory Information Management System (LIMS-Direct) is an information technology (IT) program that reports FSIS lab sample results directly from LIMS. It provides a close to real-time sample data electronically to FSIS program

personnel and other entities when applicable. FSIS Directive 10,200.1, (LEARN) System will be revised to reference LIMS-Direct.

B. The PHV is periodically to check the status of samples.

C. If the laboratory discarded the samples, the PHV is to check the reason why as indicated in LIMS-Direct and make the necessary adjustments on how he or she collects, seals, and ships the samples to make sure the laboratory does not discard future samples because of improper handling.

1. If the PHV saved tissues from the original submission, the PHV is to send a replacement sample, prepare a FSIS Form 10,000-2 in PHIS for each individual sample he or she submits, and enter all necessary information on the form. The PHV is to note in the "Remarks" block that the sample is submitted as a replacement.

2. If the PHV discarded all tissues, but the establishment has held the carcass from which he or she collected the original sample, the PHV may collect new tissue samples and resubmit them by using Form 10,000-2 and referencing the form number from the original scheduled sample submission.

D. PHVs are to print the LIMS-Direct screen of the residue results after making carcass disposition and maintain it in the office files as supporting documentation.

Guidelines for carcass and parts disposition based on results posted in LIMS-Direct

The PHV is to check LIMS-Direct and review the results of laboratory testing of residue samples already submitted. The PHV is to make final dispositions based on the results posted in LIMS-Direct. LIMS-Direct indicates whether a tissue is "Not Detected", Detected – non-violative", "Detected – violative", or "Detected but not Quantified, Violation". Follow the disposition guidelines to make the final disposition of the retained carcass and parts.

If there is no established tolerance (reported as "Detected but not Quantified, Violation) or there is a quantified violation for some part (such as organ tissue or fat) without a quantified muscle result:

- Condemn the carcass and all parts

If the residue test result is reported as "Detected – violative", use the following disposition guidelines:

- Violation **in muscle** – condemn carcass and parts
- Violation **in muscle and parts** – condemn carcass and parts

- Violation **in parts** but no violation in muscle – condemn parts, pass carcass

For NSAID or beta-agonist violation – call the PDS for disposition of carcass and parts.

C. If any test results from the FSIS laboratory show violative levels of antimicrobial residues the PHV should call the PDS, Technical Assistance/Correlation Staff, for answers to any questions.

D. When a carcass/part is retained (either by FSIS or the establishment), the PHV is to ensure that the carcass or part is released or condemned in accordance with the LIMS-Direct results and in conjunction with the above tissue guidelines. In a situation where the establishment did not elect to hold the carcass or part pending test results, the product may be subject to recall if the results are violative.

The PHV may see that LIMS-Direct reports a residue sample test result as either "Detected but not Quantified, Violation" or has a quantified violative result for some parts (e.g., organ or fat) without a quantified muscle result. This means that the identified compound does not have an established FDA or EPA tolerance for muscle. The PHV should not apply the mark of inspection to that carcass, and condemn the carcass and all parts.

Verification of Implant Usage in Pre-Ruminate Calves

PHVs are to condemn any pre-ruminant calf presented for slaughter that has an implant or evidence of implant use. PHVs do not need to collect tissue samples when there is an actual implant present.

Ante-mortem verification activities in pre-ruminant calves:

During ante-mortem inspection of pre-ruminant calves whose meat is to be labeled as "veal," inspection program personnel are to determine whether the animal has an implant.
Signs that an implant has been used are:

a. palpable implant

b. missing ears

c. ears with incisions indicating recent surgery

d. mutilated ears

e. atrophied testicles

f. unusually heavy muscle development

If any of the above signs are present in a calf, inspection program personnel are to retain the animal and tag it as "U.S. Suspect." Inspection program personnel are to use their professional judgment to determine when the entire lot (i.e., all calves) from the same producer should be tagged "U.S. Suspect."

Post-mortem verification activities in pre-ruminant calves:

Inspection program personnel are to palpate the ears of the "U.S. Suspect" carcasses for implants. Inspection program personnel are to consult with their supervisor

concerning adjustments in line speed that may be necessary to complete the inspection procedure.

NOTE: If necessary, the establishment may remove ears prior to hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment can also remove the ears when skinning the head and present them for review in a manner acceptable to the PHV.

If an implant is present, inspection program personnel will feel a linear, firm swelling under the skin when palpating the ear. The implant may feel like "beads on a string." The individual pellets that make up the implant are approximately 3 mm in size and about 2 mm apart.

Inspection program personnel are to retain the carcass of "U.S. Suspect" calves showing signs of having implants at ante-mortem inspection for the PHV to examine.

The PHV is to examine the rumen of the retained carcass to determine whether the rumen was functioning.

a. The PHV may pass the carcass for human food if the animal had a functioning rumen, and the carcass is not subject to condemnation as described in 9 CFR Part 311.

b. The PHV is to condemn the carcass if the rumen was not functioning (pre-ruminant), and the animal had

i. an implant

ii. missing ears, ears with incisions that indicate recent surgery, or mutilated ears to the extent that the PHV is unable to determine whether an implant was present. In the absence of the ear, the PHV cannot pass the carcass because there is no basis to find that it is not adulterated, and the PHV is to condemn the carcass.

If the PHV determines that a calf had an implant and a non-functioning rumen, he or she is to perform a Slaughter HACCP Verification task to verify that the establishment takes the appropriate actions under 9 CFR 417.3(a) or 417.3(b).

If the establishment fails to take appropriate corrective actions, the PHV is to issue a NR and take the appropriate enforcement action as set in FSIS Directive 5000.1.

In-plant Screening Tests

The only in-plant screening test currently used in federally inspected establishments is the KIS™ test. It only screens for antibiotics. Until August 2012, the FAST was also used as an in-plant antibiotic screen test. However, this test has been completely replaced by the KIS™ test and is no longer used. Please note that the FSIS Directives 10,800.1 and 10,220.3, addressing residues, have not yet been updated to reflect the change from FAST to KIS™ testing. Nevertheless, carcasses for sampling and testing by the KIS™ test are selected and handled in the same way as carcasses selected for the FAST.

Enforcement testing makes extensive use of rapid in-plant screening tests. In this way, only those samples that test positive by a screening test are sent to an FSIS lab for confirmation testing. Samples sent to an FSIS lab for confirmation testing because they are positive by an in-plant screen test are automatically tested for non-steroidal anti-inflammatory drugs such as flunixin or phenylbutazone.

However, if you feel the carcass may contain a violative level of a residue for which there is no official FSIS screening method, a sample taken from that carcass is sent directly to the lab for testing. A good example of this is testing for non-steroidal anti-inflammatory drugs (NSAIDs) such as flunixin or phenylbutazone. These drugs are used in older dairy cows and sows with arthritis as a means to prevent inflammatory conditions or prevent them from becoming non-ambulatory disabled. Such animals should be screened for flunixin; however, NSAIDs are not detected by the in-plant antibiotic screening tests. So, when the PHV or IIC suspects residues from NSAIDs, he or she must take samples and specifically request that the Midwestern Laboratory analyze for NSAIDs.

The in-plant screening tests provide a way to screen animals that are seen as suspicious based on their herd history, ante-mortem or post-mortem findings. They are used as a follow up on producers who have been known in the past to have residue violation issues, and also to verify the establishments HACCP system.

Establishments that slaughter certain categories of food animals must address chemical residues within their HACCP system. In establishments that slaughter cull dairy cows and/or bob veal calves, perform increased targeted testing for chemical residues if their hazard analysis does not demonstrate support for an effective residue control program. Some examples of lack of support are:

- the establishment repeatedly purchases cull dairy cows and bob veal calves from a producer without taking into account whether that producer has supplied to any establishment more than one animal with a residue violation in the last 12 months.

- an establishment does not have controls in place that address the possibility that it may receive animals from producers that are on the FSIS Repeat Residue Violator List (e.g., because it purchases animals at an auction barn that does not provide information on whether the animals are from a producer on the Repeat Residue Violator List)

If the increased rate of testing is warranted, IPP are to:

1. Test a minimum of two animals each time the establishment receives animals, and the establishment does not have a control in place that minimizes the possibility that the animals have an illegal residue,

2. Use professional judgment to determine whether additional sampling is necessary, up to 100% testing of the lot, based on the effectiveness of the establishment's residue control program at reducing or eliminating the occurrence of FSIS violative findings,

3. Continue increased testing rate on all dairy cows and bob veal as long as the establishment lacks an effective control program, and

4. Use the increased testing rate for dairy cows and bob veal from any unknown source, even if the animals appear to be normal, as well as on animals with pathologies listed in FSIS Directive 10,220.3. For bob veal, this increased testing rate is in addition to the rate described in 9 CFR 310.21.

Animal Identification and Devices

When a residue sample is taken in the establishment, USDA will request the producer/owner name and address from the establishment. The USDA inspector will also request any external identification (back tags, ear tags, etc) numbers of that carcass from the establishment.

By regulation and Law, the establishment is required to comply and provide the accurate identification requested. In addition, FSIS has signed a Memorandum of Understanding (MOU) with APHIS detailing the specific types of animal identification collected to identify livestock and poultry slaughtered at Federal establishments. Collecting complete animal identification allows traceback to the animal production unit for disease surveillance and eradication.

<u>Regulations pertaining to animal ID and connection with residue</u>

FSIS, Department of Agriculture: Chapter III

9 CFR 309.16: Livestock suspected of having biological residues.
9 CFR 309.17: Livestock used for Research
9 CFR 309.18: operations must adhere to the defined use of U.S. Suspect and U.S. Condemn tags.
9 CFR 310.2 Animal trace back: all forms of identification are required to be removed and kept coordinated with the carcass until postmortem inspection is completed.
9 CFR 310.3: Carcasses and parts in certain instances to be retained.
9 CFR 310.21: carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected parts.
9 CFR 311.30: Biological residues
9 CFR 318.20: Use of animal drugs
9 CFR 320.1(a): every person …within any of the classes specified ……is required by the Act to keep records which will fully and correctly disclose all transactions involved in his or its business subject to the Act.
9 CFR 320.3: Record retention period.
FSIS Notice 5-02: Animal Identification (expired)

Packers and Stockyards Act: Chapter II

9 CFR 201.49(a): Livestock weighed for purchase or sale must be serially numbered and scale tickets must be generated; if hot carcass weights are used for purchase, the scale must be linked to a printer to generate scale tickets with dates, names of buyers and sellers, number of head, kind of livestock, weights and the individual responsible for this task.

9 CFR 201.86(d): identity of the consignment is required until inspection has been completed.
9 CFR 201.94 and 201.95: Information and records described above must be made available to USDA.
9 CFR 71.19 -APHIS tattoos.

Animal Identification / Verification and Enforcement Activities when the Establishment fails to collect and maintain Animal Identification

Inspection program personnel are to verify that all animal identification devices remain associated with the carcass until FSIS completes the post-mortem examination.

A. FSIS verification activities:

1. Inspection program personnel are to verify that the establishment is collecting and maintaining animal identification until the completion of post-mortem inspection in accordance with 9 CFR 310.2.

2. Inspection program personnel are to collect all animal and owner identification from the establishment when they submit a sample for residue testing (e.g., livestock market or sale barn back tags, producer ear tags, feedlot identification tags, Canadian tags, and calf-hood tags [bangs]). (See: 9 CFR 310.2, 310.3, 310.21, 309.16, 309.17, 320.1 and FSIS Directive 10,220.3).

B. FSIS enforcement activities:

Inspection program personnel are to prepare a noncompliance record (NR) when the establishment fails to comply with the FSIS's regulations that apply to the identification, holding, and sampling of carcasses and parts for drug residues (9 CFR 309.16, 9 CFR 310.2, 3, .4, or .21; 9 CFR 320.1, 310,23). NRs are documented in the Other Inspection Verification task.

Residue Testing Procedures: Cattle and Swine

There are basic principles you should keep in mind when you are deciding whether or not a carcass may contain residues. The in-plant screening tests provide guidance and should be used as primary tools in the first step of the residue program.

The following is a list of the pathologies and conditions that warrant retention and testing of carcasses. Symptoms are described to help PHVs determine when to retain and test carcasses.

- Mastitis – carcasses with inflammatory ventral edema in the perineal area resulting from mastitis. Hemorrhages and yellow serous infiltrate, located ventrally, are typically present.

- Metritis – carcasses with acute metritis. Associated pathology includes enlargement of the uterine body, distension of the uterine horns with a fetid brown, red brown, or

black fluid; thinning of the uterine wall; and lack of evidence of normal uterine involution (no lines of contracture in the myometrium).

- Peritonitis and surgery – carcasses with active peritoneal inflammation associated with fibrinous exudate or fetid ascitic fluid, no matter how limited the extent of the lesions or with ventral abdominal cellulitis secondary to percutaneous abomasal surgery. Findings of surgical devices (suture, toggles, fistula devices, etc.) are only significant if they are associated with active (i.e. the presence of fibrin as opposed to chronic peritonitis with fibrous adhesions) peritoneal inflammation.

- Injection sites – carcasses with lesions associated with injections. Injection sites are likely to be found in a variety of locations including the neck, shoulder, thorax, axilla, ventral abdomen (along the subcutaneous abdominal vein), flank, hindquarter, pelvic area (perirectal) and tail. Also, look for cellulitis that is away from pressure points (e.g., tubor isschii, hip joint, stifle joint). These are generally found in the semimembranosis and semitendinosis muscle.

- Pneumonia – carcasses with acute, subacute and chronic active pneumonias; with pleural cellulitis resulting from reticulo peritonitis complex; or with embolic pneumonia.

- Pleuritis – inflammation of the pleura lining in the thoracic cavity and lungs

- Pericarditis – carcasses with fibinous or fibrinosuppurative pericarditis.

- Endocarditis – carcasses with endocarditis and acute pulmonary, renal or other embolic lesions.

- Signs of treatment – leakage around jugular veins; subcutaneous, intramuscular, or intraperitoneal signs of treatment; signs indicative treatment by mouth such as discoloration from particles found in any part of the digestive tract.

- Septicemia, pyemia or generalized disease – carcasses that are being condemned for septicemia, pyemia, or other inflammatory/infectious conditions. On antemortem or postmortem inspection – depression, elevated or subnormal body temperature, hyperemic skin, congested mucous membranes, dehydration, poor body condition, in association with an injury or inflammatory condition such as abcesses, arthritis, pneumonia, mastitis, metritis, or diamond skin

- Animals identified during ante-mortem inspection that were determined to be U.S. Suspect for residues.

- Injury or inflammatory conditions – carcasses with conditions not resulting in condemnation such as arthritis, pneumonia, mastitis, metritis, nephritis, cystitis, diamond skin

- Carcasses with acute cellulitis or other acute inflammations associated with a fibinous or fibrinosuppurative exudate in any location on the carcass or viscera.

- Beta-agonist use – excessive or unusually heavy muscle development or hyperexcitability on antemortem inspection. Heavy muscle development or a “dark cutter” on postmortem examination.

WORKSHOP

1. The agency that establishes tolerances for veterinary drugs and food additives is:

    a. OSHA.
    b. FSIS.
    c. FDA.
    d. EPA.

2. For the following conditions, which would **both** lead to a decision by the PHV to perform an in-plant residue test:

    a. Chronic pneumonia and acute fibrinous pericarditis.
    b. Acute fibrinous pericarditis and septicemia.
    c. Injection site and chronic mastitis.
    d. Diamond skin not associated with septicemia and chronic bronchopneumonia.

PREPARATION FOR MENTORING

This module covers an overview of the essentials of creating, and maintaining, a mentor-mentee relationship.

OBJECTIVES

After completing this module, you will be able to:

1. Identify different forms of mentoring, the various ways of mentoring, and the benefits of mentoring
2. Understand listening and learning styles.
3. Recognize the phases of a mentoring relationship, what makes a mentoring relationship successful, and how to end a mentoring relationship.

RESOURCE MATERIALS

- "Structure Mentoring: A new Approach That Works", InfoLine ASTD, 2004
- "The Three Debriefing Questions", International Mentoring Association, WWW.Mentoring-Association.Org, 2003
- "Leveraging Mentoring for Individual and Organization Effectiveness", Keynote presentation-D. Thomas, Coaching & Mentoring Conference, May, 2001
- USDA Professional Development Centro, Mentoring Handbook, April 2002
- "Mentoring: How to Develop Successful Mentor Behaviours", G. Shea, Crisp Publications, 1997
- "Design Productive Mentoring Programs", InfoLine ASTD, 1986
- Department of Transportation, "Mentoring Handbook, Mentoring Skills", http://dothr.ost.dot.gov/mentorhb.htm, 2000
- "The Manager's Pocket Guide to Effective Mentoring", HRD Press, 1999

Introduction

Unlike a training relationship, where there is active participation without personal involvement; the mentoring relationship, allows two or more people to form a bond. In the mentoring relationship one person (the mentor) sets an example; and the other (the mentee), learns through shadowing the mentor and asking questions to clarify what they have observed.

There are many types of mentoring, which may be either an informal mentoring relationship, or a formal mentoring relationship. Both types are based on achieving some set of pre-defined goals, which should be attainable. There is a set amount of time in which to achieve these goals; and, typically it is not a life long commitment. Regardless of the type of mentoring relationship that is established, the goal is still the same-to help individuals learn from others through positive interactive relationships.

In the context of an FSIS employee mentoring relationship, you will be sharing a formal mentor relationship. The formal mentoring relationship is one in which there is an assigned mentor interacting with an assigned mentee. The goals have been predetermined in order to benefit the organization, the mentee, and the mentor. The primary goal is to help the mentee gain a basic understanding of the in-plant environment and their role thru guided hands-on activities to achieve the mission of the Food Safety Inspection Service. To understand the FSIS mentor-mentee relationship expectations; in this module we will discuss what it means to be mentored, the requirements of mentees, and the relationship.

Forms of Mentoring

Forms of mentoring define the entrance and exit criteria of the mentoring relationship.

Mentoring relationships can be:

- Spontaneous and informal,
- Structured,
- Performance improvement,
- Fast tracking, and
- New hires.

In the “spontaneous relationship” an employee gains knowledge through working with a more experienced employee. The advice imparted to the new employee, and the questions asked by the new employee, allows the mentor to determine what level of continued support the new employee will require during the time awarded for the relationship.

The “structured relationship” focuses on ensuring that the mentee completes certain pre-determined activities related to their position. This could include such activities as obtaining performance reviews, completing skill self-assessments, or formulating personal objectives for the year.

For the “performance improvement relationship” there is a pairing of a senior employee with a less experienced employee, whose performance doesn’t meet the established standards for the less experienced employee’s position.

“Fast tracking mentoring relationships” is used when a new employee has been identified as having leadership qualities. This person is then placed into learning opportunities with senior managers that will enhance and build on those characteristics. Those opportunities allow the individual to be promoted faster within the organization on a faster cycle than they would climb the ladder under normal work progression steps.

The “new hires” mentor relationship exists when it has been determined that the person needs to gain a large amount of organizational knowledge. Organizational knowledge includes on-the-job experience skills; along with social, or contextual skills.

Ways of Mentoring

The “ways of mentoring” establishes the structure of the learning experience. That is, will the mentee and mentor meet one-on-one, will their relationship be conducted in a group setting, or can they utilize an electronic medium.

The “one-on-one mentoring relationship” allows the mentor to meet with one mentee at a time. Although the mentor may have been assigned to work with more than one mentee over a period of time, the mentor structures his/her day in such a way that allows for the mentee and mentor to speak privately for a set amount of time. This allows for free, honest and open exchanges between them.

“Under group mentoring”, the mentor meets with several mentees at a time. This has the look and feel of an informal class; during which, the students have an opportunity to ask questions. The mentor would be answering questions, and communicating basic guidelines for a task that all individuals will be conducting. During these meetings, the group needs to practice basic rules of positive communication regarding constructive criticism and respecting others.

“Electronic mentoring” permits participants in the mentoring relationship to meet long distance. This can be used for one-on-one meetings, or for group meetings. Possible mediums can be web-casting, Tandberg, e-mail, electronic bulletin boards and/or chat rooms. A very important issue with electronic medium communication is the ability to communicate with clarity. The communicators must use clarifying questions to supplement the nonverbal responses, and to explore others reactions.

Benefits of Mentoring

How does the PHV mentoring relationship benefit FSIS? The benefits are many. The organization benefits, the mentee benefits, and the mentor benefits!

