

## HACCP OVERVIEW

### Objectives

1. Describe the regulatory requirements related to the Sanitation Performance Standards (SPS).
2. Define process control and sanitary dressing procedures.
3. Describe the role of sanitary dressing procedures as part of an establishment's food safety system.
4. Describe the regulatory requirements related to the Sanitation Standard Operating Procedures (SSOP).
5. Describe the 7 principles of Hazard Analysis and Critical Control Point (HACCP).
6. Describe the regulatory requirements related to Pathogen Reduction for the *Salmonella* performance standards.
7. Describe the regulatory requirements related to Pathogen Reduction for generic *E. coli* Testing.
8. Describe the regulatory requirements for the food safety standard related to fecal contamination.
9. Explain how FSIS Directive 5000.1 is used to verify these requirements.

### Introduction

The establishment's Food Safety System is comprised of the following four main elements:

- Sanitation Performance Standards
- Sanitation Standard Operating Procedures
- HACCP
- Pathogen reduction (*Salmonella* performance standards, generic *E. coli* testing)

This module will highlight some of the regulatory requirements establishments must meet; give you a brief overview of the inspection verification tasks performed by the Consumer Safety Inspector (off-line). These tasks are described in FSIS PHIS Directive 5000.1, "Verifying an Establishment's Food

Safety System.” Although these tasks are not performed by Food Inspectors, it is important for you to know about these requirements and how compliance with them is verified because all of these activities have an impact on the environment in which you work.

In addition to covering the four main elements of the establishment’s food safety system, we will also briefly cover the establishment’s responsibility for the Food Safety Standard (Zero Tolerance) regulations and the system approach to sanitary dressing procedures.

NOTE: Regulations cited are not exact. Please refer to the actual regulations as needed.

### **Sanitation Performance Standards (SPS) (9 CFR 416.1-416.7)**

*9 CFR 416.1 General Rules. Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.*

Proper and effective sanitation practices and conditions are an essential part of all safe food manufacturing processes. Insanitary facilities and equipment and poor food handling and personal hygiene practices by employees create an environment in which pathogens and other food safety hazards can contaminate and adulterate products. Consequently, proper sanitation is a fundamental requirement under the Federal Meat Inspection Act (FMIA).

The SPS regulation requires establishments to maintain a sanitary environment. Performance standards stated in the regulations are results-oriented, allowing the establishment flexibility in achieving the specified results. Simply put, the results expected are defined in the regulation but the means or methods to achieve the results are not specified. Although establishments can use different and varying means to meet the performance standards, the required results are always the same – establishments must operate under sanitary conditions in a manner that ensures product is not adulterated and in a way that does not interfere with FSIS inspection.

NOTE: Regulations cited are not exact. Please refer to the actual regulations as needed.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances*

*used must be safe and effective and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.*

Proper maintenance of the grounds around an establishment is essential for ensuring good sanitation. Establishments are responsible for preventing sources of adulteration of product.

Establishments must implement and maintain an integrated pest control program to eliminate the harborage and breeding of pests on the grounds and within the establishment facilities and must safely and effectively use interventions, such as pesticides, fumigants, and rodenticides. This regulation does not require the integrated pest control program to be a written document. This regulation does not require that pest control substances be approved by FSIS prior to use.

The sanitation performance standard regulations also require the establishment to be responsible for the safe and effective use and storage of pesticides.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (b) Construction. (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions. (2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions. (3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.*

The performance standards for construction provide establishments, regardless of size, the flexibility to design facilities and equipment in the manner they deem best to maintain the required sanitary environment for food production.

*9 CFR Sec. 416.2 Establishment grounds and facilities (b) Construction. (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored.*

Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner that prevents the adulteration of the edible product or the creation of insanitary conditions.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (c) Lighting. Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated.*

Specific regulatory requirements for lighting combine the meat and poultry lighting requirements into one performance standard. However, FSIS has reserved specific lighting requirements in poultry establishments at the post mortem inspection stations and at reinspection stations (§ 381.36).

While establishments have flexibility in providing lighting, illumination must be adequate in quality and quantity, and well distributed. It must allow for proper monitoring of sanitary conditions and processing conditions and for examination of product for evidence of adulteration.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (d) Ventilation. Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

The Agency does not expect the establishment to completely eliminate all odors, vapors, and condensation. However, plants must control ventilation to prevent adulteration of the environment that, in turn, can lead to adulteration of product or the creation of insanitary conditions.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. Plumbing systems must be installed and maintained to: (1) carry sufficient quantities of water to required locations throughout the establishment; (2) properly convey sewage and liquid disposable waste from the establishment.*

It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water to the establishment to prevent product adulteration or creation of insanitary conditions.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;*

The design, installation and maintenance of an adequate plumbing system are key responsibilities of the establishment. Because plumbing systems carry water into establishments and convey water from the establishments, problems with plumbing systems can easily cause product contamination or adulteration.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (4)*

*Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing;*

Floor drainage must be adequate to prevent the spread of contaminants into the production environment during cleaning and normal operation.

Cross-connection between potable and non-potable water is not acceptable. The plumbing system must be installed and maintained to prevent adulteration. Back-flow devices must also be used as appropriate to prevent cross contamination of potable water sources.

*9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (6) Prevent the backup of sewer gases.*

*9 CFR Sec. 416.2 Establishment grounds and facilities. (f) Sewage disposal. Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

The establishment must ensure that sewage does not back up into processing areas. Documentation from a State or local authority approving private sewage disposal systems must be on-site and available to FSIS upon request.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse. (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.*

The water performance standard requires that potable water comply with EPA's National Primary Drinking Water regulations. Some meat establishments use private wells for their water supply.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse (2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose.*

FSIS expects establishments to produce ready-to-eat products that are free of pathogens; therefore, reuse water used to chill or cook ready-to-eat product must be free of pathogens.