Through the mentoring relationship, the organization benefits by broadening our communication tree. The communication is carried across functional areas throughout different levels in the organization versus being position, level or location specific. Information that is shared includes institutional knowledge and skills being passed from mentor to mentee, directly and specifically. This knowledge sharing helps to build culture knowledge about the organization and develops skill sets.

By being mentored, the mentee gains numerous benefits. Whether new to the organization, or through a promotion, you may be anxious about your new role. The mentoring process affords you a support system as you transition into that role. Having an experienced mentor’s guidance, you will gain insight into accomplishing your daily assigned duties; and, the mentor can be a sounding board for examining your perceptions, new ideas and plans. Additionally, the mentor will be giving you positive, constructive feedback on your development. The mentoring relationship is also the initial contact for the development of a personal organizational network for you.

The mentor benefits through personal growth that he/she gains from being a mentor to you. Beyond personal growth, they are recognized for their role as an expert as well.

Also through mentoring, the mentor is able to enhance their personal contribution to the future of the organization.

Requirements of Our Mentees

Listening skills are typically not natural, they are learned. There are two styles of listening:

- One Way – passive listening
- Two Way – active listening

One-way listening occurs when a listener tries to understand the speaker's remarks without actively trying to provide feedback. In this style of listening, there is little or no verbal feedback to indicate how the message is being received. The listener may inadvertently send non-verbal messages through body language, which may give the speaker some indication of the listener's impressions of the message. But non-verbal signals; such as nodding or smiling may be culturally or socially ingrained messaging responses that should not be misunderstood.

In two-way listening, feedback is given. First, the listener focuses fully on the speaker's statement instead of thinking about what he/she plans to say next; and, ignores outside noises or people. Your immediate response could be to paraphrase the speaker's message, demonstrating that you understood the information/question. This also prevents selective listening, or listening only to part of the statement that interest you. The paraphrasing statement may be begun by saying: "Let me make sure I'm with you so far…", or "I understand you to have said …" Then, to elicit more information from your information source, you can use "door openers"; like, "Tell me more about …." or, "I'd like to hear more about …of this". Thus, two-way listening will allow for a more engaging information exchange!

Just as individuals have personal preferences regarding color, authors, or music; there are different ways that work best for learning for each person. Unconscious/conscious learning styles (how you interact with others in group/team work and activities) must be accounted for in the mentoring relationship. Some individuals are action oriented and take up a task without reading the directions first; while others want to absorb facts before proceeding with a task. While these different adult learning styles may create friction when the two interact, the interaction should be considered as an opportunity for complimentary traits to work as one.

If the action person reaches a point of difficulty in performing a task because they do not have enough information at that point, the person reading the manual can share information with him/her. In this way, the problem can be resolved without everything having to come to a complete stop while the action person takes time-out to read.

There are various factors that shape learning styles. These are:

- Personality - the person may be introverted (shy) or extroverted (not shy), a reflection versus action style;
- Education - the person's undergraduate major may have been one involving more cerebral endeavors rather than action oriented; a reflection versus action style.

- Career Choice- work norms and personal habits
- Current job role- focused decision making practices; examples:

1. City planner = decisions based on perceptual needs
2. Social counselor = a primary use of intuition for making decisions
3. Mediator = uses discussions of different points of view prior to decision making
4. Manager = decision based on organizational goals with resources in mind
5. Problem Solver = focus and decision based on current task/problem

The Relationship

There are stages of the mentoring relationship that the relationship will progress through: “Prescriptive Stage”, “Persuasive Stage”, “Collaborative Stage”, and “Confirmative Stage”.

The prescriptive stage is the first stage of the relationship. Typically in this stage, the mentee has little or no experience at the job or in the organization. Here, the mentor will be directing, ordering and advising the mentee; thus, assuming the role of a coach, a motivator and a teacher. The mentor’s goal is to provide detailed information to the mentee on many workplace issues and procedures during this stage. Mentor’s often share their experiences, trials and anecdotes, to relate how they handled similar tasks or situations and the consequences of their actions.

In the second stage, the persuasive stage, the mentor actually persuades the mentee to find answers and seek challenges rather than relying on the mentor for getting the answers. The mentor assumes the roles of counselor, guide, and door opener here.

While in the collaborative stage, which is the third stage, the mentee has enough experience and ability to work together with the mentor to jointly solve problems. The mentor may allow the mentee to take control, and work independently at this point. Our mentor’s roles are advisor, and role model, in this stage.

In the final stage, confirmative stage, the mentee has a lot of experience and has mastered the job requirements. The mentor will be sharing wisdom and professional guidance regarding policies and people during this stage with the mentee. Mentors are seen as sponsors during this stage.

During these stages, the mentoring relationship may experience obstacles:

- Expectations may have not been clear or were unrealistic, and may require further explanation.
- Given the large amount of knowledge that the mentee must absorb during the three week mentoring period, the mentee may feel that they are being pressured by time causing stress.
- Unspoken Darwinian beliefs of “survival of the fittest”; that in the past, new veterinarian’s had to gain information through self help not through coddling.
- Poor interpersonal skills, and poor choice of language, can offer hamper communication and feedback.

Both the mentees and the mentors are being given skill building training, for you-here in this module, to overcome these obstacles.
Here are some more skill building tips that can be done at the beginning of the mentoring period:

- Restating goals- the participants should discuss the goals together at the beginning of the process, and try to identify obstacles that might prevent from meeting those goals.
- Clarifying expectations- the participants should clarify their expectations of the process for developing their working relationship.
- Building trust- the participants should remember that developing a strong relationship will take time and effort, but the process can begin with being open and realistic when discussing the goals of the mentoring process.
- Honoring commitments- the participants need to recognize that in any sound relationship, that behavior speaks louder than words. Keeping commitments helps to establish a strong relationship, and furthers trust.

Mentoring relationships end when they have met their purpose. In our formal mentoring program, we also have a predetermined time frame that helps guide the development of skill sets for a smooth transition into the FSIS workforce.

It can be frustrating to both participants if a mentee is still looking for guidance, but the mentor is no longer available for the one-on-one relationship. Therefore, it is important to end the relationship when goals are met; so that, the mentee does not continue to depend on the mentor. This does not preclude an occasional call to seek help.

In some cases, a successful mentoring relationship results in the transformation of the relationship to a peer relationship. However, both parties must agree to the transformation. Most mentors are open to an occasional call to communicate good news or to simply keep in touch. Both participants should consider the other as a member of their career network.

Expected Outcomes

In order for every mentee to be given the tools to begin their job, the “CHECKLIST FOR VETERINARY MENTORS OF PROCEDURES TO REVIEW WITH VPHO TRAINEES” was created. Through a “Show, Tell, DO” process; which is in-line with this checklist of proficiencies, the mentee is provided experienced based learning.

FSIS’ public health focus is reinforced through the mentors modeling the thoughts and actions that FSIS wants to establish as awareness in the mentee’s conscious thoughts. The mentors will be modeling the FSIS vision of becoming a World Class Public Health Agency. That is, they will model the goals:

- Improve the management and effectiveness of regulatory programs,
- Ensure that policy decisions are science based,
- Improve the coordination of food safety activities with other public health agencies,
- Enhance public education efforts,

- Protect meat, poultry and egg products against intentional contamination.

On a more personal level, a working relationship can be developed early on in your career that will afford you a professional contact for sharing ideas, getting opinions and different perspectives.

Summary

The mentoring period has been designed to give you an overview of your job within the organization. Please actively participate in the process; so that, you capture all of the benefits that the mentoring relationship offers you.

PHV INTERN / TRAINEE GUIDE FOR VETERINARY MENTORS OF PROCEDURES TO DEMONSTRATE AND EVALUATE

Intern / trainee _____ Mentor _____

Dates _____ Establishment/Species_____

Mentors should coach the intern / trainee in the following procedures and evaluate if the intern / trainee is able to interpret and/or perform the task to achieve a basic awareness or proficiency level. If a certain procedure does not apply to the species at the mentor's establishment, make sure the intern has the opportunity to be exposed to other species and to processing operations in order to be rated on those procedures. It is not acceptable for a mentor to have the intern / trainee spend a significant time during the work day reviewing CDs or other training materials. Those are covered adequately in the CFL classroom training. The mentoring time is for demonstrating, coaching and evaluating the intern / trainee on the following important in-plant "survival skills". The mentor ensures that the intern / trainee is aware of the resources available on-the-job to adequately address procedures and issues, that may arise, and has a basic awareness of how the regulatory framework is applied on the job.

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Ante Mortem Inspection	Mentor to demonstrate: ☐ Safety protocols to be followed ☐ How to observe animals at rest and in motion ☐ Knowledge of unique requirements that apply to the duty station or species slaughtered. ☐ Performs antemortem inspection at all applicable facilities. ☐ How to take official control action (suspect, condemn). ☐ Knowledge of applicable paperwork ☐ Demonstrate knowledge of &/or ability to properly handle: ☐ BSE/CNS Inspections ❑Reportable diseases ❑Foreign Animal Diseases ❑Suspect classification ❑Disabled livestock Questions for mentors to ask to test knowledge: Why does FSIS conduct ante mortem inspection? What might be some consequences of not performing thorough ante mortem inspection? How does the PHV's expertise contribute to the safety and security of the food supply during ante mortem inspection?	• Flashlight • Thermometer • Watch • Pen • PHIS • Safety equipment • Regulations • Directives • Notices • FSIS Form 6150-1 • APHIS Documentation		**High☐ Aver ☐ No☐** Has achieved basic and/or awareness proficiency of ante mortem inspection procedures and policies without significant intervention by the mentor. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Humane Handling / Poultry Good Commercial Practices	☐ Aware of the regulatory requirements for humane handling of livestock. ☐ Observes handling of animals (including birds) and stunning routines ☐ Able to discuss and evaluate the significance of recording HAT data ☐ Proficient at entering HATS data into PHIS ☐ Understands official control actions and response to egregious incidents ☐ Knows DVMS and how/when to contact ☐ Understands poultry GCPs and how this differs from humane handling of livestock ☐ Understands when to document poultry GCP NR vs MOI Questions Why are we charged with the responsibility of ensuring humane handling? Why is it important?	• Regulations • Directives • Notices • Flashlight • Pen • Note pad • U.S. Reject tag • Work safety equipment		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of humane handling and slaughter including poultry inspection procedures and policies without significant intervention by the mentor. **Comments:**
Postmortem inspection	☐ Carcass presentation and line speed responsibilities- assure line speeds and presentation are consistent and adequate and do not interfere with proper inspection. ☐ Inspection techniques – perform hand motions, observations, palpations, incisions. ☐ Knows Tuberculin Reactor inspection procedure. ☐ Carcass dispositions – recognize normal; uses public health focused thought process to diagnose abnormal conditions and diseases (acute vs chronic; localized vs systemic; impacts public health vs NFSCP); makes proper carcass dispositions. ☐ Condemned and inedible control – understand, observe, and verify that establishment maintains control. ☐ Inspection reports – properly fill out applicable reports.	• Regulations • Directives • Notices • Guidelines (NELS, SIS, etc.) • Stop watch • Knife • Hook • Locks • Seals • PHIS • FSIS PM Disposition Forms		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of postmortem inspection procedures and policies without significant intervention by the mentor. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
5000.1 methodology	<u>Cover all methods outlined in FSIS Directive 5000.1 from the inspector and supervisor perspective:</u> ☐ **Rules of Practice** – explain regulatory control actions; show tags and explain how they are used; show copies of NOIEs in the government file; walk through scenarios based on past experience. ☐ **Sanitation Performance Standards** – demonstrate performance of procedures; explain how to randomly select the requirement to verify; review how to document noncompliance and how to interact with the establishment when noncompliance occurs; show examples of NRs in the government file; walk through scenarios based on past experience; explain how to determine if the noncompliance found is Sanitation SOP (e.g., contamination/adulteration of product or product contact surface) or HACCP (contamination is food safety hazard). ☐ **SSOP** – review establishment's Sanitation SOP; demonstrate performance of procedures; review how to document noncompliance and how to interact with the establishment when noncompliance occurs; show examples of NRs; walk through scenarios based on past experience. ☐ **HACCP** – review establishment's HACCP plan and hazard analysis; demonstrate performance of HACCP, SPS, Sanitation SOP procedures; review how to document noncompliance and how to interact with establishment when noncompliance occurs; show example NRs; walk through scenarios based on past experience. ***(Continued)***	• Regulations • Directives • Notices • Establishment Sanitation SOP and HACCP plan • Establishment Sanitation SOP and HACCP records • Sample NRs • Establishment E. coli written plan and records • Salmonella sampling supplies, forms, and shipping materials; • Food safety sampling supplies, forms, and shipping materials. • PHIS sample management		**High☐ Aver ☐ No☐** Has achieved basic and/or awareness proficiency of the methods in Dir. 5000.1 described here without significant intervention by the mentor. For example, has basic proficiency and/or awareness proficiency of: Performing the HACCP, SPS, and Sanitation SOP duties without intervention .from the mentor. Preparing and submitting *Salmonella* and food safety samples correctly; completing forms accurately; making proper disposition of carcasses; retrieving results from LIMS-Direct. Reviewing generic *E. coli* records. Documenting noncompliance, Following the Rules of Practice when taking regulatory control actions.

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
5000.1 methodology (continued)	☐ **Pathogen reduction** (Salmonella Performance Standards; Campylobacter Performance Standards; Generic E. coli verification) – Demonstrate sampling procedure; explain when and how to sample; demonstrate how to complete sample submission documentation and submit samples; explain what is done when sample set failure occurs; show establishment generic E. coli written plan and records of establishment sampling; explain what to review in establishment records and what constitutes noncompliance. ☐ **Food safety sampling** (E. coli O157:H7, Listeria) – Demonstrate sampling techniques; explain why sampling is done; explain what products are sampled; explain how OPHS determines what products to sample; show how to check records of in plant testing based on instructions in Directive 5000.2; explain what constitutes noncompliance and how to document noncompliance; show how to submit samples and how to check LIMS-Direct for results.			**Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Food Safety Standard for feces, ingesta, milk (red meat), feces (poultry)	**Poultry:** ☐ On line duties. ☐ Off line duties –examine 10 randomly selected carcasses prior to chiller; identify appearance of feces ☐ Verifying compliance with HACCP requirements. **Red meat:** ☐ On line duties. ☐ Off line duties – identify appearance of feces, milk, and ingesta on heads, weasand meat, cheek meat, and carcasses. ☐ Verifying compliance with HACCP requirements.	• FSIS Directive 6420.4 • FSIS Directive 6410.1 • Establishment HACCP plan		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the Food Safety Standard for feces, ingesta, milk (red meat) and feces (poultry) described in this section without significant intervention by the mentor. For example, Identifying contamination; Knowing locations to perform procedures; Understanding establishment actions required when it occurs **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Sampling and submission of laboratory specimens for pathology and residue	☐ **Pathology** (use proper terminology describing pathologies) and **TB** – NVSL suspect granuloma submissions – identify lesions; collect representative tissues; retain carcass/product pending results; prepare tissue for submission; ship samples; security of samples; check for results in LIMS-Direct. ☐ **Residue** – Demonstrate how to use KIS™; request supplies; location for collecting sample; collect tissue samples; complete forms; make proper disposition of animals; directed/headquarters generated; timing of samples; submission of lab forms; shipping samples; sample tube preparation; check for results in LIMS-Direct; explain how to be familiar with how the establishment addresses residues in their HACCP plan and/or establishment procedures; identify animals during ante mortem and post mortem inspection that exhibit conditions and symptoms that may warrant collection of samples for residue; explain how to segregate the animals and/or have the carcasses railed out or hung back for disposition; read and interpret the test results; gather the initial producer information from the establishment: complete FSIS Form 10,000.2 correctly.	• Sample kits • Seals • Shipping labels • Regulations • Directives • Notices • Retain tags • LIMS-Direct • PHIS •		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency for sampling and submission of laboratory specimens for pathology and residues described in this section without significant intervention by the mentor. For example: Preparing and submitting samples correctly; Completing forms ; Making proper disposition of carcasses; Retrieving results from LIMS-Direct; Entering data into PHIS. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Establishment Management Communication	☐ Understand weekly meetings held, attend at least one meeting, review NRs, discuss trends, systems and public health issues; document meetings. ☐ Be prepared to institute needed meetings upon arrival to duty station.	• Relationship principles • FSIS Directive 5010.1 • NRs • PHIS • memos		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of communication with establishment management regarding preparing and conducting weekly meetings without significant intervention by the mentor. **Comments:**
Labor Management Agreement	☐ Assignment rosters/scheduling – know who prepares; know how to read it; where to find it; what to do for staffing shortages; resource people and tools. ☐ Management rights and union rights – changes from old contract to new that cause problems; no consultation; right to assign work; 10MR/12 rule. ☐ Breaks – official breaks; who is responsible for breaks; when they are given. ☐ Grievances – understand they are part of the process; don't panic; don't take it personally; what to tell bargaining unit employee about continuing to work and filing grievance later. ☐ No past practices – national bargaining; what can set up past practice; how to avoid forming a past practice; understanding supervisory chain of command.	• LER specialist contact • LER training manual • Contract • Local duty rosters/schedule • Copies of grievance and response		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the Labor Management Agreement described in this section without significant intervention by the mentor. For example, Understanding the processes and knowing who to contact with questions. **Comments:**
Procedures	**Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed**	**Tools**	**Date completed**	**Basic Proficiency and /or Awareness Proficiency Level**

NFSCP verification	☐ Using methods described in FSIS Directive 7000.1 – understands scheduling; demonstrates performance of various NFSCP (formerly OCP) procedures as appropriate (e.g., FPS for poultry; carcass AQL, net weights; formulation check; X % solution); show establishment labeling files; understands when and how to document noncompliance.	• Regulations • Directive 7000.1		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of OCP verification described in this section without significant intervention by the mentor. **Comments:**
Wellness, Health and Safety in the establishment	☐ Demonstrate safe working habits – conduct establishment tour of exits, review emergency plan; review emergency phone numbers. ☐ Use of personal protective equipment (including lockout/ tag out) – review proper use of knives; verify they have all PPE; demonstrate lockout/tag out procedures; show location of first aid kit. ☐ Safety reports – demonstrate how to complete injury reporting forms; show log of injuries; review OWCP information; share information on contact at HRD. ☐ Workplace violence – explain policies and procedures; show red folder in government files; share information on 1-800 number to report incidents.	• Emergency posters, phone numbers, evacuation plan; • Directive 4791; • Injury report forms; • OWCP Handbook; • Contact information		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of Wellness, health and safety in the establishment as described in this section without significant intervention by the mentor. For example, Demonstrating safe working habits; accessing appropriate forms; knowing how to make appropriate contacts. **Comments:**
Procedures	**Description** **The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed**	**Tools**	**Date completed**	**Basic Proficiency and /or Awareness Proficiency Level**

Water Retention Issues	☐ Able to verify compliance to applicable directive – review establishment program, records, labeling.	• Establishment protocol		**High☐ Aver ☐ Low ☐** Has achieved basic and/or awareness proficiency of water retention issues described in this section without significant intervention by the mentor. **Comments:**
Administrative	☐ Has experience in and shows competence in completion of forms and proper distribution. ☐ T&A reports (full time and WAE) – WebTA; how to check inspector's T&As; when and how to approve leave; leave balance; proper use of FMLA; who applies for what leave. ☐ Staffing – process; who to contact with questions; pull patterns; District practices. ☐ Appeals – format; how to respond; who to call with questions. ☐ Travel vouchers – Concur; where to submit; travel authorization; who to call with questions; CONUS. ☐ FSIS form 5110 – 1. – reimbursable vs. non-reimbursable ☐ Supply requisitions – show forms; how to place order; when to place order by fax, email, mail, in case of emergency; how to handle accountable items. ☐ Official reference material; able to locate, use and apply – Index, FSIS Intranet, FSIS web site; how to locate Directives, Notices, Regulations, Interim Regulations; askFSIS, etc.	• Forms • Directives • Resource persons names and phone numbers • Government files • Concur • WebTA • FSIS Intranet • FSIS web site • askFSIS		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the administrative procedures described in this section without significant intervention by the mentor. For example, Completing forms, accessing Agency resources, and making necessary contacts to get answers to questions. **Comments:**
Procedures	**Description** **The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed**	**Tools**	**Date completed**	**Basic Proficiency and /or Awareness Proficiency Level**

Administrative (continued)	☐ Official file maintenance. ☐ Computer efficiency – how to maintain files; how to locate files specifically of interest to district . ☐ Access LIMS-Direct Pathogen Reduction and Residue Data Security maintenance. ☐ Access current regulations on the internet. ☐ Use of data – understand how to use PHIS. ☐ SF 1164 – Use Notice to complete their own; review other samples for adequacy. ☐ Credit card use – discuss responsibilities.			
Human Resources Administrative Duties	☐ Awareness of practical application of: ☐ Performance evaluation; select elements, establish standards, monitor performance, complete FSIS form 4430-5, conduct evaluation interview. ☐Career counseling ☐Within-grade increase. . ☐Merit promotion. ☐Work Unit meetings – conduct one if possible. ☐What is contained in the inspector's personnel file. ☐Demonstrate in-plant application. ☐Show organization of files, bulletin boards. ☐Demonstrate use of Agency resources. ☐Reinforce the importance of setting performance standards and linking them to personnel actions.	• Government files • Bulletin boards • User guides • Electronic resources • Forms		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the human resources administrative duties described in this section without significant intervention by the mentor. For example, Understanding how to access resources, using forms, maintaining personnel files. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
IPPS Assessments	☐ **Process** – Explain when and how to conduct assessments; how to give feedback; how to document and share results; review the method; frequency = Minimum of 2 times per year; who performs and who receives the IPPS assessments. ☐ **Tools** – AssuranceNet; Show how to access Supervisory Guidelines; show how to use Form 4430-.8 and store results electronically.	• FSIS Directive 4430.3; Rev. 1 • Form 4430-8 • Supervisory Guideline and CFR • AssuranceNet • FSIS Intranet		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the IPPS assessments described in this section without significant intervention by the mentor. **Comments:**
Team leadership	☐ Open communication with inspection team – discuss expectations of both parties orally and electronically. ☐ Observe effective delegation of appropriate duties and supervision – discuss application in establishment setting with inspection personnel. ☐ Discuss expanded public health assurance duties and the team concepts of working with EIAOs and other PHVs. ☐ Problem solving observed; demonstrate inspection team's joint efforts.	• New EIAO-trained PHV GS 12 position description (or latest draft).		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of leading a team as described in this section without significant intervention by the mentor. For example, Demonstrating behaviors consistent with Agency expectations. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Export certification	☐ Certificate preparation ☐ Product examination ☐ Requirement determination ☐ Export Training- AgLearn	• Regulations • Directives (9000.1) • Notices • Export Library		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of export certification procedures described in this section without significant intervention by the mentor. **Comments:**
Recalls	☐ Explain procedures – identify District Recall Officer, District Case Specialist; explain how DO manages recalls. ☐ Understand role of PHV in recall process – explain how they may be asked to assist with effectiveness checks based on direction from DO.	• Regulations • Directives (8080.1) • Notices		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the recall procedures described in this section without significant intervention by the mentor. **Comments:**

Procedures	Description The intern / trainee should demonstrate to the mentor that these procedures/policies are understood and/or performed	Tools	Date completed	Basic Proficiency and /or Awareness Proficiency Level
Professionalism	☐ Demonstrate the level of professionalism required by the Agency. ☐ Become familiar with the Code of Ethics and Conduct. Questions How does professionalism of my direct reports and of me impact my ability to enforce regulations and improve public health?	• Handbook of Professionalism • IKE scenarios • Directive 4735.3		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of professionalism described in this section without significant intervention by the mentor. For example, Demonstrating behaviors consistent with Agency expectations. **Comments:**
Computer skills	Apply computer training : ☐ FSIS Intranet ☐ Word processing; internet use ☐ FSIS Computer Helpdesk ☐ Forms ☐ IKE & HIKE scenarios ☐ eAuthentication Use of government computer: ☐ Review how to use computer tools PHIS, LIMS-Direct, AssuranceNet ☐ Show how to send e-mails & attachments. ☐ How to access NRs & Appeals ☐ Review use of government computer criteria ☐ AgLearn access and use ☐ Location of training materials online	• PHIS • LIMS-Direct • AgLearn • Outlook • Footprints • AssuranceNet • Intranet		**High☐ Aver ☐ No ☐** Has achieved basic and/or awareness proficiency of the computer skills described in this section without significant intervention by the mentor. For example, Demonstrating skills consistent with Agency expectations **Comments:**

Mentor's Final recommendation: **I have directly observed and also have received indirect feedback (written and/or oral) regarding this intern / trainee and have taken all of this into consideration to the best of my ability. I have concluded that:**

☐ This PHV has achieved basic proficiency and/or awareness proficiency of all of the procedures detailed in this checklist.

☐ This PHV has NOT achieved basic proficiency and /or awareness proficiency of all of the procedures detailed in this checklist.

The Frontline Supervisor and/or the District Manager of this PHV have been made aware of those procedures NOT meeting basic and /or awareness proficiency. ☐ YES ☐ NO

Explanation/Comments:

Mentor Guidelines for Using the PHV Intern Checklist

1. The PHV Intern / Trainee Checklist should be used by the mentors as a guide outlining the major areas of responsibility facing the intern in his/her first position of authority in an FSIS establishment (IIC, PHV, relief PHV, etc).

2. Interns / Trainees should primarily work with mentors -- not spend a significant amount of time reading regulations or viewing informational CDs. Reference materials should be used to supplement hands-on mentoring.

3. Interns should understand and be able to perform daily operational procedures ("survival skills") that are accomplished at the mentoring facility. Mentors should cover checklist items either by intern shadowing, or through discussions and/or demonstrations.

4. Mentors should arrange alternate species training experience for interns to at least introduce those additional species. (For example: If the mentoring facility is a cattle only operation, the mentor should arrange one day visits to swine and poultry establishments for the intern, if possible).

5. If processing operations are not performed at the mentoring facility, the mentor should arrange processing training for the intern / trainee at a nearby facility, when possible.

6. If the PHV has been with the Agency for two or more years, the PHV should be assigned to you to receive one week of alternate species mentoring. If this is not the case, please discuss this with the DM and perhaps an alternate mentor can be scheduled, even if it is in another District.

7. Prior to the arrival of all PHVs, mentors should verify the assignment with the District Office. Clarify that it meets the guidelines provided herein.

8. **Mentors should submit completed PHV Intern / Trainee Checklists to their District Office no later than one week after completion of intern training.**

   Submit either by fax, mail, or electronic mail to the current District Office Training Contact.

9. District Office Training Contact will submit the checklists before the end of the week nine of the PHV 10-week program via email to the CFL Class Registration email box, via U.S. mail/FedEx, or fax to the Distance Learning Branch at:

   USDA, FSIS, OOEET, CFL, Distance Learning Branch
   5601 Sunnyside Ave
   Mail Stop: 5270
   Beltsville, MD 20705
   Phone (800) 336-3747
   Fax (301) 504-3372

Email: CFL.ClassRegistration@fsis.usda.gov

Please send an email to CFL Class Registration to alert the DLB that the completed checklist had been faxed or mailed.

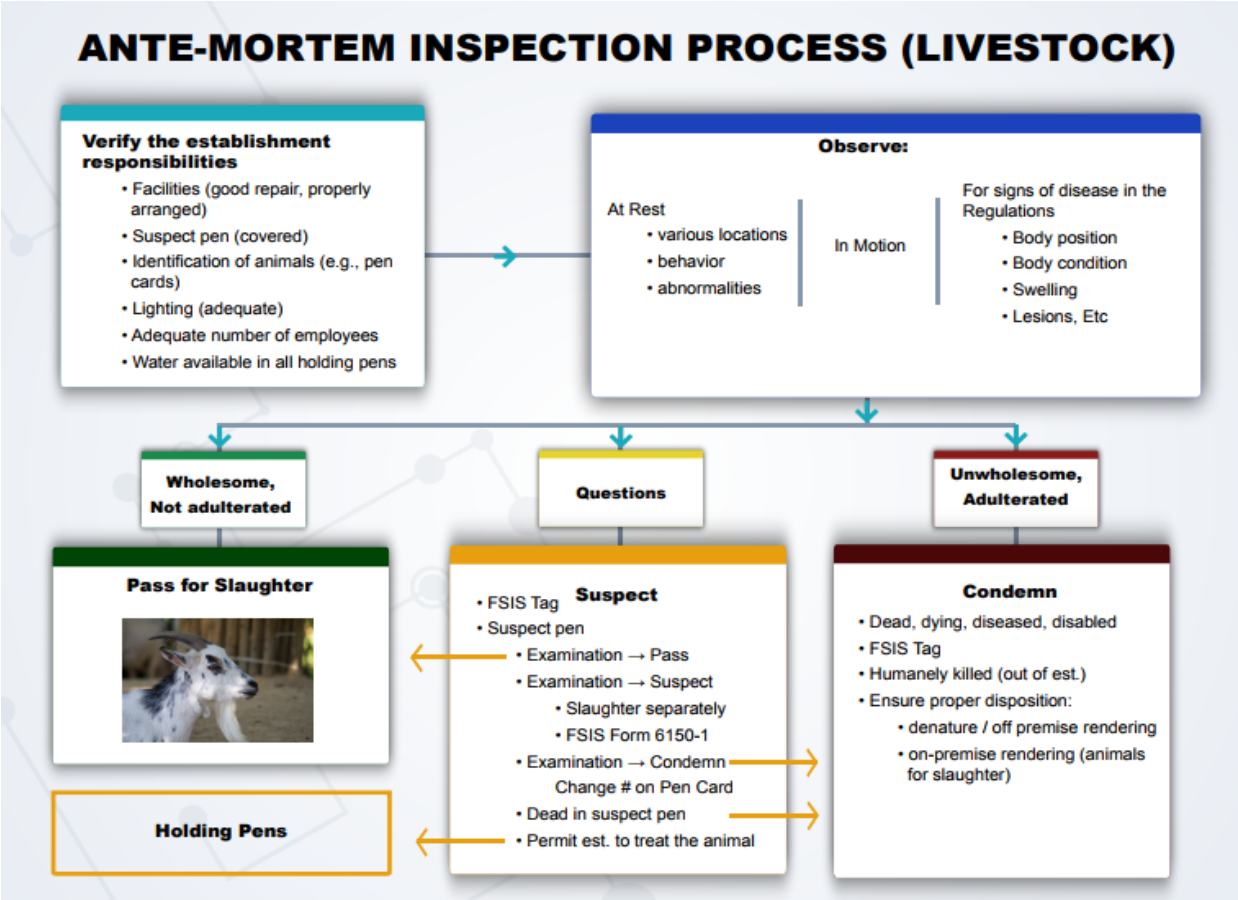
Ante-Mortem (AM) Inspection

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Ante-Mortem Learning 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. Demonstrate accountability for accountable items. **Residue Learning Objectives*** **Scientific:** 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. **Regulatory/Administrative:** 1. Given an in-plant scenario, identify the conditions and animal classes that call for a PHV to perform inspector-generated, in-plant residue test using FSIS Directive 10,800.1, Revision 1. **Taught as part of Ante-Mortem*

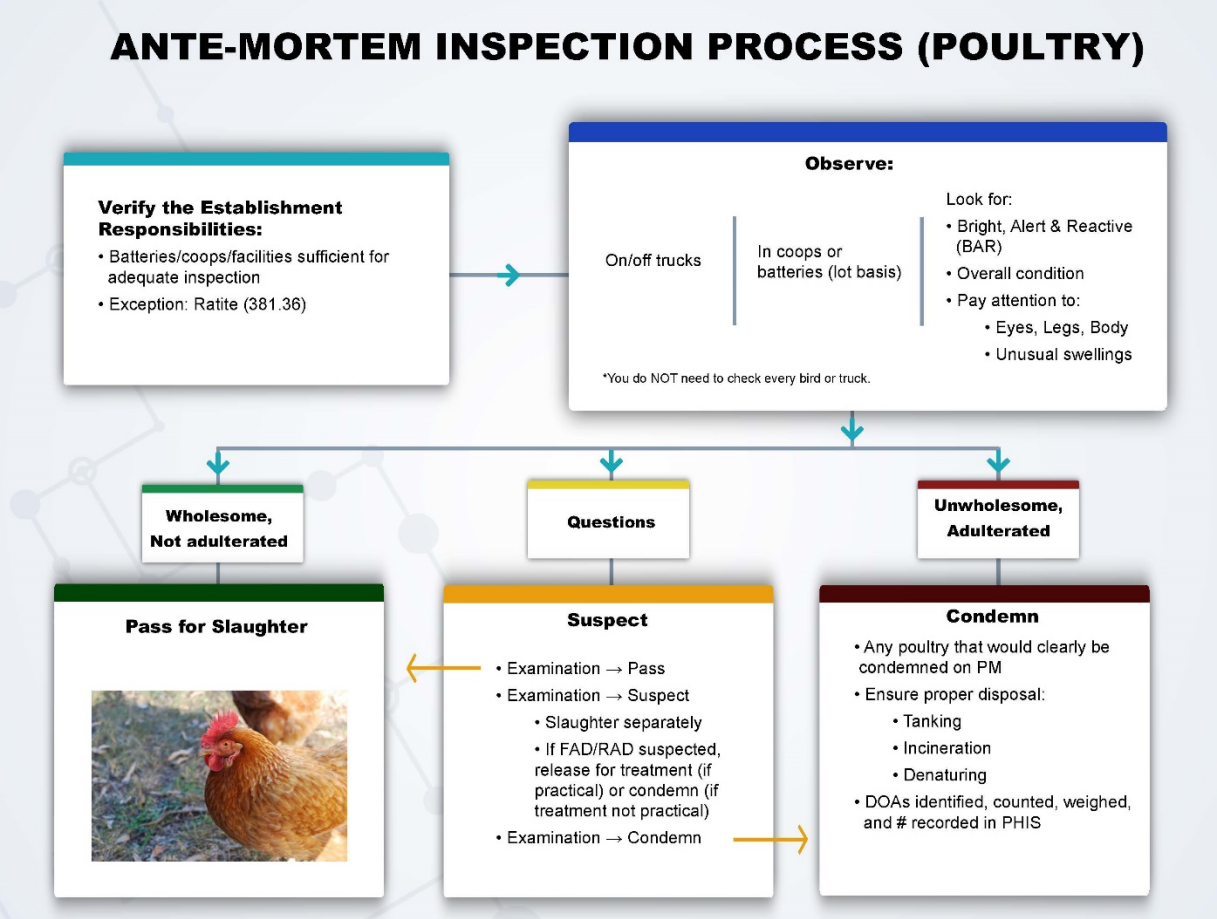
Slides	AM BIG PICTURE
2-6	Using your resources, answer the following questions for both livestock and poultry: 1) What is AM inspection? _____ _____ _____ _____ 2) Why do we do AM inspection? _____ _____ _____ _____ 3) What are the establishment requirements? _____ _____ _____ _____ _____ _____ _____ _____ 4) What are the possible outcomes? _____ _____ _____ _____

Slides	AM OVERVIEW
7	**AM Inspection Process Overview Flowchart 1**



7

AM Inspection Process Overview Flowchart 2



8	**What are the main parts in livestock AM inspection?** • Observe the animals at rest _____ _____ • Observe the animals in motion _____ _____
9	**When/where do you observe poultry during AM inspection?** • Observe the overall condition of birds _____ _____ • Before or after removal from trucks _____ _____

10	**Livestock vs. Poultry** • Livestock – ALL livestock presented for slaughter must receive AM inspection • Poultry – AM inspection performed on enough birds to get a sense of overall condition • What do you look for? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
Slides	**ALTERNATIVES TO THE NORM**
11-14	Using your resources, answer the following questions: 1) What is delayed slaughter? _____ _____ _____ _____

2) What is emergency slaughter?

_____
_____
_____
_____

3) What is voluntary segregation?

_____
_____
_____
_____

4) What species are eligible for each of the above?

_____
_____
_____
_____

5) Which establishments are eligible for each of the above?

_____
_____
_____
_____

15	**AM Dispositions Refresher!** What are the 3 possible outcomes after observation? 1. _____ 2. _____ 3. _____
16-19	**AM Dispositions** 1. _____ _____ _____ _____ _____ _____ 2. _____ _____ _____ _____ _____ _____ 3. _____ _____ _____ _____ _____ _____

20

Temperature Ranges

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:				

21

Non-Ambulatory Disabled (NAD) Cattle

- All NAD cattle MUST be condemned
- Only applies to cattle
- Why is this the case?

22

Central Nervous System (CNS) Signs

- What is wrong with the cattle pictured in the course presentation?
- What do we do with these animals?

23	**Question 1:** What ante-mortem disposition would you make with a market hog that is unable to rise and walk that has a temperature of 103.5 degrees Farenheit? _____
24	**Question 2:** What would your ante-mortem disposition be of this bovine that is unable to rise and walk due to a fractured hind leg? _____
Slides	**BEEF VIDEO**
25	Watch the video and answer the questions below. When should livestock be examined for AM inspection? (0:13) _____ _____ Are the animals provided with sufficient room? (0:21) _____ _____ Are the pens cleaned and well drained? _____ _____ 9 CFR 313.2 Handling of Livestock (a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed. Is the barn worker doing a good job? _____ _____

Does the PHV need their hearing protection on their ears?

_____

_____

What is in the blue tank? Is it available at all times?

_____

_____

D. 6100.1 – Personal Safety

(a) When IPP conduct routine ante-mortem examination of livestock, personal safety is paramount. IPP are to conduct ante-mortem verification with establishment helpers (9CFR 307.2) (a)) from a safe and suitable vantage point, taking into consideration the size and temperament of livestock.

In the ante-mortem area, is there a regulatory requirement to have a headgate?

_____

_____

What environmental conditions should you be aware of?

_____

_____

Is it sufficient to look at the floor?

_____

_____

What actions, if any, should be considered regarding this animal?

_____

_____

Is this animal a good candidate for drug residue testing? Explain your answer.

_____

_____

What do we do if we suspect the livestock?

_____

_____

_____

_____

What is a pen card? Who fills it out?

_____

_____

_____

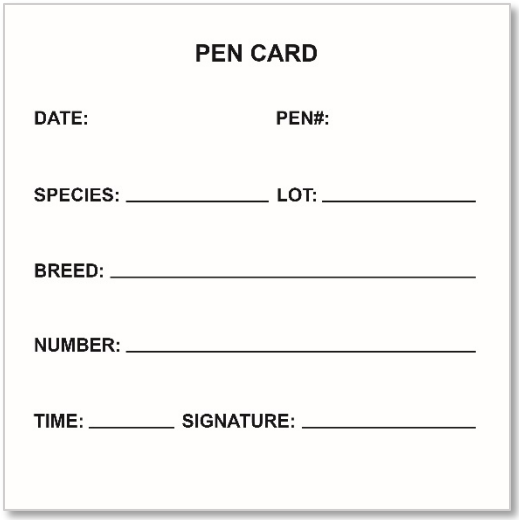
_____

_____

_____

_____

_____


PEN CARD

DATE: PEN#:

SPECIES: _____ LOT: _____

BREED: _____

NUMBER: _____

TIME: _____ SIGNATURE: _____

What are the elements of a pen card?

_____

What happens if the animals haven't received AM inspection and then go to slaughter?

_____

_____

6100.1 – Steps to follow when conducting ante-mortem inspection

- B. IPP are to perform ante-mortem inspection on the day of slaughter by observing all livestock (except at establishments that have voluntary segregation procedures described in Section XI):
  1. At rest; and
  2. In motion. IPP are to observe livestock from both sides when the slaughter class (e.g., cows and bulls) or condition of the animals (e.g., diseased, distressed) at the slaughter establishment supports observing from both sides in order to determine whether they are fit to slaughter for human consumption. At establishments where IPP other than PHVs perform ante-mortem inspection, the PHV is to correlate with the IPP on which animals the IPP are to observe from both sides.

What should IPP observe when conducting ante-mortem inspection?

- C. When performing ante-mortem inspection (9 CFR Part 309), IPP are to observe:
    1. The overall condition of each animal, including the head, with attention to the eyes, the legs, and the body of the animal;
    2. The degree of alertness, mobility, and breathing; and
    3. Whether there are any unusual swellings or any other abnormalities.

Common Abnormalities:

_____

_____

Question: Per the regulation, is it required to view both sides of the animals?

_____

_____

Question: The barn worker is using the rattle paddle as indicated.

_____

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What else do we see?

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If we want to do a residue sample, do we collect all of the animal ID? Why?

_____

_____

Slides	POULTRY VIDEO
26	Watch the video and answer the questions below. When is poultry AM inspection conducted? _____ _____ What are the safety considerations? _____ _____
Slides	**OTHER EXAMPLES**
27-29	Swine: _____ _____ _____ _____ Goats: _____ _____ _____ _____ Squab: _____ _____ _____ _____

Slides	RESPONSIBILITIES
30	Which are establishment responsibilities? Which are the PHVs?