In many cases, establishments monitor water reuse activities as part of their HACCP plans because the water treatments or conditioning can eliminate or reduce hazards they have determined to be reasonably likely to occur. The requirement that water be reused only "for the same purpose" refers to reusing water from the ready-to-eat area only in the ready-to-eat area, and reusing water from the not-ready-to-eat areas only in not-ready-to-eat areas. For example, chiller water or water from the final bird washer that is reconditioned can be reused in the scalding.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse (3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.*

Establishments can reuse water in a manner that does not adulterate product or create insanitary conditions. The performance standards allow the reuse of water in numerous processing contexts, as long as the establishment takes actions necessary to ensure that the water does not adulterate product and that sanitation is not compromised.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse (4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas.*

Some establishments recondition their water through an advanced wastewater treatment facility, either onsite or under contract. To prevent establishments from using water from sewage lines, reconditioned water must never have contained

human waste. Because reconditioned water is of high quality, it can be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse (5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product.*

Any water can be used for any purpose in edible or inedible product areas, provided it:

- has never contained human waste.  
Establishments must not reuse water from sewage lines, therefore, it is required that the reuse water never have contained human waste.
- has been conditioned to be free of pathogenic organisms.  
Reuse water must be free of pathogenic organisms to prevent their spread throughout the establishment, which could lead to cross-contamination of product.
- does not contact edible product.  
Reuse water might contain coliforms or chemical or physical contaminants, so it cannot contact edible product.

*9 CFR 416.2 (g) Water supply and water, ice, and solution reuse (6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.*

To prevent contamination or adulteration of the product, establishments must not use water contaminated with pathogens, chemicals, or physical contaminants in edible product areas.

*9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets. (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.*

OSHA standards (29 CFR 1910.141) for lavatories must be followed when plants are constructed or remodeled. FSIS does not regulate the number of lavatories required. The establishment must maintain lavatory facilities in good repair and in a sanitary manner.

*9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets (2) Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.*

*9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets (3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.*

Leaking refuse receptacles may allow the spread of contaminants into the environment, which could then lead to cross-contamination of product and product areas.

*9 CFR 416.3 Equipment and utensils. (a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.*

Establishments may select any method to clean utensils and equipment as long as they are maintained in a sanitary condition.

*9 CFR 416.3 Equipment and utensils (b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.*

Equipment and utensils must be designed in a manner that allows FSIS inspection personnel to view them for compliance with sanitary requirements. They must be located so that they are safely accessible to inspection prior to and during operation.

*9 CFR 416.3 Equipment and utensils (c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions.*

*Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.*

Receptacles used for storing inedible product must be properly and conspicuously marked, and never used for edible product or create insanitary conditions.

*9 CFR 416.4 Sanitary operations. (a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.*

Generally, establishments clean and sanitize their facilities once a day; however, some establishments conduct chemical cleanup less often.

*9 CFR 416.4 Sanitary operations (b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.*

During the normal course of operations meat products should not come in contact with non-food contact surfaces. If non-food contact surfaces are not properly cleaned and sanitized, insanitary conditions could result, leading to potential adulteration of product.

*9 CFR 416.4 Sanitary operations (c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use.*

It is required that meat products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available for FSIS review. The documentation can vary with the nature and intended use of that chemical.

Meat establishments must ensure that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately.

*9 CFR 416.4 Sanitary operations (d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.*

As product moves through the process, there might be elements in the environment that could adulterate it. Employees who move and handle product improperly are another possible source of contamination. The establishment must decide, depending upon the situation and the circumstances within the establishment, how the product should be protected through all phases of the process. For example, the establishment might cover the product when it is stored in the cooler to prevent contamination.

*9 CFR 416.5 Employee hygiene. (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.*

*9 CFR 416.5 Employee hygiene. (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.*

*9 CFR 416.5 Employee hygiene. (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.*

FSIS has authority to take action against any unhygienic practice that could result in insanitary conditions or adulterated product. This includes handling procedures that might contaminate edible products or create insanitary conditions.

*9 CFR 416.6 Tagging insanitary equipment, utensils, rooms or compartments.* When the Consumer Safety Inspector finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he or she will attach a "U.S. Rejected" tag to it. Equipment, utensils, rooms, or compartments that are tagged cannot be used until they are made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag. The regulatory control action should remain in effect until the establishment has taken corrective action and has proposed effective preventive measures.

## SANITARY DRESSING – A SYSTEMS APPROACH

### Introduction

This module has two purposes. First, we will provide some background information about sanitary dressing and the procedures in the slaughter processes for cattle and how they may impact sanitary dressing. Second, we will provide some information on how the off-line inspector verifies compliance using the instructions in FSIS Directives 6410.1 and the thought process for using the systems based approach to making compliance determinations.

### Definitions

**Process Control Procedure:** A defined procedure or set of procedures designed by an establishment to provide control of operating conditions that are necessary for the production of safe, wholesome food. The procedures typically include observing or measuring system performance, analyzing the results to set control criteria, and taking action when needed to ensure that the system continues to perform within the control criteria. The procedure would include planned measures taken by the establishment in response to any loss of process control. In addition, the procedure can be used as support for decisions made in the hazard analysis.

**Sanitary Dressing:** Practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat food product in a sanitary environment.

**Contamination of Carcasses and Parts:** Carcasses and parts, based on organoleptic inspection, have been prepared, packed, or held under insanitary conditions that may have caused them to come into contact with filth, or that may have caused them to be injurious to health and are condemnable unless they can be effectively reprocessed. Contamination can originate from two sources:

1. Substances not related to the species being slaughtered like, oils, rail dust, condensate, and unidentified foreign material.
2. Substances related to the species being slaughtered like digestive content, milk, ingesta or bile. Sanitary dressing procedures minimize this type of contamination.