Establishment Responsibilities	PHV Responsibilities

Slides	ACCOUNTABLE ITEMS
31-33	**Accountable Items Activity** Which items are accountable? Which are non-accountable items?

Accountable Items	Non-Accountable Items

35	**Accountable Items – Inventory Form** Notes: _____ _____ _____ _____ _____

Slides	ANTE-MORTEM CASE STUDIES: CASE STUDIES PART 1
36-38	**Case Study: NAD Bovine** While performing ante-mortem inspection in a livestock facility, you note NAD bovine. Choose the correct outcome: _____ _____ Click to view the 6150-1 Form. _____ _____ What needs to be completed when an animal is ante-mortem condemned? _____ _____ _____ _____ _____ _____ Why are NAD cattle ineligible for slaughter? _____ _____ What other actions would a PHV take if other neurological symptoms were noted, such as twitching, nystagmus, seizures, circling in an ambulatory animal, etc.? _____ _____

39	**Case Study: NAD Swine** What if the animal was a NAD pig or sheep instead of a bovine and the temperature is 104 degrees Farhenheit? Which of the following options would be your best choice? _____ _____ This particular animal may not be able to move on its own, and will require some form of equipment to move it to slaughter. What is considered an acceptable method to move this animal? _____ _____ What other symptoms, if present, would result in an ante-mortem condemnation? _____ _____ What other steps would a PHV need to take if neurological signs were present? _____ _____
40-42	**Case Study: Acti** You are performing AM insepction at a livestock facility and a beef cow is identified to have a mandibular mass. Which of the following options would be your best choice? _____ _____ § 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. _____ _____

	§ 311.9 Actinomycosis and actinobacillosis _____ _____
43-44	**Case Study: Poultry** You're at an establishment that slaughters spent hens. You have a truck with 5% dead on arrival (DOA), and it is extremely hot outside. What is your disposition for the lot in this situation? _____ _____ True or False? DOA birds must be tagged with Z-condemn tag. _____ _____ True or False? DOA birds must be denatured or secured in a properly marked container by government seal. _____ _____ True or False? DOA birds must be weighed and reported on Form 9061-2 (Poultry Condemnation Certificate). _____ _____ True or False? Establishments may bring DOA birds into the establishment if they watch them closely. _____ _____

Slides	ANTE-MORTEM CASE STUDIES: CASE STUDIES PART 2
45	As you make your diagnoses and dispositions, think about: • What is the information? _____ _____ • Where can you look to get more information? _____ _____ • When do you go to your supervisor? _____ _____
46-50	**AM Inspection: Case Study 1** While performing ante-mortem inspection at a livestock facility, you notice a dairy cow with a lesion on her udder. What is the correct diagnosis? _____ Based on your diagnosis, which of the following options would be your best choice? _____ Do you need to conduct a KIS test on PM? _____ § 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. _____ _____ § 311.16 Carcasses so infected that consumption of the meat may cause food poisoning. _____ _____

51-55	**AM Inspection: Case Study 2** While performing ante-mortem inspection at a livestock facility, you notice a beef/dairy cow with a mass protruding from her eye. What is the correct diagnosis? _____ Based on your diagnosis, which of the following options would be your best choice? _____ _____ Do you need to conduct a more thorough post-mortem examination? _____ _____ § 309.2(e) Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. _____ _____ § 309.6 Epithelioma of the eye. _____ _____
56-58	**AM Inspection: Case Study 3** While performing ante-mortem inspection at a livestock facility, you notice a beef/dairy cow with bulging eyes. What is the correct diagnosis? _____ Based on your diagnosis, which of the following options would be your best choice? _____

	§ 309.2(a) Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. _____ _____ § 311.11 Neoplasms _____ _____
59-63	**AM Inspection: Case Study 4** While performing ante-mortem inspection at a livestock facility, you notice a pig with a skin condition. What is a possible diagnosis? _____ _____ Based on your diagnosis, which of the following options would be your best choice? _____ _____ § 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. _____ _____ Do we see diamond-skin in other species of livestock? _____ _____

	What other signs/symptoms should you take into consideration? 1. Monitor temperature _____ _____ 2. Would taking this particular animal's temperature cause excessive and undue stress? _____ _____ 3. Are there other animals affected? _____ _____
Slides	**ANTE-MORTEM KNOWLEDGE CHECK**
65-70	**Knowledge Check 1** State the body temperature (in Farenheit) at which each of the following species must be condemned. (a) Cattle: _____ (b) Sheep: _____ (c) Swine: _____ **Knowledge Check 2** Which tag should be used for tagging an animal found dead in the pens? _____ _____ **Knowledge Check 3** A non-ambulatory disabled (NAD) animal is _____.

	Knowledge Check 4 Choose the answer that best completes this sentence. An animal is considered U.S. Suspect when it: _____ _____ _____ **Knowledge Check 5** Emergency slaughter is: _____ _____ _____ **Knowledge Check 6** Select those that the official establishment is required by regulation to provide: _____ _____ _____ _____
Slides	**SUMMARY**
71	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Humane Handling & Good Commercial Practices

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. Select acceptable methods for moving a conscious, disabled animal 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 GCP's according to prescribed standards. **Regulatory/Administrative:** 4. Differentiate between situations in which a PHV would document an MOI, (e.g., mistreatment of live birds) and other situations in which a PHV would document a noncompliance. 5. 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. 6. Given scenarios, recognize the humane handling responsibilities in the Delivery/Holding context that apply to FSIS, the establishment or both, and use the Humane Slaughter Act and 9 CFR 313 to determine whether an establishment's animal handling is compliant.

Slides	HUMANE HANDLING
2	**Humane Slaughter** The use of humane methods in the slaughter and handling of livestock: • Prevents needless suffering • Safer working conditions • Improves quality of meat products
3	**First Humane Slaughter Law** Humane Slaughter Act of 1958 • Voluntary for packers that did not sell to the Federal government • Required animals be rendered insensible prior to slaughter

4	**Humane Methods of Livestock Slaughter Act (1978)** • Humane methods became mandatory • Two methods specified as humane • Livestock must be rendered insensible to pain before being shackled, hoisted, thrown, cast, or cut _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

5	**Humane Slaughter Act of 1978**
	
	Section 1906
	• Ritual slaughter
	  ○ Kosher
	  ○ Halal

6	**FSIS Regulatory Basis** • Humane Slaughter of Livestock Act 1978 _____ _____ _____ • FMIA Section 603 _____ _____ _____ • CFR 9 Part 313 – Humane Slaughter of Livestock _____ _____ _____ • Directive 6900.2 _____ _____ _____ _____ _____ _____ • FSIS Notice 09-18 _____ _____ _____ _____ _____

7	**Humane Methods of Livestock Slaughter Act**
	
	• FSIS Notice 09-18
	• Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves
	  ○ Non-ambulatory disabled cattle, including veal calves, that are offered for slaughter, must be condemned and promptly euthanized
	  ○ Removes a provision in 9 CFR 309.13(b)
	
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8	**Additional Resources** • FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock ○ Federal Register Docket No. FSIS-2013-003 • Humane Interactive Knowledge Exchanges (HIKEs) • askFSIS _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

9	**Systematic Approach** • Conduct an initial assessment • Design facilities and implement practices • Evaluate periodically the handling methods • Respond to the evaluations • FSIS Notice 34-18

10	**Ritual Slaughter** • Stunning is not required • Razor-sharp knife used • Death due to blood loss

11	**Scenario 1** At a particular goat slaughter establishment that performs ritual slaughter, the religious authority has stipulated that the animals be knocked with a captive-bolt stun gun after the ritual cut. While observing slaughter at this establishment, the CSI observes a goat being ritually cut and then stunned with a captive-bolt device. The animal is laid on the floor prior to shackling where it promptly raises its head and rolls up to a sitting position with its front legs tucked in. The establishment employee in the area is in the process of shackling and hoisting another animal and does not notice the animal in the sitting position until the inspector brings it to his attention. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

12	**Scenario 2** A steer is ritually slaughtered and, after the ritual cut and bleed-out period, is hung on the overhead rail for dressing. An establishment employee, noticing the animal's sides moving in a rhythmic manner, lightly taps one eye which elicits a slow eye blink. He immediately picks up a hand held captive bolt gun from a stand in the hoisting area and applies it to ensure the animal remains insensible throughout the dressing procedure. The employee reports it to management, who then investigate for possible causes and corrective actions as part of its systematic approach to humane handling and slaughter. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

13	**Truck Unloading** • Part of establishment • Meet regulatory requirements • APHIS 28 Hour Law • Can perform AM inspection on truck

14	**Scenario 3** A sow goes down at the bottom of the truck unloading chute. Dozens of swine continue to exit the trailer for several minutes repeatedly stepping on and hitting the downed sow which vocalizes loudly in response. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

15	**Scenario 4** As a truckload of market hogs are unloaded, it is apparent that there are a considerable number of "slow moving" animals in the group. The establishment employees recognize this and sort the "slow moving" hogs into a separate lot according to the establishment's program for handling such animals. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

16	**9 CFR Part 313.1 – Humane Slaughter of Livestock** • 313.1 – Pens, Driveways, and Ramps ○ Kept in good repair ○ Kept free of objects which may injure, cause pain ○ Provide good footing _____

17	**Scenario 5** Ice, snow, or mud buildup is causing cattle to slip and slide on the unloading chute. Two animals fall down but immediately rise and appear unhurt. • Does this scenario represent noncompliance? _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

18

Pop Quiz! – Image 1

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Pop Quiz! – Image 2

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Pop Quiz! – Image 3

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21	**Scenario 6** Several nail heads are protruding from the wooden boards on the inside of the unloading chute. Large clumps of hair are adhered to some nail heads. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

22

Pop Quiz! – Image 4

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23	**9 CFR 313.2 – Handling of Livestock** • Drive at walk, minimum excitement • No sharp objects • Electric prods <50 volts _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

24	**Scenario 7** An electric battery operated prod is used only occasionally on balking swine at the conveyor-restrainer entrance. The prod is never used on the anus, eyes, ears, or other sensitive parts and is not used excessively on any of the animals. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

25	**Scenario 8** Establishment employees used an electric prod to shock all of the cattle when moving them up to the stunning area even though they don't appear to be balking. Numerous animals "flinch" in response to the prodding. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

26	**9 CFR Part 313.2 (Continued)**
	
	• Handling of Disabled animals
	  ○ No dragging of conscious animals
	  ○ Stunning
	• Access to water and feed
	  ○ Water in all holding pens
	  ○ Feed if held over 24 hours
	• Secondary entrances
	
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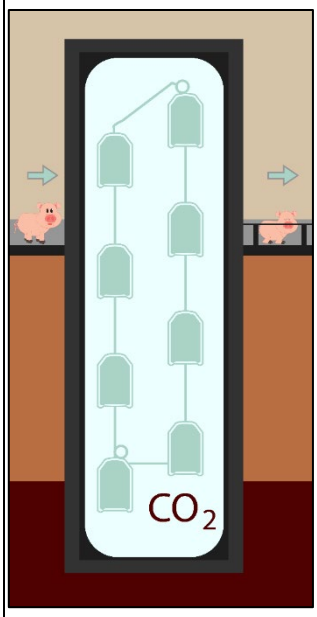
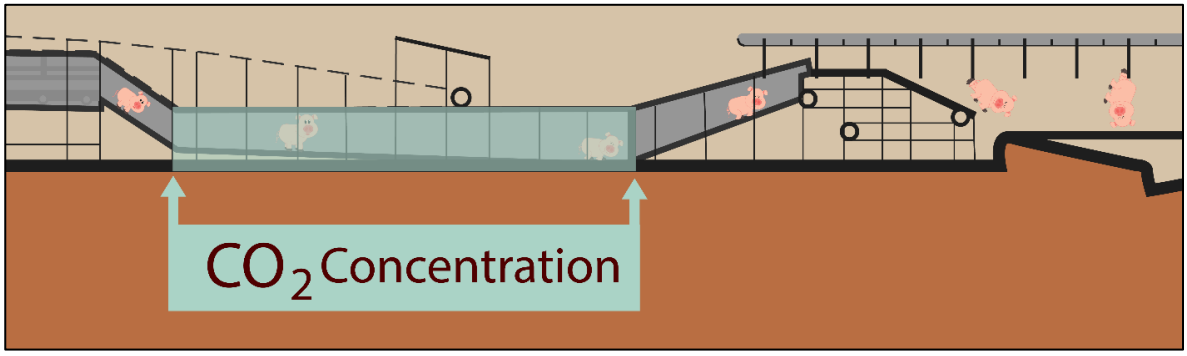
27	**Scenario 9** An establishment employee drags a non-ambulatory disabled conscious lamb from the front of a trailer. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

28	**Scenario 10** Cattle are left in the alleyway overnight and cannot reach the water troughs. All animals appear to be in good condition. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

29	**9 CFR 313 – Stunning Methods** • Chemical: Carbon Dioxide • Mechanical: Captive Bolt • Mechanical: Gunshot • Electrical _____ _____ _____ _____ _____ _____ _____ _____
30	**Chemical: Carbon Dioxide** • Approved for swine, sheep, and calves • Must induce anesthesia quickly and calmly • Equipment must be in good repair • Instruments/indicators must be available for inspection • CO_2 levels must be consistent _____ _____ _____ _____ _____ _____ _____ _____

31	**Chemical: Carbon Dioxide (Continued)** 
32	**Chemical: Carbon Dioxide Administration** 

33	**Scenario 11** A group of market hogs are hung on the line after carbon dioxide stunning. Prior to the stick, one hog begins to show signs of a potential return to sensibility with rhythmic breathing and spontaneous blinking. Establishment employees notice this and immediately stun the animal with a handheld captive bolt gun kept at that location specifically for that purpose. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

34	**Mechanical Stunning**
	
	• Approved for cattle, calves, sheep, swine, goats, and equine
	• Two types:
	  ○ Captive Bolt
	  ▪ Powered by air or gunpowder cartridge
	  • Penetrating
	  • Non-penetrating
	  ○ Gunshot
	
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35	**Captive Bolt: Penetrating** _____ _____ _____ _____ _____ _____ _____ _____

36	**Captive Bolt: Non-Penetrating** _____ _____ _____ _____ _____ _____ _____ _____

37	**Captive Bolt Stunning**
	
	• Require well-trained operators
	• Must be able to consistently produce immediate unconsciousness with one shot
	• Air pressure powered guns:
	  ○ Have accurate gauges
	  ○ Have consistent air pressure
	  ○ Be adjustable for larter/smaller animals
	• All parts of head may be saved for food
	
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38	**Scenario 12** Inspectors at the cattle head inspection station notice that some heads have 2 or 3 "knock holes". They notify offline IPP of the multiple knock holes. The offline inspector immediately proceeds to the stunning area and observes that establishment personnel consistently produce insensibility with one shot of the captive bolt gun. The establishment has a good history of properly stunning animals and sometimes the employee doing the knocking administers additional "security" knocks to ensure animals remain insensible. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____

39	**Gunshot** • Approved for cattle, calves, swine, sheep, goats, and equine • Must produce unconsciousness with one shot • All head tissues must be condemned except the tongue _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

40	**Scenario 13** A small caliber rifle is discharged into the center of the forehead of a mature bull with a heavy winter coat. The bull vocalizes and remains standing but does not try to move away from the establishment employee who fired the rifle. The employee reloads the rifle and repeats the procedure with the same result and the animal is now very agitated and bleeding from the head. A third shot has the same ineffective results and a fourth shot finally renders the bull insensible. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

41	**Scenario 14** A small caliber rifle is discharged into the center of the forehead of a mature bull with a heavy winter coat. The bull vocalizes and remains standing but does not try to move away from the establishment employee who fired the rifle. The employee immediately picks up a loaded higher caliber rifle from its holding rack next to the stunning box and discharges it. This second shot renders the bull insensible as determined by its falling to the floor and its wide open blank eyes. To assure the bull is insensible, the employee reaches down and lightly taps one eye; there is no response to the tap. The establishment has a good history of consistently rendering animals, including bulls, insensible with a single shot. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

42	**Gunshot**

43	**Scenario 15** A small heifer is in a large knocking box with plenty of room to move around and the operator is attempting to "chase" the animals head to deliver the stunning blow with a captive bolt knocking device. The operator completely misses the first attempt and, as the animal continues to move around to avoid the stunner, the second attempt strikes the animal's head off-center. The animal vocalizes loudly as a result but still does not go down. After two more unsuccessful attempts and several minutes, the animal is properly stunned. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

44	**Electrical Stunning**
	
	• Approved for swine, calves, cattle, sheep, and goats
	• Two methods depending upon electrode placement:
	  ○ **Head only stunning:** stun to bleed interval should not exceed 30 seconds
	  ○ **Head to body stunning (cardiac arrest):** stun to bleed interval not as critical
	
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45	**Electrical Stunning**

46	**Scenario 16** A head fork (or wand) placed behind the ears is used to electrically stun a market hog. The hog becomes stiff, goes down, and appears properly stunned. By the time it is hoisted on the line, rhythmic breathing has returned, the eyes begin to blink normally, and the front feet begin paddling motions. An establishment employee sticks the animal's neck and it responds with vocalization, struggling, and trying to lift its head while looking around until it expires from blood loss about 30 seconds later. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

47	**Scenario 17** An establishment uses a head-thorax (chest) electrical stunning device with two separate wands. An establishment employee places one wand in the hollow immediately behind one ear and the second wand on the middle of the thorax and then energizes the electrical stunner. The animal exhibits rigor, i.e., muscles become stiff with head lifted slightly, when the stunner is energized. When the wands are removed the pig drops but within a few seconds stands up fully conscious. The establishment employee does not know what to do and applies the device again with the same results. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____

48	**Exercise** View the video clips and answer the following: What method of stunning is used in each clip? Video Clip 1:

	Video Clip 2:

	Video Clip 3:

	Video Clip 4:

	Video Clip 5:

	Video Clip 6:

49

Discussion

Assessing Consciousness

How to Determine Insensibility

(Revised August 2007)

by Temple Grandin
Dept. of Animal Science
Colorado State University

In both captive bolt and electrically stunned animals kicking will occur. Ignore the kicking and look at the head. To put it simply, THE HEAD MUST BE DEAD. When cattle are shot with a captive bolt, it is normal to have a spasm for 5 to 15 seconds. After the animal is rolled out of the box or hung up its eyes should relax and be wide open.

Below are the signs of a properly stunned animal:

1. The legs may kick, but the head and neck must be loose and floppy like a rag. A normal spasm may cause some neck flexing, but the neck should relax and the head should flop within about 20 seconds. Check eye reflexes if flexing continues. Animals stunned with gas stunning equipment should be limp and floppy though they may exhibit slow limb movement.
2. The tongue should hang out and be straight and limp. A stiff curled tongue is a sign of possible return to sensibility. If the tongue goes in and out, this may be a sign of partial sensibility.
3. When the animal is hung on the rail, its head should hang straight down and the back must be straight. It must NOT have an arched back righting reflex. When a partially sensible animal is hung on the rail it will attempt to lift up its head. It will be stiff. Momentary flopping of the head is not a righting reflex.
4. When captive bolt is used the eyes should be wide open with a blank stare. There must be no eye movements. Immediately after electrical stunning the animal will clamp its eyes shut, but they should relax into a blank stare.
5. When captive bolt is used the animal must NEVER blink or have an eye reflex in response to touch. In electrically stunned pigs eye movements can be misinterpreted when untrained people indiscriminately poke at the eyes. It is often best to observe without touching the eye. If a pig blinks with a natural blink where the eye closes and then re-opens it is not properly stunned. If you are not sure what a natural blink looks like, go and look at live pigs in the yards (lairage) before assessing insensibility.
6. Rhythmic breathing must be absent. Gasping is a sign of a dying brain and is OK. A twitching nose (like a rabbit) may be a sign of partial sensibility.
7. In captive bolt stunned animals, insensibility may be questionable if the eyes are rolled back or they are vibrating (nystagmus). Nystagmus is permissible in electrically stunned animals, especially those stunned with frequencies higher than 50 or 60 cycles.
8. Shortly after being hung on the rail, the tail should relax and hang down.

9. No response to a nose pinch. Animals entering a scald tub must not make a movement that is in direct response to contact with the hot water. For all types of stunning this is an indicator of possible return to sensibility.
10. No vocalization (moo, bellow or squeal)

The above methods can be used for determining insensibility for all types of stunning and for ritual slaughter which is done without stunning. Just remember, kicking reflexes are normal in captive bolt stunned animals, electrically stunned animals and after ritual slaughter. They should be absent or very feeble for $C0_2$. Captive bolt stunning induces instant insensibility by both concussion and physical destruction of the brain. Stunner maintenance is essential to maintain maximum hitting power.

Electrical stunning, renders an animal instantly insensible by inducing a grand mal epileptic seizure. Scientific research has shown, that in order to induce the seizure the electric stunner must be set at a minimum of 1.25 amps for market weight pigs and 1 amp for sheep. Large sows will require 2 or more amps. If lower amperages are used the stunner may induce cardiac arrest but the animal will feel the shock because the seizure was not induced. Electrical frequencies up to 800 hz (cycles) can be used. Frequencies over 800 hz should not be used. Research has shown that 1500 cycles failed to induce instant insensibility. Animals that are dehydrated may have high electrical resistance and be difficult to stun.

In some plants, cattle or sheep are immobilized after electric stunning with a small electric current to stop kicking. This immobilizer current completely masks signs of return to sensibility. To assess return to sensibility the immobilizer current MUST be turned off. Electric immobilization is highly distressful to animals and it must never be confused with electric stunning, which induces instantaneous insensibility by passing a high amperage current through the brain.

If an electrically stunned animal blinks within 5 seconds after stunning this is a sign that the amperage is too low. In electrically stunned animals, blinking should be checked within 5 seconds and after 60 seconds. In most plants blinking will not be found immediately after stunning, because the plant is using the correct amperage. After it has been verified that the amperage is set correctly, the most important point to observe for signs of return to sensibility is 60 seconds after electrical stunning. This provides time for the eyes to relax after the epileptic seizure. Checking for signs of return to sensibility after bleeding insures that the animal will not recover.

When stunned animals are viewed from a distance, the most important signs to look for in a properly stunned animal are:

1. A floppy head
2. Tongue hangs straight out and is limp
3. The back and head hang straight down. There is no arched back righting reflex.

Animals that show all three of the above signs will be insensible and blinking and other eye reflexes will be absent.

Order of the events which indicate Return to Sensibility:

1. Single feeble eye reflex in response to touch (probably still insensible and not conscious).
2. Return of rhythmic breathing. This is a primary indicator of poor stunning and it may occur before the corneal reflexes.
3. Spontaneous natural blinking without touching (recommended sign for determining return to sensibility for regulatory purposes). In large plants this is easier to assess than rhythmic breathing.
4. Response to a painful stimulus such as pricking the nose with a pin. The stimulus must be applied to the head to avoid confusion with spinal reflexes.
5. Righting reflex and raises it's head.
6. Fully conscious and sensible. Complete return to sensibility can occur within 15 to 20 seconds after eye reflexes appear if an electrically stunned animal is not bled.

The American Meat Institute guidelines require that ALL of the signs of return to sensibility MUST be absent to pass an audit. Even thought an animal is probably insensible if it shows a weak corneal reflex or tongue movement, it is starting the process of return to sensibility. Weak indicators of return to sensibility can be abolished by improved stunning practices. Slaughter plants are not research laboratories where conditions are carefully controlled. Therefore a much greater margin of safety is required to ensure that the animal remains insensible.

An animal showing any of the above signs must be immediately re-stunned before any slaughter procedures are started.

50	**Scenario 18** A heifer has been stunned and hung on the line in the "stack". The animal's head and eyes give the appearance of being properly stunned (e.g., no blinking, no righting reflex, no rhythmic breathing, loose floppy tongue) but the legs are kicking violently. An establishment employee designated to watch the stack notices the kicking animal and immediately delivers a blow with a handheld captive bolt gun. The kicking continues despite the additional blow. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

51	**Scenario 19** A steer has been stunned with a captive bolt and hung on the line. While in the stack prior to sticking, the animal is vocalizing, observed to be blinking its eyes, swallowing and attempting to raise its head up towards and in line with its spine (i.e., a righting reflex). Establishment employees do not notice this animal until IPP attract their attention and have them render the steer insensible. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

52	**9 CFR 313 Enforcement Actions** • Notify establishment management • Tag equipment or area • Operations resumed if corrected and assurances given to not recur _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

53	**9 CFR 313 Enforcement Actions (continued)**
	
	• Document HH MOI Created in PHIS through the associated slaughter task
	  o Under “Findings” Tab
	  o Check “non-regulatory concerns”
	  o Select “Create/Edit MOI” button)
	
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54	**9 CFR 313 Enforcement Actions (continued)** • Egregious violations • Suspension of inspection • Contact DVMS/District Office _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

55	**Other Species**
	
	• Species not covered under the Humane Methods of Slaugher Act
	  ○ Exotics
	  ▪ 9 CFR 352.10
	  ▪ 9 CFR 352.10(a)(5)
	• Contact DVMS
	
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Slides	HUMANE ACTIVITIES TRACKING SYSTEM (HATS)
56	**HATS**
57	**HATS** • Assure humane handling requirements are met • Records the time spent performing humane handling related activities ○ Nine categories

58	**HATS**
	
	• FSIS Directive 6900.2, Rev. 2
	• Public Health Information System (PHIS)
	  ○ Livestock Humane Handling task
	  ○ Information recorded under HATS tab
	  ○ Information to be included in NRs
	
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59	**HATS**
	
	• IPPS Assignments
	  ○ 1 or more HATS activities
	  ○ Results into PHIS
	
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60	**HATS Analysis** • Who performs verification? _____ _____ _____ • All categories verified? _____ _____ _____ • Predictable patterns? _____ _____ _____ • Time entries reasonable? _____ _____ _____

61	**HATS: Nine Categories** • Category I – Adequate Measures for Inclement Weather • Category II – Truck Unloading • Category III – Water and Feed Availability • Category IV – Handling During Antemortem Inspection • Category V – Handling of Suspect and Disabled • Category VI – Electric Prod/Alternative Object Use • Category VII – Observation of Slips and Falls • Category VIII – Stunning Effectiveness • Category IX – Check for Conscious Animals on the Rail _____ _____ _____

62	**HATS: Category I**
	
	• Adequate Measures for Inclement Weather
	• How does the establishment adapt to inclement weather?
	  ○ 9 CFR 313.1(b)
	  ○ 9 CFR 313.2(e)
	
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63	**HATS: Category II**
	
	• Truck Unloading
	• Humane handling practices while unloading livestock
	  ○ 9 CFR 313.1(a)
	  ○ 9 CFR 313.1(b)
	  ○ 9 CFR 313.2(a)(b)
	  ○ 9 CFR 313.2(d)
	
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64	**Scenario 20** A local rancher is unloading a group of thirty small weaning pigs from a gooseneck trailer onto a ground level alley floor with no ramp. The pigs are jumping off the trailer and three of them, unable to gain traction upon landing, fall to the ground. The fallen pigs struggle to regain their footing and run excitedly into the alley but appear to be unhurt. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

65	**HATS: Category III** • Water and Feed Availability ○ 9 CFR 313.2(e) _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

66	**Scenario 21** Pens are overfilled with pigs to the extent that many cannot reach the water troughs. All of the animals appear in good condition. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

67	**HATS: Category IV**
	
	• Handling during Ante-mortem Inspection
	• *Note: This category only addresses verification activities covered by 9 CFR part 309.*
	  ○ 9 CFR 313.2(a)
	  ○ 9 CCFR 313.2(b)
	
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68	**Scenario 22** Brahma-cross cattle are running down the chute and alleyway from the unloading dock. They appear very excited and some foot slippage occurs but establishment employees are following recommended animal handling practices and do not appear to be doing anything to make them run or be excited. Floor surfaces are a slip resistant waffle-type concrete pattern. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

69	**Scenario 23** Bob veal calves are being calmly moved through an alleyway into a knocking box. One bob veal calf goes down just prior to the knocking box entrance. An establishment employee shocks the calf repeatedly with an electric prod. The calf vocalizes and tries to avoid the prodding but does not rise and the prodding continues. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

70	**HATS: Category V**
	
	• Handling of Suspect and Disabled
	  ○ 9 CFR 313.2(d)
	  ○ 9 CFR 313.1(c)
	
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71	**Scenario 24** A non-ambulatory disabled (NAD) dairy cow is present in a pen of animals presented for ante-mortem inspection by the establishment. When the establishment employee presenting the animals for ante-mortem realizes the cow is unable to rise, he moves the other cows to an adjacent pen in a calm manner that avoids any injury to the NAD cow. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

72	**Scenario 25** An establishment employee is operating a forklift using its sharp, bare metal forks to roll and lift a non-ambulatory disabled conscious cow. The cow vocalizes loudly in response. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

73	**HATS: Category VI**
	
	• Electric Prod/Alternative Object Use
	  ○ 9 CFR 313.2
	  ○ *Note: Does not include time spent performing category II or ante-mortem inspection*
	
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74	**Scenario 26** A cow in a chute with limited room to move (stopped animal in front and gate behind) is shocked repeatedly in the anus. The cow vocalizes loudly and tries to push against the animal ahead. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

75	**HATS: Category VII**
	
	• Observations for Slips and Falls
	  ○ 9 CFR 313.1(b)
	  ○ 9 CFR 313.2(a)
	
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76	**HATS: Category VIII**
	
	• Stunning Effectiveness
	  ○ Instructions for these regulations are set out in FSIS Directive 6900.2
	  ○ Religious slaughter
	  ○ 9 CFR 313.2(f)
	  ▪ 9 CFR 313.5
	  ▪ 9 CFR 313.15
	  ▪ 9 CFR 313.16
	  ▪ 9 CFR 313.30
	
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77	**Scenario 27** A small corral is loaded with multiple hogs for the purpose of stunning prior to slaughter. The first animal is stunned with scissor-type electrodes across the head and immediately goes down appearing to be insensible. Within a few seconds after release from the head scissors, the animal begins strong reflex kicking in the hind legs repeatedly striking a nearby hog which cannot get away due to the crowded condition. The hog vocalizes loudly as a result of being kicked and becomes increasingly agitated because of the kicking of the stunned animal. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

78	**Scenario 28** An attempt is made to stun a non-ambulatory disabled sow in the ante-mortem pens with a captive bolt gun but the animal moved its head at the last moment and the attempt failed, missing the head completely. The animal did not appear excited as a result of the missed attempt and the operator immediately applied another shot from a pre-loaded backup device with was successful in properly stunning the sow. The establishment has a good history of properly stunning non-ambulatory disabled animals. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

79	**HATS: Category IX**
	
	• Check for Consicous Animals on the Rail
	  ○ Section 1902 HMSA
	  ▪ 9 CFR 313.2(f)
	  • 9 CFR 313.5
	  • 9 CFR 313.15
	  • 9 CFR 313.16
	  • 9 CFR 313.30
	  ○ Religious slaughter
	
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80	**Scenario 29** A steer has been stunned with a pneumatic captive-bolt stunner and hung on the line in the "stack". The animal's head and eyes give the appearance of a properly stunned animal (i.e., no blinking, head hanging straight and floppy, and a loose floppy tongue). However, when the stick is administered the head is raised abruptly to the right and holds in that position for 3 to 4 seconds before dropping back into its original position. • Does this scenario represent noncompliance? _____ _____ _____ _____ _____ _____ • If so, is it an egregious situation? _____ _____ _____ _____ _____ _____ • What action should be taken by inspection personnel? _____ _____ _____ _____ _____ _____

81	**Off-hour HATS** • Off-hours truck unloading • Animals held over • AM injuries • Disabled or non-ambulatory animals • Public reports • AM deads _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

82	**HATS: Trend Determinations** • FSIS Directive 6900.2 • HAT categories should be helpful in NR association for the “same cause” _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

83	**HATS: Time Documentation**
	
	• PHVs and non-PHVs enter hours spent verifying each HATS category
	  ○ Quarter hour increments
	  ○ Large establishments
	  ○ Very small establishments
	
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Slides	POULTRY

84	**Poultry**
	
	• Statutory authority
	  ○ Poultry Products Inspection Act (21 U.S.C. 453(g)(5))
	• Regulatory authority
	  ○ 9 CFR 381.65(b)
	
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85	**Poultry (Continued)**
	
	• Other Agency issuances:
	  ○ FSIS Directive 6100.3
	  ○ FSIS Directive 6110.1
	  ○ FSIS Directive 7000.1
	  ○ HIKE Scenario 01-05
	  ○ Federal Register Docket No. 04-037N
	
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86	**Poultry (Continued)**
	
	• FSIS Directive 6100.3 and FSIS Directive 6110.1
	  ○ Verification
	  ○ Documentation
	
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87	**Poultry (Continued)**
	
	• FSIS Directive 6100.3
	  ○ Enforcement actions
	  ○ Poultry Good Commercial Practices task
	
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88	**Poultry (Continued)** • Noncompliance Records • Memorandum of Interview Letters _____ _____ _____ _____ _____ _____ _____ _____

Slides	KNOWLEDGE CHECK
89-	**Knowledge Check 1** Which of the following could be instances of noncompliance that could cause injury or discomfort to animals during unloading, weighing, or driving to the stunning area? (Select all that apply) _____ An unloading ramp with a 2-inch section of the planing missing. _____ Several bolts protruding from the pen posts. _____ Ante-mortem pens not covered. _____ Icy runways. _____ Floors in the pens are smooth concrete. **Knowledge Check 2** “Surgical Anesthesia” is best described as: _____ _____ **Knowledge Check 3** “Ritual Slaughter” is best described as: _____ _____ **Knowledge Check 4** Which of the following implements or methods, if not used in excess, could be used to drive or move livestock under Part 313 of the Regulations? (Select all that apply) _____ Canvas slapper. _____ Wooden club. _____ Battery-operated prod. _____ Bull whip. _____ Electric prod attached to AC current (transformer available). _____ Whistle. _____ Electric prod attached to AC current (no transformer available). _____ Flat-blade shovel. _____ Light leather strap, 2 inches wide. _____ Hand-held metal prod. _____ Lead goat.

Knowledge Check 5

The following methods are approved for humanely stunning animals: Caron Dioxide, Captive Bolt, Gunshot, and Electrical. _____

Knowledge Check 6

Animals that are delivered to the slaughter establishment at 3:30 p.m. on Monday are intended to be slaughtered no later than noon on Tuesday, would require both water and feed. _____

Knowledge Check 7

Inspector's Responsibilities

Establishment's Responsibilities

A. Provide adequate pens in good repair.
B. Adhere to all humane slaughter requirements.
C. Frequenly observe stunning procedures to determine whether livestock are insensivle to pain before shackling and bleeding.
D. Provide water and feed when necessary for animals.
E. Report any noncopmliance of humane handling regulatory requirements.
F. Provide acceptable means to move disabled animals.
G. Reject areas/equipment when inhumane treatment is observed.

Knowledge Check 8

You are performing the ante-mortem assignment and you observe an establishmet employee driving animals with a sharp pointed implement. Which of the following statements best describes the action you should take as identifieid in the regulations?

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	Knowledge Check 9 An animal that is conscious and not able to stand or walk, should be moved by which of the following methods? _____ _____ _____ _____ **Knowledge Check 10** An injured alert U.S. suspect may be dragged from the suspect pen to the knocking box. _____ **Knowledge Check 11** The establishment is using firearms to stun livestock. Which of the following is a true statement? _____ _____ **Knowledge Check 12** What action can be taken in response for historical trends of inhumane handling at an establishment? _____
Slides	**SUMMARY**
102	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Sanitary Dressing, Procedures for Controlling Contamination, and Food Microbiology

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. List potential situations of concern in the Delivery/Holding context, e.g., food security, ramifications for pathogens, etc. 2. Identify and explain conditions in the Delivery/Holding area that can affect sampling conducted during Processing. 3. Given a scenario depicting establishment practices such as mud-scoring, identify issues and conditions that could skew sampling results conducted during Processing. **Regulatory/Administrative:** *[None for this topic in this context.]*

Slides	INTRODUCTION
2	**Sanitary Dressing, Procedures for Controlling Contamination, and Food Microbiology: Introduction Activity** • List two examples EACH for both livestock and poultry in the livestock hauling/handling/pens that will affect Sanitary Dressing and Food Micro. Livestock: 1. _____ _____ 2. _____ _____ Poultry: 1. _____ _____ 2. _____ _____
Slides	**POULTRY RECEIVING SCENARIO – REVEAL PART 1**
4	**Poultry Receiving Scenario: Reveal Part 1** Scenario Facts Notes: _____ _____ _____ _____ _____ _____ _____ _____ _____

5	**Poultry Receiving Scenario: Reveal Part 1 (Continued)** Do you see any concerns/significant findings at this point based upon the scenario and pictures? Image 1 _____ _____ _____ _____ Image 2 _____ _____ _____ _____ Image 3 _____ _____ _____ _____ Image 4 _____ _____ _____ _____

6	**Poultry Receiving Scenario: Reveal Part 1 Discussion** Discussion Question 1: What would you do next? _____ _____ _____ _____ Discussion Question 2: Why do eggs on a trailer raise a concern with the young broilers being presented for slaughter? _____ _____ _____ _____ Discussion Question 3: What does this indicate about sanitation at the receiving step? _____ _____ _____ _____ Discussion Question 4: Could this affect the procedures for controlling contamination throughout slaughter, Sanitary Dressing operations, and Micro results? _____ _____ _____ _____

6	**Poultry Receiving Scenario: Reveal Part 1 Discussion Continued** Discussion Question 5: Has the establishment considered all the effects to their food safety system before, during, and after processing? _____ _____ _____ _____ Discussion Question 6: Are there any food defense concerns that you have at this establishment? _____ _____ _____ _____

Slides	POULTRY RECEIVING SCENARIO – REVEAL PART 2
8	**Poultry Receiving Scenario: Reveal Part 2** Scenario Facts Notes:

9	**Poultry Receiving Scenario: Reveal Part 2 Discussion** How would this contribute to the uptick in positive *Salmonellae* samples in this establishment?

Slides	SANITARY DRESSING KNOWLEDGE CHECK
11-12	**Knowledge Check 1** Which of these factors could affect the adequacy of the establishment's sanitary dressing procedures and the microbial results measuring process control? • Condition of the facility in which the animals are raised • Breed (i.e., Holstein, Angus) • Length of haul • Weather: rain, snow, heat • Age of establishment • Size of establishment • Feed withdrawal

YES	MAYBE/DEPENDS	NO

Knowledge Check 2

	Which of these factors could affect the adequacy of the establishment's sanitary dressing procedures and the microbial results measuring process control? • Construction of the poultry cages (e.g., wood, composition, plastic, iron, stainless steel) • Concrete vs. dirt pens • Number of employees • /sex of animal • Cleanliness of pens or cages • Length of time in the pens

YES	MAYBE/DEPENDS	NO

Slides	SUMMARY
13	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Requirements to Demonstrate Process Control of Slaughter

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 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 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. **Regulatory/Administrative:** *[None for this topic in this context.]*

Slides	INTRODUCTION
2	**Kickoff Activity** Learning Objective Notes:

3	**Group Activity** Using your resources, make a list of the steps needed to conduct the slaughter process. • Directive 5000.1 – Verifying an Establishment's Food Safety System _____ _____ _____ • Directive 6410.1 – Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age _____ _____ _____ • Directive 6420.5 – Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens _____ _____ _____ • Directive 10010.1 – Sampling Verification Activities for Shiga Toxin-Producing *Escherichia Coli* (STEC) in Raw Beef Products _____ _____ _____ • Directive 10010.2 – Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products _____ _____ _____

4	**Group Activity Discussion** Poultry Verification Steps: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ Livestock Verification Steps: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Slides	SANITARY DRESSING KNOWLEDGE CHECK
6-11	**Knowledge Check 1** You must complete the task on the day you being the task. _____ **Knowledge Check 2** The steps you are to evaluate are only to be after evisceration. _____ **Knowledge Check 3** You are only to evaluate micro data generated from slaughter. _____ **Knowledge Check 4** One observation from insanitary dressing practice is sufficient to complete the task. _____ **Knowledge Check 5** Evaluate only a single aspect of the slaughter process. _____ **Knowledge Check 6** You are to review data generated from MOIs and NRs from the past week. _____

Slides	PART A: POULTRY PROCEDURES FOR CONTROLLING CONTAMINATION THROUGHOUT THE SLAUGHTER AND DRESSING OPERATION
13	**Poultry Slaughter Process** Discussion 1 • What would you look for at this point in the process? _____ _____ _____ _____ • What might go wrong and what would be evidence of that? _____ _____ _____ _____ Discussion 2 • What would you look for at this point in the process? _____ _____ _____ _____ • What might go wrong and what would be evidence of that? _____ _____ _____ _____

Discussion 3

- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Discussion 4

- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Discussion 5

- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Discussion 6

- What do you think are some major differences between the Poultry Slaughter and Beef Slaughter procedures, based on what has been shown so far?