### The Role of Sanitary Dressing in the Food Safety System

FSIS continues to find positive *E. coli* O157:H7 results in samples of ground beef and trim, and to have recalls - some associated with human illness. These positive results can be attributed to ineffective sanitary dressing and process

control procedures that lead to insanitary conditions during slaughter. FSIS believes that establishments should focus more closely on their sanitary dressing and process control procedures to prevent carcass contamination.

### **Effective Sanitary Dressing Procedures Prevent Carcass Contamination**

Effective sanitary dressing and process control procedures are crucial to an establishment's ability to produce a clean, safe, and wholesome product. Establishments must handle beef carcasses, organs and other parts in a sanitary manner and prevent contamination with fecal material, urine, bile, hair or dirt, or foreign matter in accordance with 9 CFR 310.18(a). Since these sources can contain pathogens, establishments should reduce the potential for exposure to any food safety hazard during removal of hide, feet, GI tract, and internal organs. Sanitary dressing procedures must be designed to prevent insanitary conditions and they must prevent the contamination of carcasses.

### **Sanitary Dressing Procedures are Part of the Food Safety System**

Sanitary dressing procedures lay the foundation for an effective food safety system including HACCP Critical Control Points (CCPs) designed to prevent, eliminate, or reduce hazards to acceptable levels.

Establishments must operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure product is not adulterated, as required by SPS regulations, 9 CFR 416.1- 416.5. Examples of means to achieve this include:

- Maintaining adequate separation of carcasses, parts and viscera during dressing.
- Routinely cleaning and sanitizing equipment and hand tools used to remove contamination or to make cuts in the carcass.
- Arranging equipment to prevent the contact of successive carcasses with contaminated equipment.
- Washing hands and aprons frequently.
- Implementing decontamination and antimicrobial intervention treatments such as carcass washes or sprays, to address contamination that could not be prevented in the slaughter process.

The point of sanitary dressing and process control is to prevent the creation of insanitary conditions (i.e., contamination) and to ensure that carcasses are as clean as possible throughout the entire slaughter operation. The establishment should not be waiting until just before the carcasses complete the slaughter process to address sanitary dressing.

Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other prerequisite programs.

A food safety system includes all aspects of the operation, from the beginning of the product flow at receiving to the end of the process, labelling and shipping. Establishment's must consider all potential food safety hazards that may occur.

They must consider the animals entering the establishment. How clean or muddy are transport trucks? How often should the holding pens be washed down? Are animals hauled long distances? How many animals can be unloaded before they are subjected to overcrowding? How does the condition of the animals effect or overwhelm establishment antimicrobial interventions? Consider what will happen to the primal or sub primal parts when they are shipped from the establishment. Consider the testing that product intended for grinding will undergo. How can the establishment ensure product is safely stored at a proper temperature? These are just a few of numerous factors and variables that can impact carcass contamination, effectiveness of antimicrobial interventions, and pathogen testing results.

## **Systems Approach to FSIS Verification**

The thought process for verifying these procedures is for the inspection program personal (IPP), especially the off-line inspector, to use a system based approach. Verification activities begin at live receiving and continue through the whole process flow through slaughter, fabrication and grinding operations. This means that the Agency expectation is for the establishment not to wait until the final rail to verify sanitary dressing and process control procedures.

Verification of a food safety system requires that inspection program personnel (IPP) evaluate production operations by looking at all aspects of those operations and assessing the interactions between them. IPP accomplish this through the observation of the establishment's implementation of a variety of plans and procedures (e.g., HACCP plan, Sanitation SOP, prerequisite programs, FSIS and establishment testing results). IPP also review the documents associated with those plans and procedures.

IPP should think beyond the boundaries of the slaughter floor. FSIS verification does not end when carcasses leave the slaughter area. Carcasses move on to fabrication and become fabricated products like rounds, steaks, trimmings and ground beef. Any contamination incidents on the slaughter floor can impact in the microbial quality of the resulting ground product.

## **Possible Indications of Loss of Control**

The following examples are types of findings that can indicate loss of control:

- A comparison of results of current and previous IPP reviews indicates there has been an increase in contamination.
- Evidence that contamination events are not being effectively prevented.
- Input indicating there is an increase in positive pathogen results from either FSIS or establishment microbiological testing.

When the information gathered suggests that the establishment has lost process control, IPP are to determine if the establishment has taken measures to restore process control. Examples of measures an establishment may take include: cleaning of contaminated equipment, removing excessive mud via cattle washes, or additional checks to verify process control. Certain events that could indicate the need for additional tasks could be: online IPP feedback, muddy conditions on trucks, animals, pens and increased fecal findings.

## Potential Contamination Points in the Slaughter Process

FSIS has identified the points in the slaughter process where carcasses are most vulnerable to contamination. This was determined through scientific literature review as well as best practice guidance created by industry. The steps listed are in sequential order for ease of presentation but are not all inclusive.

### Beef Slaughter Process – Potential Contamination Points

- A. Live receiving/holding:** When cattle arrive, there is an increased potential for contamination with enteric pathogens such as *E. coli* O157:H7, other shiga toxin-producing *E. coli* (STEC), and *Salmonella* due to their presence on the hide and in feces. Transport to the slaughter facility, loading and unloading, and commingling with other cattle can cause stress and an increased shedding of pathogens.
- B. Sticking:** This is the point in the process where the animal is bled. The establishment must minimize contamination of the carcass during the cut.
- C. Hide removal (manual and mechanical):** This is the step where the hide is removed from the animal. Hides are known to be a significant source of contamination (e.g., dust, dirt, feces, and mud). It is important to maintain sanitary conditions when handling the hide.
- D. Wash cabinets:** Can be utilized at point(s) in the slaughter process. Measures need to be implemented by establishments to prevent cross contamination during use.
- E. Bunging:** A cut is made around the rectum to free it from the carcass, and then it is tied off to prevent spillage of fecal material.