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- What might go wrong and what would be evidence of that?

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Discussion 7

- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Overall Procedure

- What do you think are some major differences between the Poultry Slaughter and Beef Slaughter procedures?

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Slides	PART B: LIVESTOCK SANITARY DRESSING
15	**Livestock Slaughter Process – Beef** ***Sticking:*** What is sticking? _____ _____ _____ _____ • What would you look for at this point in the process? _____ _____ _____ _____ • What might go wrong and what would be evidence of that? _____ _____ _____ _____

Hide Removal:

How does an establishment employee remove the hide?

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During the hide removal process, what factors could increase the possibility of carcass cross-contamination?

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After Hide Removal: After the hide is removed, what other interventions could occur?

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Wash Cabinets:

- What effect would the proper use of the intervention have on the level of microbial contamination?

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- What effect would improper use of the intervention potentially have on the level of microbial contamination?

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What process is shown in this picture?

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Discussion Question:

- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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What process is being shown in this picture?

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- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Rodding the Weasand:

What else, beyond the carcass, might be affected by improper sanitary dressing procedures at this point?

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Head Removal:

What else, beyond the carcass, might be affected by improper sanitary dressing procedures at this point?

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Evisceration:

What is evisceration?

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What else, beyond the carcass, might be affected by improper sanitary dressing procedures at this point?

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Carcass Splitting:

Carcass splitting tool: What tool is used to split the carcass vertically in half?

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Head & Cheek Processing:

Sanitary dressing procedures: Which previous sanitary dressing procedure might affect microbial or visible contamination at this step?

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Additional wash cabinets, steam pasteurization cabinets, and organic acid application cabinets, can all occur near the end of the slaughter process.

Insanitary dressing procedures: If sanitary dressing procedures have been inadequate, what are the potential results at the end of the process regarding visible contamination and microbial contamination?

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	Cooler: Cooler Question: How might conditions in the cooler affect microbial load on the carcasses? _____ _____ _____ _____
16	**Livestock Slaughter Process – Swine** What is the procedure being shown here? _____ _____ _____ _____ • What would you look for at this point in the process? _____ _____ _____ _____ • What might go wrong and what would be evidence of that? _____ _____ _____ _____

What procedure is being shown here?

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- What would you look for at this point in the process?

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- What might go wrong and what would be evidence of that?

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Brisket Opening:

What else, beyond the carcass, might be affected by improper sanitary dressing procedures at this point?

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Head Removal:

What else, beyond the carcass, might be affected by improper sanitary dressing procedures at this point?

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What procedure is being shown here?

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If sanitary dressing procedures have been inadequate, what are the potential results at the end of the process as far as visible contamination and microbial contamination are concerned?

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Slides	BEEF SLAUGHTER PROCESS SCENARIO
18-19	**Scenario Part 1** Scenario Part 1 Notes: _____ _____ _____ _____ _____ _____ **Scenario Part 1 Debrief** Discussion Question 1: What records did you review performing the Beef Sanitary Dressing task at Open Beef? _____ _____ _____ _____ _____ _____ Discussion Question 2: Why are those records important in determining if Open Beef's slaughter process is in control? _____ _____ _____ _____

20	**Scenario Part 2** Scenario Part 2 Notes: _____ _____ _____ _____ _____ _____

Monday, September 5, 2016	Tuesday, September 6, 2016	Wednesday, September 7, 2016	Thursday, September 8, 2016	Friday, September 9, 2016
Documents: • NR AAA8149210419624 N-1 • NR AAA8149210563293 N-1 • Graph of Open Beef STEC Testing 8/19-9/3 • Open Beef Antemortem Pen Maintenance Record 9/516 • Open Beef CCP-1B Monitoring Log 9/5/16 • Open Beef GMP-3 Monitoring Log 9/5/16 • Open Beef Receiving Log for Slaughter on 9/5/16 • Open Beef Slaughter GMP 3	Documents • MOI Weekly Meeting 9/6/16 • Open Beef Antemortem Pen Maintenance Record 9/6/16 • Open Beef CCP-1B Monitoring Log 9/6//16 • Open Beef GMP Monitoring Log 9/6/16 • Open Beef Receiving Log for Slaughter on 9/6/16 • Open Beef Slaughter GMP 3	Document • NR AAA8149215090715 N-1 • Open Beef Antemortem Pen Maintenance Record 9/7/16 • Open Beef CCP-1B Monitoring Log 9/7//16 • Open Beef GMP Monitoring Log 9/7/16 • Open Beef Receiving Log for Slaughter on 9/7/16 • Open Beef Slaughter GMP 3	Document • NR AAA8149215090815 N-1 • Open Beef Antemortem Pen Maintenance Record 9/8/16 • Open Beef CCP-1B Monitoring Log 9/8//16 • Open Beef GMP Monitoring Log 9/8/16 • Open Beef Receiving Log for Slaughter on 9/8/16 • Open Beef Slaughter GMP 3	Document • NR AAA814924091015 N-1 • NR AAA8149215090915 N-1 • Open Beef Antemortem Pen Maintenance Record 9/9/16 • Open Beef CCP-1B Monitoring Log 9/9/16 • Open Beef GMP Monitoring Log 9/9/16 • Open Beef Receiving Log for Slaughter on 9/9/16 • Open Beef Slaughter GMP 3
Notes for Monday:	Notes for Tuesday:	Notes for Wednesday:	Notes for Thursday:	Notes for Friday:

Saturday, September 10, 2016	Monday, September 12, 2016	Tuesday, September 13, 2016	Wednesday, September 14, 2016
Documents: • MOI Special Meeting 9/10/16 • NR AAA81492150909N-1 • NR AAA814909107815N-1 • NR AAA8149439191015N-1 • Open Beef Antemortem Pen Maintenance Record 9/10/16 • Open Beef CCP-1B Monitoring Log 9/10/16 • Open Beef GMP Monitoring Log 9/10/16 • Open Beef Receiving Log for Slaughter on 9/10/16 • Open Beef Slaughter GMP 3 • Open Beef Generic *E. coli* Process Control Chart	Documents • Open Beef Antemortem Pen Maintenance Record 9/12/16 • Open Beef CCP-1B Monitoring Log 9/12/16 • Open Beef GMP Monitoring Log 9/12/16 • Open Beef Receiving Log for Slaughter on 9/12/16 • Open Beef Slaughter GMP 3 • Open Beef Generic *E. coli* Process Control Chart	Document • Large PHIS Blank NR • NR AAA8149356091316N-1 • NR AAA8149372091316N-1 • Open Beef Antemortem Pen Maintenance Record 9/12/16 • Open Beef CCP-1B Monitoring Log 9/12/16 • Open Beef GMP Monitoring Log 9/12/16 • Open Beef Receiving Log for Slaughter on 9/12/16 • Open Beef Slaughter GMP 3	Document • Graph of Open Beef STEC Testing 8/19 – 8/3 • Graph of Open Beef STEC Testing 9/5 – 9/12 • Large PHIS Blank NR • NR AAA8149356091115N-1 • Open Beef generic E coli Process Control Chart 9/5/16 • Open Beef Slaughter GMP 3
Notes for Saturday:	Notes for Monday:	Notes for Tuesday:	Notes for Wednesday:

21	**Monday, September 5, 2016** Review the documents in today's folder. • Graph of Open Beef STEC Testing 8-19-16--9-3-16.docx _____ _____ _____ _____ • NR AAA8149210419624N-1-First Sanitary Dressing NR-416 3a 416 4a.docx _____ _____ _____ _____ • NR AAA8149210563293N-1 First floor drain plugged 416.2e4.docx _____ _____ _____ _____ • Open Beef Ante-Mortem Pen Maintenance Record 90516.docx _____ _____ _____ _____

- Open Beef CCP-1B Monitoring Log-09-05-16.docx

- Open Beef GMP-3 Monitoring Log 09-05-16.docx

- Open Beef Receiving Log for Slaughter on 9-5-16.docx

- Open Beef Slaughter GMP 3.docxOpen Beef Slaughter GMP 3.docx

	Discussion Question 1: At the weekly meeting scheduled for tomorrow with establishment management, would you discuss either of the NRs with them? _____ _____ _____ _____ Discussion Question 2: If so, would you document these discussions? _____ _____ _____ _____ Discussion Question 3: If you would document these discussions, how would you document them? _____ _____ _____ _____
22	**Tuesday, September 6, 2016** Review the documents in today's folder. • MOI Weekly Meeting 9-6-16 Open Beef.docx _____ _____ _____ _____

- Open Beef Ante-Mortem Pen Maintenance Record 90616.docx

- Open Beef CCP-1B Monitoring Log-09-06-16.docx

- Open Beef GMP-3 Monitoring Log 09-05-06-16.docx

- Open Beef Receiving Log for Slaughter on 9-6-16.docx

- Open Beef Slaughter GMP 3.docx

Discussion Question 1: Do you have any concerns at this point?

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Discussion Question 2: Are there any other tasks you'd perform at this point?

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Discussion Question 3: Do you have any concerns from reading the MOI?

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23	**Wednesday, September 7, 2016** Review the documents in today's folder. • NR AAA8149215090715N-1 Second Sanitary Dressing NR 416.3a 416.4a.docx _____ _____ _____ _____ • Open Beef Ante-Mortem Pen Maintenance Record 90716.docx _____ _____ _____ _____ • Open Beef CCP-1B Monitoring Log-09-07-16.docx _____ _____ _____ _____ • Open Beef GMP-3 Monitoring Log 09-05-07-16.docx _____ _____ _____ _____

- Open Beef Receiving Log for Slaughter on 9-7-16.docx

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- Open Beef Slaughter GMP 3.docx

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Discussion Question 1: What happened today?

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	Discussion Question 2: Are there any other tasks you'd perform at this point? _____ _____ _____ _____ _____ _____ _____ _____ Discussion Question 3: Are you starting to be concerned about Open Beef's sanitary dressing proceudres and process control? _____ _____ _____ _____
24	**Thursday, September 8, 2016** Review the documents in today's folder. • NR AAA8149215090815N-1 Third Sanitary Dressing NR 416.3a 416.4a.docx _____ _____ _____ _____

- Open Beef Ante-Mortem Pen Maintenance Record 90816.docx

- Open Beef CCP-1B Monitoring Log-09-08-16.docx

- Open Beef GMP-3 Monitoring Log 09-05-08-16.docx

- Open Beef Receiving Log for Slaughter on 9-8-16.docx

- Open Beef Slaughter GMP 3.docx

Discussion Question 1: What happened today?

	Discussion Question 2: If things don't change, what do you think is going to happen next? _____ _____ _____ _____ _____ _____ _____
25	**Friday, September 9, 2016** Review the documents in today's folder. • NR AAA814924091015N-1 Fourth Sanitary Dressing NR 416.3a 416.4a.docx _____ _____ _____ _____ • NR AAA8149215090915N-1 First Zero Tolerance NR 310.18a 417.2c4.docx _____ _____ _____ _____ • Open Beef Ante-Mortem Pen Maintenance Record 90916.docx _____ _____ _____ _____

- Open Beef CCP-1B Monitoring Log-09-09-16.docx

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- Open Beef GMP-3 Monitoring Log 09-05-09-16.docx

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- Open Beef Receiving Log for Slaughter on 9-9-16.docx

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- Open Beef Slaughter GMP 3.docx

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Discussion Question 1: What happened today?

Discussion Question 2: What else do you think you should do at this point?

26-27	**Scenario Part 3** Scenario Part 3 Notes: _____ _____ _____ _____ _____ **Scenario Part 3 Debrief** Discussion Question 1: Since there is a trend in noncompliance, what statement must you make during the weekly meeting and document in the MOI? _____ _____ _____ _____
28-29	**Saturday, September 10, 2016** Review the documents in today's folder. • MOI Special Meeting 9-10-16 Open Beef RGK3415024410G.docx _____ _____ _____ _____

- NR AAA81492150909N-1 Second Zero Tolerance NR.docx

- NR AAA814909107815N1-Floor drains plugged-associated-416.2e4.docx

- NR AAA8149439191015N-1 Fifth Sanitary Dressing NR 416.3a 416.4a.docx

- Open Beef Ante-Mortem Pen Maintenance Record 91016.docx

- Open Beef CCP-1B Monitoring Log-09-10-16.docx

- Open Beef generic E. coli Process Control Chart 9-2-16-9-8-16docx.docx

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- Open Beef GMP-3 Monitoring Log 09-05-10-16.docx

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- Open Beef Receiving Log for Slaughter on 9-10-16.docx

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- Open Beef Slaughter GMP 3.docx

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Discussion Question 1: What information did you gain from the Generic *E. coli* process control chart?

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Discussion Question 2: Are there any other microbiological test results that you might want to examine?

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Discussion Question 3: Is there anything else that you might have wanted to discuss at the special meeting?

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Saturday, September 10, 2016 – In-depth Document Review

1. Review NR #AAA8149216091015N/1. What happened?

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2. What other task are you going to need to perform?

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3. What establishment HACCP records will you want to examine?

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4. Review CCP-1 Monitoring Log. What does it show?

5. What else happened on Saturday?

	6. At this point, do you think we have enough evidence, or pieces of the puzzle, to conclude that the establishment is in noncompliance with 9 CFR 416.1 and 9 CFR 310.18(a)? _____ _____ _____ _____ 7. What pieces of the puzzle are we still lacking? _____ _____ _____ _____
30-31	**Scenario Part 4** Scenario Part 4 Notes: _____ _____ _____ _____ _____

	Scenario Part 4 Debrief Discussion Question 1: How would you prioritize all these things that you have to do? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
32	**Monday, September 12, 2016** Review the documents in today's folder. • Open Beef Ante-Mortem Pen Maintenance Record 91216.docx _____ _____ _____ _____ • Open Beef CCP-1B Monitoring Log-09-12-16.docx _____ _____ _____ _____

- Open Beef generic E. coli Process Control Chart 9-2-16-9-9-16docx.docx

- Open Beef GMP-3 Monitoring Log 09-05-12-16.docx

- Open Beef Receiving Log for Slaughter on 9-12-16.docx

- Open Beef Slaughter GMP 3.docx

Discussion Question 1: What happened today?

Discussion Question 2: What do you think is the most significant thing that happened today and why?

Discussion Question 3: Should you call or e-mail the FLS, and if so, what would you report?

33	**Scenario Part 5** Scenario Part 5 Notes: _____ _____ _____ _____ _____
34	**Tuesday, September 13, 2016** Activity Notes: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

	Discussion Question 1: What happened today? _____
35	**Scenario Part 6** Scenario Part 6 Notes: _____ _____ _____ _____ _____

36	**Wednesday, September 14, 2016** What do the graphs (Graph of Open Beef STEC Testing 09-05-2016 and Graph of Open Beef STEC Testing 8-19-16 to 09-03-016) show? What does the chart (Open Beef Generic *E. coli* Process Control Chart 09-05-12-16) tell you?

Discussion Question 1: How many NRs have there been citing noncompliance with 9 CFR 416.2(e)(4) when the drains in Pen 6 in the holding area were plugged and the cattle to be slaughtered became more contaminated?

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Discussion Question 2: How many times do their records show they found that the drain in Pen 6 was plugged?

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Discussion Question 3: How many NRs have there been citing noncompliance with 9 CFR 416.3(a) and 416.4(a) because the establishment wasn't implementing their Slaughter GMP-3?

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Discussion Question 4: How many times do their records show that they observed employees not properly implementing their Slaughter GMP-3?

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Discussion Question 5: How many NRs have there been citing noncompliance with 9 CFR 417.2(c)(4) and 9 CFR 310.18(a) in which we found a deviation from the critical limit for zero tolerance for fecal, ingesta, and milk at CCP 1-B?

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Discussion Question 6: How many times do the establishment's CCP 1-B monitoring records indicate that they found a deviation from the critical limit for zero tolerance for fecal, ingesta, and milk while monitoring?

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Discussion Question 7: Did IPP do anything else to express their concern over the establishment's sanitary dressing procedures and lack of process control?

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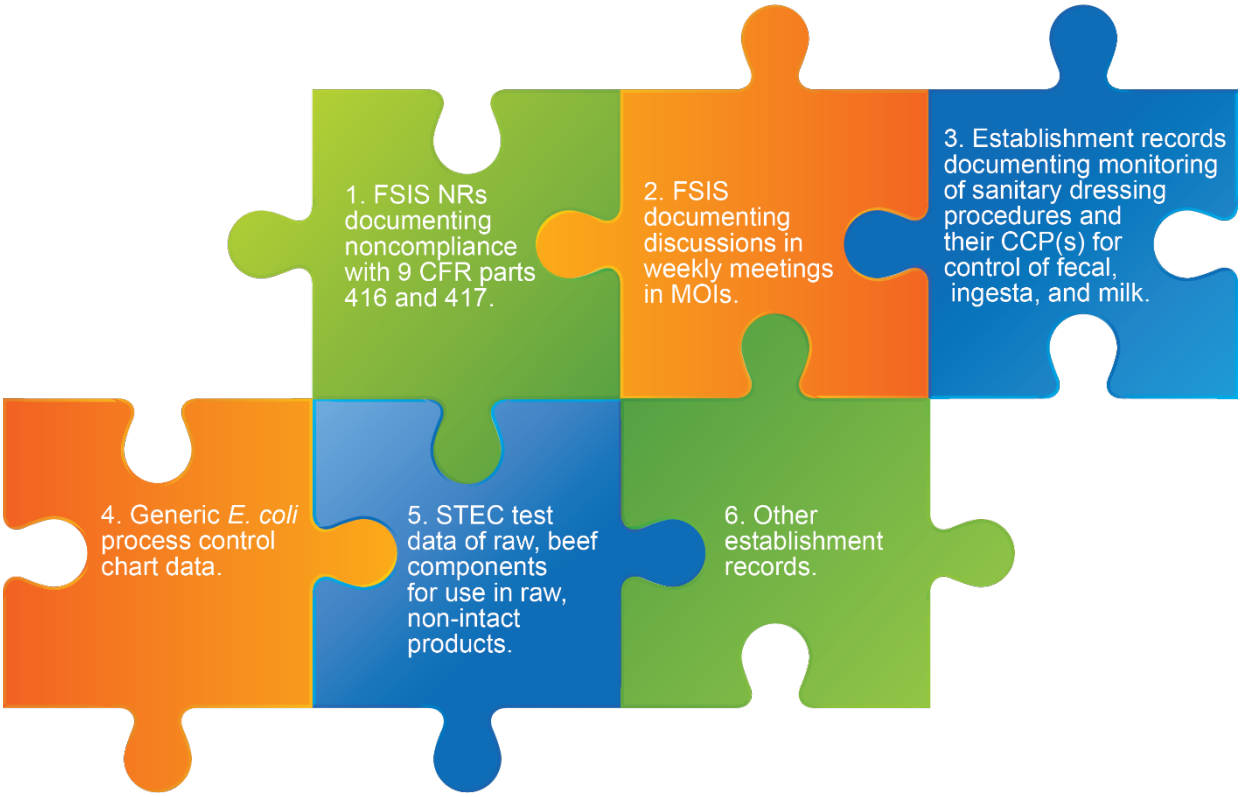
Wednesday, September 14, 2016 (Continued)

What are the pieces to the puzzle in determining whether an establishment's sanitary dressing procedures are effective and the process is in control?

The six pieces represent what is needed to determine if an establishment's sanitary dressing procedures are effective and the process is in control.