- F. **Brisket opening:** This is the point where the brisket is split.
- G. **Head removal:** It is important to maintain sanitary conditions when removing the head because cross contamination can occur if the head comes into contact with insanitary heads, equipment and employees.
- H. **Rodding the weasand (esophagus):** The establishment uses a metal rod to free the esophagus from the trachea and surrounding tissues. Weasand meat can be salvaged for use in raw ground beef production. Typically the weasand is tied off to prevent rumen spillage.
- I. **Evisceration:** Viscera are removed including edible offal, heart, intestines, paunch, liver and spleen. If viscera are not handled properly or if employee hygiene is poor, contamination of the carcass and edible offal can occur.
- J. **Carcass splitting:** This is the point where carcasses are split vertically into two halves.
- K. **Head and cheek meat processing:** Meat is removed from the head and cheek. This meat can be used in the production of raw ground beef products.

## Establishment Interventions

An intervention is a process step that has the purpose of eliminating or reducing a hazard to an acceptable level. How well the establishment performs its sanitary dressing procedures directly impacts whether the decontamination and antimicrobial intervention treatments will be effective and accomplish their intended results.

### Overwhelming the System

When incoming contamination overwhelms the intervention treatments, reduction of *E. coli* O157:H7 or other pathogens may no longer meet the standard of reduction. So even though the establishment may have validated interventions at strategic locations in the slaughter process, it doesn't afford them any leeway or allowance for sloppy dressing procedures or poor employee hygiene, such as rupturing guts, not cleaning hands, gloves, knives or equipment. The interventions will not achieve their intended effect if the incoming bacterial loads on the hide or feathers are so great that they overwhelm the antimicrobial properties.

## Determining and Documenting Noncompliance

Compliance determinations will be made by off-line personnel using the GAD thought process: gather information by asking questions, assess the information, and determine compliance.

### Indications of Potential Noncompliance

Some observation findings such as those listed below should serve as prompts to direct IPP to points in the process where sanitary dressing procedures are not being properly implemented.

- Repeated or ongoing noncompliance related to contamination of carcasses with feces, milk or ingesta at the final rail for livestock (zero tolerance).
- Increased contamination of carcasses or parts due to environmental conditions, like weather or season or other factors affecting the condition of incoming animals that have not been addressed by the establishment.
- Feedback from IPP indicating an increase in positive pathogen results from either FSIS or establishment results.
- Inappropriate design or use of facilities, equipment, or utensils for the type or size of cattle slaughtered.
- Feedback from on-line IPP indicating increased incidents of carcass contamination.

Incidental contamination (e.g., ingesta, feces, foreign material, rail dust) does not automatically represent an insanitary condition. Even if there are observations of contamination on carcasses during the slaughter process, the establishment still has the opportunity to implement measures that will address the contamination before the carcasses complete the slaughter process. IPP must assess the available information and evaluate each occurrence of incidental contamination to determine whether the establishment has failed to prevent the creation of insanitary slaughter conditions prior to carcasses completing the process.

After assessing the information gathered during FSIS verification, off-line IPP are to determine whether noncompliance exists.

## Summary

Sanitary dressing procedures are critical to preventing insanitary conditions, particularly at the vulnerable points in the slaughter process. Contamination on the carcasses is the result of an insanitary condition caused by ineffective sanitary dressing procedures. Reducing *E. coli* O157:H7, and other pathogens

such as STEC and *Salmonella*, is a regulatory requirement and ensure food safety. The slaughter process is a system, so IPP must remember to use a system based approach in evaluating the entire slaughter system. Compliance with sanitary dressing and process control procedures is determined in relation to the entire food safety system, not just one contamination incident.

### **Sanitation Standard Operating Procedures (SSOPs)**

According to 9 CFR 416.11-15, the establishment is responsible for developing, implementing, and maintaining written Sanitation Standard Operating Procedures (SSOPs) that meet the requirements of Part 416. These SSOP regulations are not cited here, but can be found online in the Code of Federal Regulations (CFR). Insanitary facilities or equipment, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. Sanitation SOPs clearly define the establishment's responsibility to consistently follow effective sanitation procedures that will substantially minimize the risk of product contamination and adulteration.

It is a regulatory requirement that the plant create written SSOPs describing the daily procedures conducted before and during operations to prevent direct contamination or adulteration of products.

The written procedures must identify pre-operational and operational sanitation procedures. At a minimum, SSOPs must address the cleaning of food contact surfaces of facilities, equipment, and utensils. The regulation does not specify how much detail SSOPs must contain.

The Sanitation SOP must contain:

- The frequency the procedures in the SSOP are conducted
- Identification of the employee(s) or position responsible for the implementation and maintenance of the SSOPs

The establishment must take corrective actions any time the establishment or FSIS determines that the SSOP has failed to prevent direct product contamination or adulteration of product. SSOP failure can be the result of either not implementing or not maintaining the SSOP, and it can occur before or during operations.

Establishments must initiate corrective actions when either the plant or FSIS determines implementation of the procedures fails to prevent direct product contamination or adulteration. Establishments must implement all three parts of the corrective action, i.e., they must:

- 1) dispose of contaminated or adulterated product appropriately
- 2) restore sanitary conditions
- 3) prevent recurrence of failure

Corrective actions may also include reevaluation and modification of the Sanitation SOP or the procedures specified in it. However, it might not be necessary to modify the SSOP in every case.

Establishments must maintain daily records that document they are carrying out the sanitation procedures outlined in the SSOP, including the corrective actions taken. Plant management may exercise flexibility in designing records. There is no set format, and records do not have to be included in the written SSOP.

The Consumer Safety Inspector verifies that SSOPs are developed, implemented, maintained, and that they are effective. FSIS also verifies that the establishment maintains daily records.

### **HACCP: Establishment Responsibilities**

FSIS has the overall authority and oversight to regulate meat/poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat/poultry products. When the Pathogen Reduction/HACCP System Final Rule was published in July 1996, and the regulation was first implemented in large establishments in January 1998, in small establishments in January 1999, and in very small establishments in January 2000, FSIS required all establishments that produce federally inspected meat and poultry products to design and operate HACCP systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment's particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

### **The 7 Basic Principles of HACCP**

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) Working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. This paper is not a regulatory document. However, it is a document that was utilized by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is

helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan which will be regulated under Title 9 Code of Federal Regulation (CFR) Part 417.

## **The 7 HACCP Principles**

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

### *Principle 1: Conduct a hazard analysis.*

A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) identified the purpose of the hazard analysis in its guidance document as a process used to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

A hazard is defined by NACMCF as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Establishments must consider all three types of hazards – biological, chemical, and physical – at each step of the production process.

### Biological Hazards

The biological hazards of meat and poultry products result from the presence of potentially pathogenic bacteria in and on the live animal, including intestinal contents and exterior surfaces such as hide, hair, and hooves. Bacterial contamination of carcass surfaces is an unavoidable consequence of processing animals into meat and for human consumption. The types of bacteria present on the live animal or bird will largely determine the bacterial population that exists on the carcass surface. Consequently, products derived from carcasses will contain the same types of bacteria present on the carcass surfaces. Establishments must do their best to control or reduce the hazard, or to prevent it from entering

the process, as discussed previously in SPS, sanitary dressing and process control.

The prevalence of the pathogen **Salmonella** in beef, lamb, pork, and poultry carcasses varies greatly. The overall contamination of meat and poultry carcasses with these pathogens depends not only on the numbers of the pathogens on the hair, feathers, skin, and in the intestinal tract of the animals, but is also significantly affected by the degree of cross-contamination occurring from these sources during slaughter and processing.

*Escherichia coli* is commonly found as part of the normal bacteria of the intestinal tract of humans and animals. Some strains, including **Escherichia coli O157:H7**, can cause serious illness in humans. Cattle may carry *Escherichia coli* O157:H7 in the intestinal tract at the time of slaughter, although it is actually harmless to these animals. Beef has been implicated in a number of foodborne illnesses associated with this pathogen. Contamination with *Escherichia coli* O157:H7 can be reduced through the use of sanitary dressing procedures during slaughter (dehiding and evisceration) and pathogen reduction intervention treatments (organic acid rinses, hot water rinses, and steam pasteurization). FSIS considers raw ground beef contaminated with *E. coli* O157:H7 and other Shiga toxin-producing *E. coli* (STEC), to be adulterated, unless the ground beef is further processed to destroy this pathogen.

### Chemical Hazards

Animals may be presented at slaughter with violative levels of chemical residues. This hazard includes chemical residues resulting from use of, or exposure to, drugs, pesticides, and other compounds. For example, dairy cows may be given antibiotics by the producer to treat infections like mastitis, and failure to observe the required withdrawal time may result in violative residues. Some examples of environmental contaminants that may be consumed by animals include lead, cadmium, mercury, arsenic, dioxins, or polychlorinated biphenyls or PCBs.

The potential health consequences of exposures to chemicals in food can be serious, are often inadequately understood, and deserve serious consideration. The long-term and cumulative effects of exposure associated with chemicals in food pose special difficulties in identifying and addressing these risks. Chemical residues have been linked through research to various types of cancers. The public health concerns associated with the long-term effects of exposure to chemicals from ingestion of food is not well understood or well documented.

### Physical Hazards

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Physical hazards, such as pieces of metal, sometimes occur because equipment has not been properly

maintained. In some processes, such as raw-ground, product may be received that is contaminated by foreign material, which if not controlled, may subsequently become incorporated into the ground product. Foreign material would include non-animal objects such as metal, wood, rubber, glass, steel, lead, or other objects.

Typical public health concerns associated with consuming products that contain physical hazards include broken teeth and damage, such as tears, to the mouth, esophagus, stomach, and intestines. These physical hazards may obstruct air passages or intestines. In some cases, death may result due to suffocation or infections (intestinal blockages). Small children are particularly susceptible to problems brought on by physical hazards since their body structures are smaller, and the physical objects may have a greater effect.

### Flow Charts

At each step in its processes, the establishment must determine what food safety hazards may be associated with that step, if that hazard is reasonably likely to occur in the process, and what controls will be used to prevent, eliminate, or reduce the hazard to an acceptable level.

Different establishments may have identified different hazards as reasonably likely to occur and different control measures for them, even though their processes may appear to be similar. The hazard analysis shall include hazards that can occur before, during and after entry into the plant. This provides a basis for determining the critical control points (CCPs).

### *Principle 2: Determine critical control points*

The hazards that were identified in the hazard analysis must be addressed in the HACCP plan. A hazard is controlled by one or more critical control points (CCPs).

A **critical control point** is defined as a point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Examples of CCPs include product temperature, certification of incoming product, microbiological testing, testing for foreign objects such as metal contamination, the chemical concentration of a carcass rinse or spray, and other such parameters.