39	**Conclusion** Does NR #AAA81493560911115N-1 capture that information and explain why there is noncompliance with 9 CFR 416.1 and 9 CFR 310.18(a)? _____ Has the establishment been given due process? _____ **You now have the tools to evaluate sanitary dressing procedures!**
Slides	**SUMMARY**
40	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

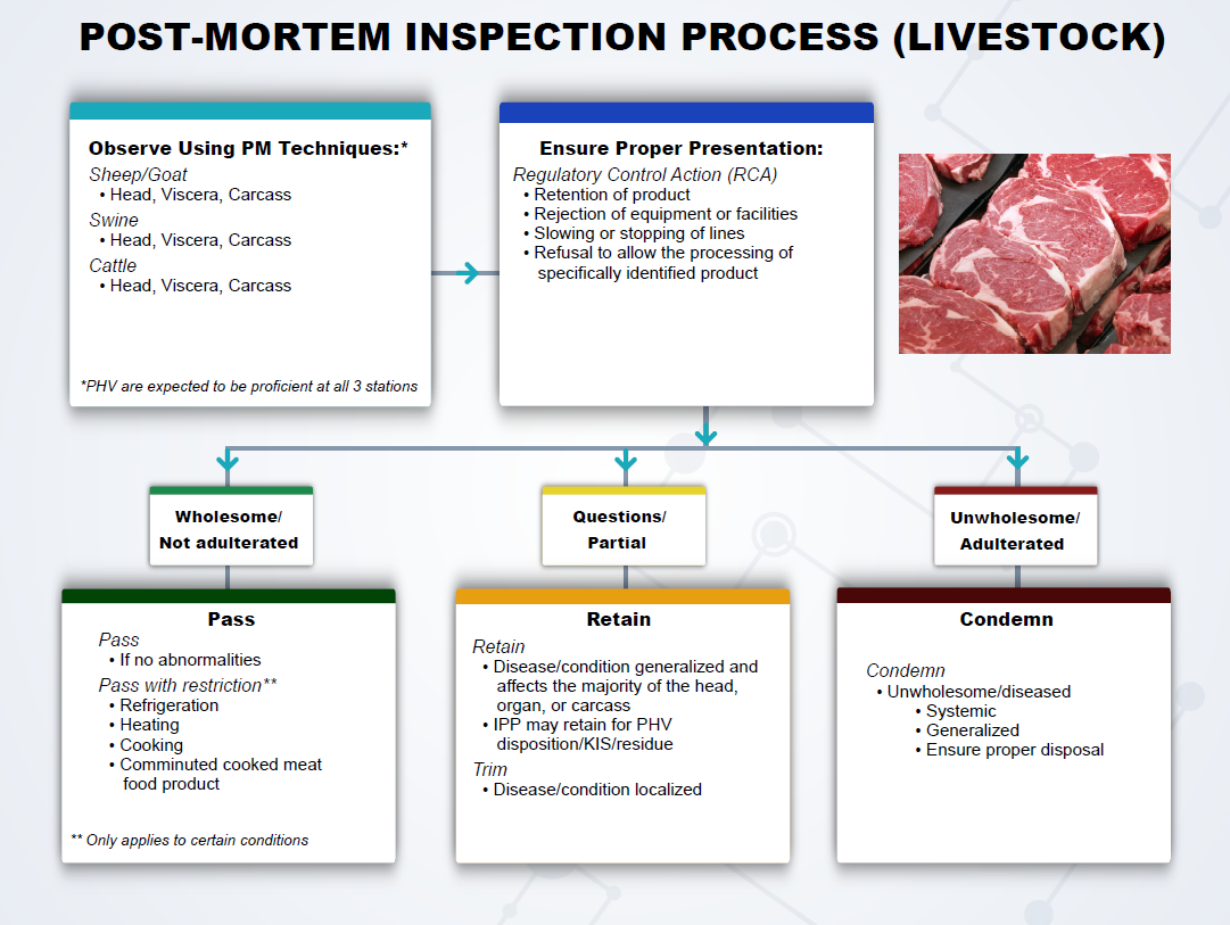
Post-Mortem (PM) Inspection

TABLE OF CONTENTS

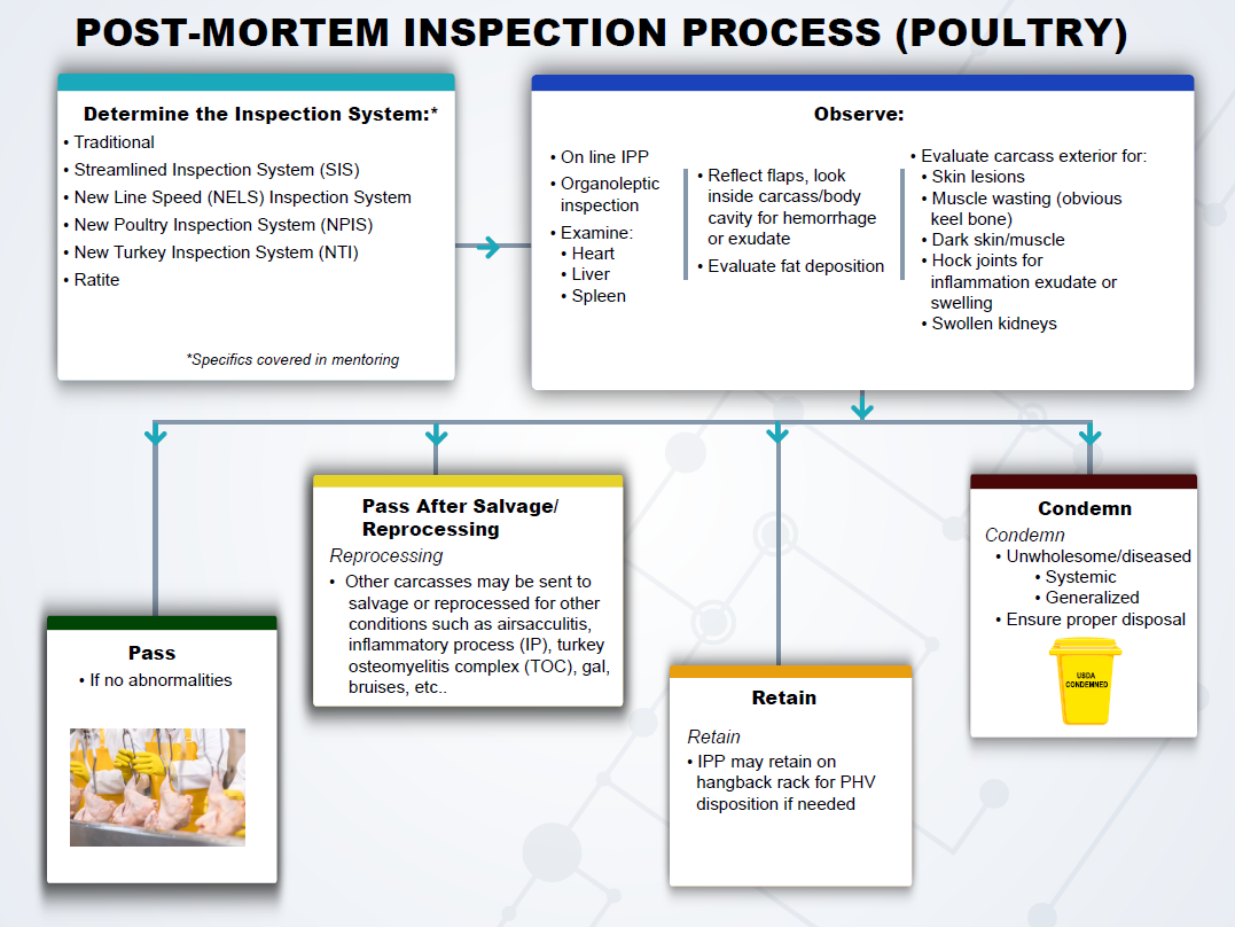
Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. Given a scenario, conduct post-mortem inspection in livestock and poultry. 2. Given a scenario, demonstrate actions a PHV takes if an establishment has not met its responsibilities per 9 CFR Part 310 (livestock) or doesn't meet the ready-to- cook standard in 9 CFR 381.1 (poultry). 3. Given scenarios, apply 9 CFR Part 311 for livestock, 9 CFR Part 381.80-93 for poultry, and agency issuances to make supportable, post-mortem dispositions. 4. Given scenarios in the Slaughter/Kill Floor context, differentiate among contamination, post-mortem changes due to processing methods (such as scalding, dehairing, and picking), and true pathology. 5. Given scenarios, apply the GAD process to sample collection, i.e., what to collect, when to collect, etc. **Regulatory/Administrative:** 1. Given scenarios, verify that the establishment uses compliant methods to dispose of livestock carcasses condemned at post-mortem inspection.

Slides	PM BIG PICTURE
2-6	Using your resources, answer the following questions for both livestock and poultry: 1) What is PM inspection? _____ _____ _____ _____ _____ 2) Why do we do PM inspection? _____ _____ _____ _____ _____ 3) What are the establishment requirements? _____ _____ _____ _____ _____ 4) What are the possible dispositions? _____ _____ _____ _____ _____

Slides	PM OVERVIEW
7	**PM Inspection Process Overview Flowchart 1**



7	**PM Inspection Process Overview Flowchart 2**



Slides	CATTLE PM INSPECTION PROCEDURES
8	Watch the video and take notes in the space provided.

Slides	SWINE PM INSPECTION PROCEDURES
9	Watch the video and take notes in the space provided.

Slides	SHEEP/GOAT PM INSPECTION PROCEDURES
10	Watch the video and take notes in the space provided.

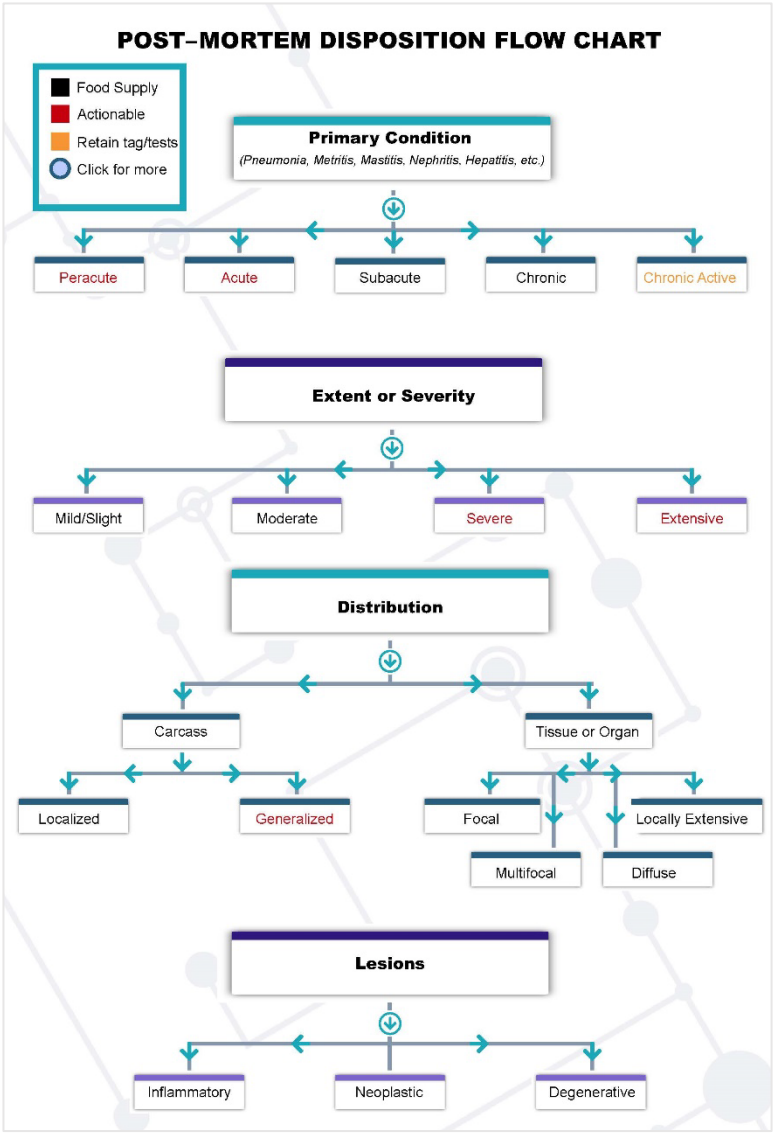
Slides	CHICKEN PM INSPECTION PROCEDURES
11	Watch the video and take notes in the space provided.

Slides	DISPOSAL OF INEDIBLE
12-13	Answer the following questions for both livestock and poultry: 1) How should establishments dispose of condemned or inedible product? _____ _____ _____ _____ 2) What are the correct steps? _____ _____ _____ _____ _____

Slides	DISPOSAL OF INEDIBLE VIDEO
14	Take notes in the spaces provided below and answer the interspersed questions. _____ _____ What is a condemned barrel? What is an inedible barrel? _____ _____ _____ _____ _____ _____ _____

	Is this a noncompliance? Why or why not? _____ _____ _____ _____ What actions should you take in cases of noncompliance? _____ _____ _____ _____ _____ _____ What destruction method is the worker using? Is it compliant? _____ _____ _____ _____ What other methods can be used? For which species? _____ _____ _____ _____

Slides	PM DISPOSITION THOUGHT PROCESS INFOGRAPHIC
15	



Slides	PM DISPOSITION THOUGHT PROCESS: 6 QUESTIONS
16	**6 Questions to Arrive at a Sound and Supportable Decision** 1. _____ _____ 2. _____ _____ 3. _____ _____ 4. _____ _____ 5. _____ _____ 6. _____ _____
Slides	**MULTI-SPECIES DISPOSITIONS CASE STUDIES: PART 1**
19-26	**Case Study 1: Cattle** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____ Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ 1. What tissue do I need to collect for a KIS test? _____

	2. If the KIS test is positive, what tissue do I need to collect and submit for a residue test at the FSIS Eastern Lab? _____ What else do you need to collect for this case? _____ Why do you collect this? _____ What is your disposition? _____ Other notes: _____ _____ _____ _____
27-32	**Case Study 2: Swine** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____ Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ What is your disposition? _____ Other notes: _____ _____ _____ _____

33-38	**Case Study 3: Goat** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____ _____ _____ Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ What is your disposition? _____ Other notes: _____ _____ _____ _____
39-45	**Case Study 4: Poultry** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____

	Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ What is your disposition? _____ Other notes: _____ _____ _____ _____ _____ _____
46-52	**Case Study 5: Cattle** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____ Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ What is your disposition? _____

	Other notes: _____ _____ _____ _____ _____ _____
53-58	**Case Study 6: Swine** Ante-mortem findings: _____ Post-mortem findings: _____ _____ _____ _____ _____ _____ Do you need to submit samples to the lab to make a diagnosis? Yes / No Do you have reason to conduct an in-plant residue (KIS) test? Yes / No What is the correct diagnosis? _____ What is your disposition? _____ Other notes: _____ _____ _____ _____

	What if you saw a bird with a cooked appearance of the deep pectoral muscle and/or viscera? Is this a sign of pathology or something else going on? _____ _____ _____ _____
Slides	**MULTI-SPECIES DISPOSITIONS CASE STUDIES: PART 2**
61	It's time to put your diagnostic and disposition skills to the test! You will complete a series of intermediate and difficult case studies individually and in small groups throughout the week. Take notes in the spaces provided below. Click on the link to open the part 2 presentation.
1-4	*Note: the slide numbers will start over because this is a separate presentation.* The resources on these first few slides are here as your reference. You should use them as you review each case study. _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

5 - 10	**Case Study 1: Cattle**
11-16	**Case Study 2: Poultry**

17-23	**Case Study 3: Cattle**
24-29	**Case Study 4: Swine**

30-36	**Case Study 5: Cattle**
37-42	**Case Study 6: Goat**

43-49	**Case Study 7: Cattle**
50-55	**Case Study 8: Poultry**

56-61	**Case Study 9: Swine**
62-68	**Case Study 10: Cattle**

69-74	**Case Study 11: Swine**
75-80	**Case Study 12: Cattle**

81-86	**Case Study 13: Poultry**
87-93	**Case Study 14: Swine**

94-99	**Case Study 15: Cattle**
100-105	**Case Study 16: Goat**

106-111	**Case Study 17: Swine**
112-118	**Case Study 18: Cattle**

119-124	**Case Study 19: Swine**
125-130	**Case Study 20: Poultry**

131-136	**Case Study 21: Cattle**
137-144	**Case Study 22: Cattle**

145-152	**Case Study 23: Swine**
153-158	**Case Study 24: Goat**

159-164	**Case Study 25: Cattle**
165-170	**Case Study 26: Swine**

171-176	**Case Study 27: Poultry**
177-183	**Case Study 28: Cattle**

184-189	**Case Study 29: Swine**
190-196	**Case Study 30: Cattle**

197-203	**Case Study 31: Swine**
204-209	**Case Study 32: Cattle**

210-217	**Case Study 33: Sheep**
218-223	**Case Study 34: Poultry**

224-231	**Case Study 35: Swine**
232-237	**Case Study 36: Cattle**

238-244	**Case Study 37: Swine**
245-254	**Case Study 38: Cattle**

255-260	**Case Study 39: Swine** _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
261-266	**Case Study 40: Poultry** _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ Now, return to the first Post-Mortem presentation to complete the knowledge check.

Slides	POST-MORTEM KNOWLEDGE CHECK
61-67	1. True or false? The post-mortem inspection procedures for livestock are the same across species. _____ 2. True or False? Diseases, abnormalities, and contamination can occur at any place on a carcass or its parts. _____ 3. Choose the answer that best completes this sentence. Systemic diseases and abnormalities are most likely to produce visible lesions in the lymph nodes because the lymph nodes _____. 4. What is the first step in the post-mortem inspection process for livestock? _____ 5. If a carcass is wholesome except for a localized disease condition, the correct outcome is: _____ 6. Which of the following are establishment requirements for livestock post-mortem inspection (regardless of the number or placement of the inspection stations)? _____ _____
Slides	**SUMMARY**
68	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Residue Detection

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. Given a scenario, describe how and when 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:** 1. Identify the conditions and animal classes that call for a PHV to perform an in-plant residue test, based on FSIS Directive 10,800.1, Revision 1. 2. Describe how to use LIMS-DIRECT to access residue laboratory test results.

Slides	RESIDUE DETECTION: BIG PICTURE
2-4	Using your resources, answer the following questions: 1) Why do we do residue testing? _____ _____ _____ _____ 2) Who decides what residue levels are allowed? _____ _____ _____ _____ _____ _____ _____ _____ 3) As a PHV, what are your responsibilities related to residue testing? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Slides	RESIDUE OVERVIEW
5	**Match the Federal Agencies with Their Roles** FSIS _____ _____ _____ _____ FDA _____ _____ _____ _____ EPA _____ _____ _____ _____

6	**Which conditions should prompt residue testing?** **Should** Prompt Testing _____ _____ _____ _____ Should **Not** Prompt Testing _____ _____ _____ _____
7	**If testing is prompted, what do you need to collect?** **Do** Need to Collect _____ _____ _____ _____ Do **Not** Need to Collect _____ _____ _____ _____

8	**Sampling Discussion** What is the difference between directed residue sampling and inspector generated sampling? _____ What happens to the carcass and parts pending results in each situation? _____ _____ _____ _____ _____ _____

Slides	KIS TEST
9	**KIS Test Discussion** What is a KIS test? _____ _____ _____ When should you conduct a KIS test? _____ _____ _____ _____ What actions should you take if the results are positive? _____ _____ _____ _____ _____ What should you do if they are negative? _____ _____ _____ _____ _____ _____

10	**KIS Test Video** Take notes in the space provided below:

Slides	LIMS Direct
11	**LIMS Direct: Sample Status and Results** _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
Slides	**CASE STUDIES**
13	**Case Study 1** You are performing ante-mortem at a beef slaughter establishment and observe this animal. 1) What condition is this? _____ 2) What is the appropriate disposition? _____ 3) Would you perform any test? _____

14	**Case Study 2** You are performing ante-mortem at a cull cow/bull slaughter establishment and observe this lesion on a cow. 1) What condition is this? _____ 2) Do you need to residue test? _____
15	**Case Study 3** You are performing ante-mortem at a cull cow/bull slaughter establishment and observe this cow. 1) What condition is this? _____ 2) Do you need to residue test? _____

16	**Case Study 4** You are performing ante-mortem at a market hog slaughter establishment and observe this animal. 1) What condition is this? _____ 2) Do you need to residue test? _____
17	**Case Study 5** 1) What condition is in this kidney? _____ 2) Would you perform any test? _____ 3) Would you condemn the kidney and pass the carcass? _____ 4) If yes to either question 2 or 3, why? _____

18	**Case Study 6** 1) What tissue is this? _____ 2) Is there pathology present? _____ 3) Should you perform a residue test? What type of residues would you expect? _____
19	**Case Study 7** 1) What tissue is this? _____ 2) Is there pathology present? _____ 3) Would you observe any signs on ante-mortem? _____ 4) Should you perform a residue test? What type of residues would you expect? _____

20	**Case Study 7 (Cont'd)** You perform the KIS test and get the results. How do you interpret these results? _____ _____ _____ _____ What action should you take, if any? _____ _____ _____ _____
21	**Case Study 8** 1) What would cause focal necrosis in the prescapular region? _____ 2) Would you perform a KIS™ test? _____ 3) Why or why not? _____

22-24	**Case Study 8 (Cont'd)** You perform the KIS test and get the results. How do you interpret these results? _____ _____ _____ _____ What action should you take, if any? _____ _____ _____ _____ You submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS lab. The FSIS laboratory reports a "Detected - violative" residue result! What should you do? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

	What would you do if the results had come back with either of the following results instead? • Not detected _____ _____ _____ • Detected – not quantified violation _____ _____ _____
25	**Case Study 9** 1) What species is this? _____ 2) What condition is this animal exhibiting? _____ 3) Should you perform a KIS™ test? _____ 4) If yes, why? _____

26-27	**Case Study 9 (Cont'd)** You perform the KIS test and get the results. How do you interpret these results? _____ _____ _____ _____ What action should you take, if any? _____ _____ _____ _____ You submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS lab. The FSIS laboratory reports a "Detected – non-violative" residue result! What should you do? _____ _____ _____ _____ _____ _____

Slides	RESIDUE DETECTION KNOWLEDGE CHECK
28-32	**Knowledge Check 1** True or false? Animals exhibiting clinical signs of septicemia should be tested for residues. _____ _____ **Knowledge Check 2** Which of the following actions is most appropriate if you conduct a KIS test and the results are negative, but you suspect a non-antimicrobial chemical residue may be present in the carcass? _____ _____ _____ _____ _____ **Knowledge Check 3** True or false? Animals exhibiting clinical signs of chronic pathology should be tested for residues. _____ _____ **Knowledge Check 4** Match the required amount of sample to the correct type of sampling. • One (1) lb. muscle sample • Two (2) lb. muscle sample • Directed Sampling • Inspector Generated Sample (KIS)

Slides	SUMMARY
33	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Noncompliance Records

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** *[None for this topic in this context.]* **Regulatory/Administrative:** 1. Given scenarios in the Slaughter/Kill Floor context, identify situations that warrant a regulatory control action. 2. For those situations that warrant a regulatory control action, 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 PHIS. 4. Demonstrate how to document discussions of noncompliance trends in an MOI. 5. Identify the appropriate regulatory actions that can be used in cases when the same noncompliance occurs repeatedly, e.g., tag the equipment, tag the room, stop the line, etc.