For **each** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable. Establishments must have documentation

supporting all of these decisions, and they must be able to demonstrate that their plan designs are valid and effective in operation.

*Principle 3: Establish critical limits*

The next step in the development of a HACCP plan is to establish critical limits for each critical control point. **Critical limits** (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states that a CL is a **maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The establishment must consider the food safety standard that must be met at each CCP. Critical limits are designed to ensure applicable targets or performance standards pertaining to the specific process or product.

Critical limits are most often based on process parameters such as temperature, time, physical dimensions, or presence of target pathogens. Critical limits must be actual values that can be measured or quantified.

*Principle 4: Establish monitoring procedures*

Once critical limits are set for each CCP during the HACCP plan development, procedures must be established to monitor the CCPs to determine whether the critical limits are being met. **Monitoring** is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Establishments are responsible for determining the procedure used to monitor each CCP. Monitoring procedures should be designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

When it is not possible to monitor a CCP on a continuous basis, then it is monitored intermittently and the frequency must be determined. The frequency selected should be adequate to determine that the CCP is under control.

*Principle 5: Establish corrective actions*

Next, the establishment determines corrective actions for each CCP that must be taken in cases where the CL is not met. The specific corrective actions depend upon the process used and type of food produced.

When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers. The corrective actions consist of the following:

- Identifying and eliminating the cause of the deviation,

- Ensuring that the CCP is under control after the corrective action is taken,
- Ensuring that measures are established to prevent recurrence, and
- Ensuring that no product affected by the deviation is shipped.

*Principle 6: Establish recordkeeping and documentation procedures*

When developing the HACCP plan, the establishment must ensure that the HACCP system has an effective recordkeeping system. **Records** are written evidence documenting the operation of the HACCP system. All measurements taken at a CCP, and any corrective actions taken, should be documented and kept on file. These records can be used to trace the production history of a finished product. If any questions arise about the product, a review of records may be the only way to determine whether the product was produced in a safe manner according to the HACCP plan. The **HACCP plan** outlines the formal procedures the establishment will follow to meet the seven principles.

The **supporting documentation** includes the rationale used to establish CCPs, critical limits, monitoring procedures and frequencies, corrective action procedures, and verification procedures and frequencies. This includes all scientific references, regulatory resources, and materials from other sources (e.g., extension services, academic experts, consultants, industry trade associations) that have been used in the development of the HACCP plan.

The **daily operational records** are what most of us think of when we think of HACCP records. These include the actual records from the implementation of the HACCP plan (monitoring, corrective actions, and verification).

The HACCP regulation requires that HACCP records:

- Contain the date and time of the activity reflected on the record
- Contain the signature or initials of the employee making the entry
- Have the information entered on the record at the time it is being observed
- Contain actual observations or data values obtained

*Principle 7: Establish verification procedures*

HACCP systems must be systematically verified. Verification establishes the accuracy of, or confirms the monitoring of, the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. After initial validation, the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine

whether the HACCP plan needs modification and revalidation to achieve its food safety objective. Establishments must also be able to provide supporting documentation for the verification procedures and frequencies specified in the HACCP plan.

Ongoing verification activities consist at a minimum of **calibration procedures** (if there are instruments that require calibration), **direct observations** of monitoring and corrective actions, and **records review**. All three of these will be described in the HACCP plan, as applicable.

### **HACCP: FSIS Responsibilities - Inspection Verification Tasks**

FSIS responsibilities are outlined in **FSIS PHIS Directive 5000.1**. The off-line inspectors, known as Consumer Safety Inspectors, are responsible for properly performing the tasks as described in this Directive. The information in the Directive describes the regulatory thought process.

The regulatory process for conducting HACCP tasks is as follows:

- **Methodology**
- **Decision-making**
- **Documentation**
- **Enforcement**

#### *Verification Methodology*

#### *The Five Regulatory Requirements*

There are four regulatory requirements that the establishment must comply with during the day-to-day or ongoing operation of the HACCP system. These regulatory requirements are:

1. Monitoring
2. Verification
3. Recordkeeping
4. Corrective Actions

CSI's use the GAD thought process that is described in Directive 5000.1 that the off-line CSI uses when verifying regulatory requirements includes:

- gathering information by asking questions,
- assessing the information, and
- determining regulatory compliance.

For each of the regulatory requirements, the Directive outlines questions to consider. This thought process is used to verify all of the regulatory requirements.

There are two general types of HACCP verification tasks:

- 1. Hazard Analysis Verification (HAV) Task:** This task directs the CSIs to review the hazard analysis for all HACCP process categories in the establishment. CSIs are to use the recordkeeping and the review and observation components to verify that the establishment meets the regulatory requirements for the hazard analysis.
- 2. HACCP Verification Task:** CSIs are to use the recordkeeping and review and observation components to verify that the establishment is effectively implementing the procedures set out in its HACCP system. CSIs are to verify that the establishment meets all HACCP regulatory requirements, including monitoring, verification, recordkeeping, and corrective action for all CCPs for a specific production.

CSIs are also to verify the implementation of prerequisite programs or other control measures the establishment uses to show that specific hazards are not reasonably likely to occur.

## **Pathogen Reduction**

### ***Salmonella***

FSIS established the *Salmonella* verification program in 1996 as part of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems Final Rule. The PR/HACCP Final Rule established *Salmonella* performance standards that are used to verify process control in meat and poultry slaughter and processing establishments that produced certain classes of product (9 CFR 310.25(b)(1) and 381.94(b)(1), respectively). The performance standards were developed using national baseline studies conducted before the rule's implementation. Since then, FSIS has conducted additional prevalence and risk assessments for pathogens in FSIS regulated products, revised the performance standards to meet public health goals, and has published a number of Federal Register Notices (FRN).