Slides	NONCOMPLIANCE RECORDS (NR) REVIEW
3-7	Based on your knowledge of NRs, answer the following questions: • What should be included in an NR?

- Why is an NR important for Establishment Management?

- What information are IPP required to input into the Public Health Information System (PHIS)?

- What are the three enforcement actions that can be taken?

8	**Parts of an NR** What sections need to be completed in an NR?

Slides	BEEF SCENARIO NRS
10	**Review of Scenario NRs** NR Notes:

11	**Documenting NR Discussions** Review the two Memorandums of Interview (MOIs) from the Beef Scenario. • MOI Weekly Meeting 9-6-16 Notes: _____ _____ _____ _____ • MOI Special Meeting 9-10-16 Notes: _____ _____ _____ _____ Discussion Question 1: What should be included in an MOI? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Discussion Question 2: Why is it important to create an MOI?

Discussion Question 3: When can FSIS take Regulatory Control Actions (RCAs)?

Discussion Question 4: What types of progressive enforcement actions can FSIS take?

12	**Time to Practice!** Review the scenario and then complete an NR based on the information presented in the scenario. Scenario Notes:

	Complete an NR based on the scenario. NR Notes: _____ _____ _____ _____ _____ _____ _____ _____ _____
Slides	**SUMMARY**
13	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Professionalism

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** *[None for this topic in this context.]* **Regulatory/Administrative:** 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.

Slides	INTRODUCTION
2-6	**Professionalism: Big Picture** Using your resources, answer the following questions: • What is professionalism at FSIS? _____ _____ _____ _____ • Why is it important to be professional? _____ _____ _____ _____ • What are some examples of unethical conduct at FSIS? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

	• What are some possible consequences of inappropriate conduct? _____ _____ _____ _____ _____ _____ _____ _____
7	**Ethics: The HATCH Act** Purpose of Act: • *"...to ensure that federal programs are administered in a nonpartisan fashion, to protect federal employees from political coercion in the workplace, and to ensure that federal employees are advanced based on merit and not based on political affiliation."* _____ _____ The HATCH Act & Candidates Seeking to Visit Federal Agencies Notes: _____ _____ _____ _____ The HATCH Act & Social Media: Recent OSC Case Notes: _____ _____ _____ _____

Slides	PROFESSIONALISM SCENARIOS
9	**Scenario A: Romantic Relationships** Discussion Question 1: Is this professional behavior? Why or why not?

Discussion Question 2: How does this behavior compare to the definition of professionalism?

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Discussion Question 3: What is the potential impact for food safety/bio-security?

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Discussion Question 4: What impact does it have on the Agency's credibility?

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Discussion Question 5: What might be the outcome of this situation?

Discussion Question 6: How could you have prevented or avoided this behavior?

	Discussion Question 7: How would you demonstrate your professionalism in this situation? _____ _____ _____ _____ _____ _____
10	**Scenario B: Attitude, Initiative, and Communication** Discussion Question 1: Which one of the FSIS Inspectors exhibited professionalism? Why? _____ _____ _____ _____ Discussion Question 2: How does this behavior compare to the definition of professionalism? _____ _____ _____ _____ Discussion Question 3: What is the potential impact for food safety/bio-security? _____ _____ _____ _____

Discussion Question 4: What impact does it have on the Agency's credibility?

Discussion Question 5: What might be the outcome if the CSI had not taken action?

Discussion Question 6: How could you have prevented or avoided this behavior?

	Discussion Question 7: How would you demonstrate professionalism if you were the Food Inspector in this scenario? _____ _____ _____ _____

11	**Scenario C: Relationships, Touching, or Hitting** Discussion Question 1: Is this professional behavior? Why or why not?

Discussion Question 2: How does this behavior compare to the definition of professionalism?

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Discussion Question 3: What is the potential impact for food safety/bio-security?

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Discussion Question 4: What impact does it have on the Agency's credibility?

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Discussion Question 5: What might be the outcome of this incident?

Discussion Question 6: How could you have prevented or avoided this behavior?

	Discussion Question 7: How would you demonstrate professionalism in this scenario? _____ _____ _____ _____ _____ _____ _____ _____ This scenario is… _____!
12	**Scenario D: Horseplay** Discussion Question 1: Is this professional behavior? Why or why not? _____ _____ _____ _____ Discussion Question 2: How would a professional respond? _____ _____ _____ _____ Discussion Question 3: How does this behavior compare to the definition of professionalism? _____ _____ _____ _____

Discussion Question 4: What is the potential impact for employee safety/food safety/bio-security?

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Discussion Question 5: What impact does it have on the Agency's credibility?

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Discussion Question 6: What might be the outcome of this incident?

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Discussion Question 7: How should this be handled if an establishment employee threw the object?

Discussion Question 8: How could you have prevented or avoided this behavior?

	Discussion Question 9: How would you demonstrate your professionalism in this situation? _____ _____ _____ _____
13	**Scenario E: Dress, Appearance, and Sanitation** Discussion Question 1: Is this professional behavior? Why or why not? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ Discussion Question 2: How does this behavior compare to the definition of professionalism? _____ _____ _____ _____ _____ _____

Discussion Question 3: What is the potential impact for food safety/bio-security?

Discussion Question 4: What impact does it have on the Agency's credibility?

Discussion Question 5: What might be the outcome of this incident?

Discussion Question 6: How could you have prevented or avoided this behavior?

Discussion Question 7: How would you demonstrate professionalism in this scenario?

14	**Your Turn!** Think of a time that you saw unprofessional, or inappropriate, behavior in the workplace. • In what environment did it occur (i.e., slaughter, processing, or office)? _____ _____ _____ _____ • What occurred? _____ _____ _____ _____ • Why was it inappropriate? _____ _____ _____ _____ • How should a supervisor act in this situation? _____ _____ _____ _____

Slides	ENSURING PROFESSIONALISM IN THE WORKPLACE
16	**Ensuring Professionalism in the Workplace** What can you do to ensure professionalism in the workplace?
17	

	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
18-19	**Documenting Personnel Issues: Caution Letters** Informal discipline at FSIS: 1. Counseling _____ _____ 2. Instruction _____ _____

3. Caution

_____

_____

Caution Letter Examples:

_____

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Tips to remember when writing caution letters:

1. _____

_____

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2. _____

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3. _____

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_____

20	**Documenting Personnel Issues: Takeaways** 1. The best practice at FSIS is to handle all personnel disciplinary issues on your own. _____ _____ 2. When handling a personnel issue, of the following individuals, who should NOT be involved? _____ _____ _____ 3. Proper documentation of events is key to effectively handle personnel issues. _____ _____ Remember to always learn from your mistakes!
Slides	**PROFESSIONALISM KNOWLEDGE CHECK**
22-26	**Knowledge Check 1** You do not need approval for outside employment or activity when it has nothing to do with your government job. _____ **Knowledge Check 2** You just found out that the establishment will be working overtime tonight. Since you will not be able to get to your emergency small animal veterinary clinic job because of the overtime, you can use the government phone to call them and let them know. _____

	Knowledge Check 3 When you have a work-related ethics question, you should ask: _____ **Knowledge Check 4** You can sell personal items, such as your car, washer, bicycle, etc., to establishment employees and co-workers as long as you first put up a notice on the establishment's bulletin board. _____ **Knowledge Check 5** Which of the following is considered an appropriate action? _____ _____
Slides	**SUMMARY**
27	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Foreign or Other Reportable Animal Disease: Part 1

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. Given a scenario, identify specific, ante-mortem signs in livestock or poultry that suggest a foreign or other reportable animal disease (FORAD). 2. Demonstrate how to convey to IPP a professional commitment to FORAD in this work context. 3. Demonstrate how to train IPP to recognize specific, ante-mortem signs of FORAD and report them to a PHV. **Regulatory/Administrative:** 1. Given a scenario in the delivery/holding context, follow FSIS Directive 6000.1 to respond to ante-mortem signs of FORAD. 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 Organization for Animal Health. 7. Identify animal diseases that PHV's must report to the District Office. 8. Explain how to teach IPP, plant 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.

Slides	FAD/RAD INTRODUCTORY VIDEO
2	**FAD/RAD Introductory Video** Take notes in the space provided below:

Slides	FOREIGN/REPORTABLE ANIMAL DISEASE & YOUR ROLE
3	**Foreign/Reportable Animal Disease & Your Role** As in-plant supervisors, how will you convey the importance and recognition of FAD and RAD to IPP? _____ _____ _____ _____ _____ _____ How will you train IPP to recognize specific signs of FAD and RAD and report them to a PHV? _____ _____ _____ _____ _____ _____
Slides	**CASE STUDIES**
4-10	**Case Study 1: Poultry AM** You are the PHV at a large chicken slaughter establishment that slaughters approximately 100,000 birds in a shift. It is a very nice day in late March and you've been enjoying watching the Canada geese migrate north. While performing your AM inspection, you walk out to the docks where the trucks are parked to be unloaded and observe that approximately half of the birds on three trucks are dead. All the other birds on those three trucks are depressed and coughing. You look closer and note that most of the live birds have combs and wattles that are swollen and blue.

On many of the live birds, you observe that there is swelling around their eyes with their eyes almost swollen shut.

While examining the birds on the lower tier of the truck, you are hit by green, watery diarrhea from a bird on one of the upper tier cages. About that time, the receiving foreman comes by.

You ask if the birds on the three affected trucks are from the same grower. He checks and tells you that they are all from the same grower and have been hauled from about sixty miles away. You ask if that's all of them. He says that it is.

What signs have you seen? What do those signs suggest?

_____

_____

_____

Could the weather have caused the high death loss?

_____

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_____

What should you do at this point?

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What information would you need to relay to the District Office?

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	If you are informed by APHIS that the birds are coming from an HPAI control zone, what do you need to do? _____
11-15	**Case Study 2: TB AM** You received a call from the FLS yesterday that a lot of restricted dairy cattle would be arriving today with a VS 1-27 form (Restricted Animal Movement). An inspector notifies you that the lot has arrived and there is a mix of TB Reactors, TB Suspects, and TB Exposed animals. Draw lines to match the APHIS cattle TB classifications with their correct definition: 1. TB Reactor 2. TB Suspect 3. TB Exposed Category I 4. TB Exposed Category II 5. TB Exposed Unclassified A. Cattle that have been moved from an infected herd before the time the infection was disclosed, but after the herd apparently became infected. When traced, these animals are critical for establishing the disease status of the receiving herd B. Any bovid (genus Bos) or bison that shows a response to an official tuberculosis test and is classified a reactor by the testing veterinarian or DTE, or any suspect animal that is classified a reactor by the DTE upon slaughter inspection or necropsy, histopathological examination, PCR assay, and/or culture of selected tissues collected by the Federal or State veterinarian performing or supervising the slaughter inspection or necropsy. C. Restricted cattle that do not have a TB exposed category specified, and are therefore handled as under Category II. D. Any cattle or bison that show a response to the CFT test and are not classified reactor, or any cattle or bison that have been classified as suspect by CCT tests; the bovine interferon gamma assay; or any other official test for tuberculosis. E. Cattle that are part of a known affected herd that test negative or are untested. These cattle may move to slaughter as routine culls of individual animals or by entire herd.

What is the AM disposition for animals designated as a TB Reactor?

_____

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_____

After performing AM inspection, you condemn a TB Reactor due to cachexia, a TB Suspect due to fever, and a TB Exposed Category I due to NAD. What actions should you take next?

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	Draw lines to match the PM inspection procedure you will use for each TB classification (*note*: some classifications require more than one procedure/line): 1. TB Reactor 2. TB Suspect 3. TB Exposed Category I 4. TB Exposed Category II 5. TB Exposed Unclassified A. Routine PM procedure B. Modified expanded PM procedure C. Expanded PM procedure D. Routine PM procedures by any IPP with PHV in attendance
16-21	**Case Study 3: Poultry AM** You are conducting AM inspection during the 2nd shift (night shift) of a large chicken slaughter establishment that slaughters approximately 200,000 birds in two shifts. The birds are on trucks waiting to be unloaded. It is July and the weather is 90 degrees with 50% relative humidity. There are functional water misters and fans blowing on the birds. You walk out to the docks where the trucks are parked and bring a flashlight to ensure you have adequate lighting for inspection.

You observe that approximately 70% of the birds on all four trucks are dead. All of the other birds are depressed, coughing, sneezing, or weak, and you notice some are mouth breathing. You also see that some birds are paralyzed and have tremors, while others are gazing straight up, as though they are looking at the stars.

You examine a few of the dead birds and see swelling of the necks and edema around the eyes.

You ask the night shift supervisor if the birds on the affected trucks are from the same grower. She checks and tells you that they are all from the same grower and have been hauled from about 20 miles away.

Could the weather have caused the high death loss?

_____

_____

_____

What signs have you seen? What do those signs suggest?

_____

_____

_____

What should you do at this point?

_____

_____

_____

_____

What information would you relay to the District Office?

_____

_____

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_____

	Do you need to make a diagnosis? _____ _____ _____
22-28	**Case Study 4: Cattle AM** An inspector has called you to perform AM inspection on a dairy cow that has been placed in the suspect pen. The cow is ambulatory but staggering, has a head tilt, and is aggressive. What differentials would you consider for this animal? _____ _____ _____ _____ _____ _____ What action do you take next? Choose one of the options (there is one best answer). _____ _____ _____ After you have made an AM disposition, are there any further actions you should take? If so, what action(s)? _____ _____ _____ _____

	When notifying the District Office of a possible RAD/FAD, what information should be collected and communicated? _____ _____ _____ _____ _____ _____ After notifying the DO (and APHIS VS), a VMO from APHIS VS was dispatched to collect samples from the condemned cow. You are informed several days later that the tests have come back as positive for BSE. What further actions should you consider? _____ _____ _____ _____ _____ Since you condemned this cow at AM, no contaminated product entered the slaughter environment or commerce. APHIS VS initiated a traceback investigation to determine the origin of the infected cow and if any others may be infected. Your prompt actions prevented the public from exposure to the BSE prion and likely severe negative economic impacts to the U.S. livestock industry.
29-36	**Case Study 5: Swine AM** You are the PHV at a hog establishment that slaughters 8,000 hogs a day. The hogs generally come from Illinois to this establishment located in Pennsylvania. It is early in the a.m. and you head out to the pens with your AM kit: • Includes a thermometer, U.S. Rejected/Retained tags, note pad, pen, flashlight and everything you need to perform your AM inspection.

You walk out to the pens and notice that while one truck is unloading, the hogs are exhibiting lameness and lethargy. You get up closer to look at the pigs that have been placed in a pen.

You request that they bring some of those animals to the suspect pen and have them take a temperature of a hog and you see the animal has a fever of 105° F.

True or False? This hog should be condemned for pyrexia.

_____

_____

These lesions are classic clinical signs of which type of disease?

_____

_____

Because of the lesions you have observed, you should:

_____

_____

At this point you make your assessment: _____

_____

_____

Your differential diagnoses would be: _____

_____

_____

True or False? Before you take any action, you are required to make a diagnosis.

_____

_____

Slides	FAD/RAD KNOWLEDGE CHECK
37-40	**Knowledge Check 1** True or false? Foreign animal diseases (FAD) are transmissible livestock or poultry diseases believed to be absent from the U.S. and its territories that have a potential significant health or economic impact. _____ _____ **Knowledge Check 2** Which of the following (on screen) are foreign animal diseases? _____ _____ _____ _____ **Knowledge Check 3** Why is the control of FADs important? _____ _____ _____ _____
Slides	**SUMMARY**
41	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.

Foreign or Other Reportable Animal Disease: Part 2

TABLE OF CONTENTS

Slides	LEARNING OBJECTIVES
N/A	**Scientific:** 1. Given a scenario in the Slaughter/Kill Floor context, identify specific, post-mortem signs in livestock and poultry that suggest a FORAD. 2. Given a post-mortem inspection scenario, demonstrate how to respond to a suspected FORAD. 3. Demonstrate how to train IPP to recognize post-mortem signs of FORAD and report them to a PHV. **Regulatory/Administrative:** 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 FORAD according to FSIS Directive 6240.1, FSIS Guideline No. 4, and APHIS-VS TB Sample Submission Manual for Meat Inspection Personnel.

Slides	FAD/RAD & YOUR ROLE RECAP
2	What key takeaways did you learn from FAD/RAD when covered in the Delivery/Holding context? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ What are some PM signs of FAD/RAD that you might observe in the Slaughter context? _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Slides	TB SUBMISSION MANUAL REVIEW
3	**TB Submission Manual Review** Briefly review the TB submission manual and record the key points. What are the biggest takeaways?

Slides	CASE STUDY
4-7	**FAD/RAD Case Study** IPP have railed out 2 beef carcasses for veterinary disposition over the past hour. What differentials would you consider? _____ _____ _____ _____ _____ _____ _____ _____ _____ **Actions** What action do you take next? _____ _____ _____ _____ **What If…?** What if you requested the animal's ID devices, and the establishment couldn't provide them? _____ _____ _____ _____ _____ _____

	What if the carcass was a pig? _____ _____ _____ _____ _____ _____ What if this animal came in as a known tuberculin test reactor (i.e., an animal that has reacted to an official test) for TB? _____ _____ _____ _____ _____ _____ _____
Slides	**SRM**
8-9	**Specified Risk Material (SRM)** • Bovine Spongiform Encephalopathy (BSE), or Mad Cow Disease, is a foreign animal disease. • PHVs play a role in protecting public health, including ensuring SRM removal. **SRM Video** Take notes in the space provided below: _____ _____ _____

	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
Slides	**SRM COMPLIANCE ACTIVITY**
10	**SRM Compliance Activity** In your group: • Review Directive 6100.4 • Identify one thing that you would do to verify an establishment's controls for SRM compliance and one thing that would be a noncompliance _____ _____ _____ _____ _____ _____ _____ _____ _____

Slides	FAD/RAD KNOWLEDGE CHECK
11-14	**Knowledge Check 1** True or false? As the level of TB decreases, it becomes increasingly important to have an adequate number of granulomatous lesions submitted to effectively detect an affected herd. _____ _____ **Knowledge Check 2** Which of the following are SRMs found in the head of cattle 30 months of age or older? _____ _____ _____ _____ **Knowledge Check 3** True or false? Bovine tuberculosis only causes lesions in old cattle. _____ _____ _____ _____
Slides	**SUMMARY**
15	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are **not** counted. They are for your use only.