FSIS originally selected *Salmonella* as the target organism because it is a commonly reported cause of foodborne illness and is present in all major species. The *Salmonella* genus includes over 2,300 serotypes. *Salmonella* bacteria are the most frequently reported cause of foodborne illness. According to the Centers for Disease Control and Prevention (CDC), salmonellosis causes

an estimated 1.4 million cases of food borne illness and more than 400 deaths annually in the United States.

IPP will collect samples using on-going scheduled sampling (routine sampling) using a moving window approach to assess process control.

Raw meat ground products, sampled and **analyzed for *Salmonella*** include:

- Ground and chopped raw meat from cattle carcasses (beef or veal which may or may not contain added ingredients, spices, or seasonings), that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)) and hamburger (9 CFR 319.15(b)). Sampled products may contain meat derived from advanced meat recovery (AMR) systems, but AMR meat by itself is not sampled.
  - Products that are **not** sampled in this program include beef patties as defined in 9 CFR 319.15(c), and fabricated steaks and similar products as defined in 9 CFR 319.15(d).

**Note:** *Salmonella* verification sample sets for raw ground beef products have been discontinued with the exception at establishments that recently exceeded the performance standard and are in 'Category 3' (FSIS Notice 28-14). FSIS also discontinued collecting MT43S samples in very low volume grinding establishments. In addition, raw beef samples collected for STEC analysis are also analyzed for *Salmonella*.

**Note:** FSIS is not currently sampling and testing for *Salmonella* in steers or heifers, cows or bulls, or market hogs per FSIS Directive 10,250.1.

### ***Salmonella* Performance Standards for Ground Beef<sup>1</sup>**

Product class	Pathogen	Performance standard	Number of samples tested	Sampling Method	Maximum number of positives to achieve standard	Revised Standard Implemented
Ground Beef	<i>Salmonella</i>	7.5%	53	One sample per event	5	N/A

<sup>1</sup> As per Directive 10,250.1

For ground beef, an establishment can have no more than 5 positive sample results out of 53 samples in the moving window.

## **Generic *E. coli* Testing**

### **Livestock**

## **Generic *E.coli* Testing for Livestock Slaughter Operations**

Each official establishment that slaughters livestock is required to test for *Escherichia coli* Biotype I or generic *E. coli*. An establishment employee selects the samples for generic *E. coli* testing. The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter establishments. FSIS verifies that the establishment meets the regulatory requirements for generic *E. coli* testing.

Fecal contamination is one of the principal sources of pathogenic organisms that contaminate livestock carcasses. *Escherichia coli*, Biotype I, also called generic *E. coli*, is an indicator of fecal contamination because it is common in the intestinal tract of food animals. The intestinal tract is also the primary pathway for contamination of meat and poultry with pathogens such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. Ongoing *E. coli* testing by livestock and ratite slaughter establishments helps them determine whether the slaughter process is under control or whether carcasses are being contaminated with feces. In other words, generic *E. coli* testing is a process control indicator for fecal contamination.

Sections 310.25(a) of the meat regulations and 381.94(a) of the poultry regulations addresses the regulatory requirements that establishments need to meet for generic *E. coli* testing. Slaughtered livestock that will not receive the FSIS mark of inspection (such as custom exempt livestock) are exempt from generic *E. coli* testing.

### **Performance Criteria**

FSIS has developed performance criteria for livestock using the excision sampling technique. Generic *E. coli* performance criteria are not enforceable regulatory standards. Performance criteria are numbers published in the regulations that represent the highest expected microbial loads on carcasses when the slaughter process is under control. They give livestock slaughter establishments guidance about the effectiveness of their slaughter process in preventing fecal contamination. Test results that meet the criteria in the regulations provide evidence that the establishment is maintaining adequate process control for fecal contamination and sanitary dressing.

Furthermore, the generic *E. coli* baseline results (statistical process control criteria) published in the Federal Register Notice on February 17, 2005 (Docket

Number 02-046N), using the sponging sampling technique, can serve as a valuable support to establishments that slaughter cattle and swine in assessing the effectiveness of their process, using their own test results.

**NOTE:** Establishments must use statistical process control to evaluate their test results when they slaughter species or use sampling techniques for which the Agency has not developed performance criteria.

### **Inspection Program Personnel (IPP) Responsibilities**

FSIS responsibilities are outlined in FSIS PHIS Directive 5000.1. The IPP is responsible for understanding and properly performing the Generic *E. coli* verification task in the Public Health Information System (PHIS) as described in this Directive. The Generic *E. coli* verification task addresses the regulatory requirements 9 CFR 310.25(a) or 381.94(a) the establishment must meet when developing the written generic *E. coli* testing procedure.

IPP are to perform the Generic *E. coli* verification task on a **routine** basis (priority scale level 6) at the frequency specified in the establishment's task list. IPP are also to initiate a **directed** Generic *E. coli* verification task if they observe noncompliance with the generic *E. coli* testing requirements while performing other tasks or when instructed to do so by supervision or other policy issuances.

### **Generic *E. coli* Testing Verification**

Establishments that slaughter livestock must develop a written sampling procedure that identifies the employees designated to collect samples, the locations of sampling, how randomness is achieved, and measures to ensure sample integrity as described in 9 CFR 310.25(a)(2)(i) and 381.94(a)(2)(i), respectively.

IPP verify that establishment meets the applicable regulatory requirements for generic *E. coli* testing by reviewing the establishment's written sampling procedure, observing the designated establishment's employee executing the written sample procedures and reviewing the establishment's records. IPP are to document the results of their tasks in PHIS, including any noncompliance, according to the instructions described in FSIS Directive 5000.1.

*E. coli* testing requirements are met if the establishment successfully executes the activities addressed in its written procedure, analyzes samples, and keeps records of test results. An *E. coli* Testing Summary Chart (Attachment 1 of this module) is provided as a reference for the species tested, testing frequencies, sample locations, sample sites, and sampling methods allowed by regulation. It is a quick and easy inspection aid when conducting the Generic *E. coli* verification task.

IPP must understand what each section of the regulation means in order to conduct the Generic *E. coli* verification task. The IPP addresses the requirements in 9 CFR 310.25(a) and 381.94(a) as follows:

**1. Sample collection – livestock samples (paragraph (a)(1) of section 310.25 and 381.94)**

*E. coli* testing must be done in establishments that slaughter any market class of cattle, swine, sheep, goats, horses, mules, and equines. **If a combination of types of livestock is slaughtered, the establishment samples only from the species it slaughters in the largest number**

**2. Sampling requirements – location and technique (paragraph (a)(1)(i) and paragraph (a)(2)(ii) of section 310.25 and 381.94)**

The IPP should remember the following things when considering the sample location and technique.

- The location refers to the place within the establishment where the sample is collected.
- Livestock samples are collected after they have been in the cooler for a minimum of 12 hours. There is no maximum time limit. Carcasses can be selected while on the rail or after the final wash and set aside in a convenient spot in the cooler for testing after cooling. It is acceptable to select random samples before carcasses enter the cooler.
- Hot-boning operation samples are taken after the final wash prior to boning.

The sampling site refers to places on the carcass where samples are collected. There are two sampling methods an establishment may use to collect generic *E. coli* samples.

- Excision
- Sponging

Excision sampling is aseptically cutting a surface section from the livestock carcass and sending the tissue sample for laboratory analysis. .

Sponging is aseptically swabbing the surface of the livestock carcass or ratite carcass with a sterile sponge and sending the sponge to the laboratory for analysis.

The chart below provides an easy reference for species and the sampling methods allowed.

<b>Excision</b>	<b>Sponge</b>
Beef Swine	Beef Swine Equine Goats Sheep

Samples must be taken from specific sites on livestock carcasses. The three sites from which excision samples on cattle or sponge samples on cattle, sheep, goat, and equine carcasses must be taken are the:

- Flank
- Brisket
- Rump

In the case of hide-on carcasses for the above species, the sponge samples must be taken from:

- Inside the flank
- Inside the brisket
- Inside the rump

For swine carcasses, three excision or sponge samples must be taken from the:

- Belly
- Ham
- Jowls

**3. Sample requirements – frequency (paragraph (a)(1)(i) and paragraph(a)(2)(iii), (a)(2)(iv), or (a)(2)(v)) of section 310.25 and 381.94**

For *E. coli* testing purposes, livestock slaughter establishments are divided into two categories: very low volume establishments (VLV) and greater than very low volume establishments (>VLV). The categories of establishments are based on the establishment's annual slaughter volume.

Very low volume establishments are described as follows (paragraph (a)(2)(v)):

- Cattle, goats, sheep, horses, or other equine: Annually slaughter fewer than 6,000 head
- Swine: Annually slaughter fewer than 20,000 swine

- Livestock combination: Annually slaughter fewer than a combination of 6,000 cattle, plus sheep, goats, horses, or equines that equal no more than 20,000 animals total

Very low volume establishments begin sampling the first full week they operate after June 1<sup>st</sup>. They continue collecting at least one sample per week in each week they operate until 13 samples are completed. The series of 13 tests must show process control before the series can be ended. If the 13<sup>th</sup> test indicates that the sanitary dressing process is out of control, the establishment must continue to test until process control is regained.

The 13 samples should not be collected in one day or even one week. Sampling over a period of time provides a better indication of the process control of the establishment than taking all samples at once.

Seasonal VLV operations must complete all *E. coli* testing during whichever months it operates. For example, a seasonal goat slaughter establishment that operates from September through December must begin testing during its first full week of operations and complete 13 tests before operations end in December.

Establishments slaughtering more than the numbers indicated above for VLV establishments are classified as greater than very low volume establishments (paragraph (a)(2)(iii)).

Greater than very low volume establishments use the following frequencies for testing.

Cattle, sheep, goats, horses, or equines	1 test per 300 carcasses
Swine	1 test per 1,000 carcasses

Greater than very low volume establishments must sample at the above frequencies or a minimum of at least once per week, whichever is greater. For example, an establishment that slaughters 9,000 cattle per year must sample once per week (a total of 52 samples per year), not only 30 samples per year as indicated by the 1 test per 300 carcasses frequency (30 samples for 300 carcasses = 9,000 carcasses).

**4. Sample requirements – random selection of carcasses (paragraph (a)(1)(i), (a)(2)(i), and/or (a)(2)(ii) of section 310.25 and 391.94**

For generic *E. coli* testing the regulations require that livestock carcasses for sampling be selected at random (paragraph (a)(2)(i)). Different methods, like random number tables, computer-generated random numbers, or drawing cards, may be used. Whatever the establishment chooses to use must be written into the *E. coli* sampling procedure.

If more than one shift is operating at the establishment, the sample can be taken from either shift, provided the sample selection time is based on the appropriate sampling frequency.

**5. Sample analysis – paragraphs (a)(1)(ii) and (a)(3) of section 310.25 and 381.94**

Some establishments conduct their own analyses. FSIS assumes establishments following the "Guidelines for *E. coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments", respectively, will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results. Because these guidelines are not regulatory requirements, the establishment may choose to use a comparable sampling technique and be in compliance.

**6. Records of test results – paragraph (a)(1)(iii) and (a)(4) of section 310.25 and 381.94**

Establishments are required to keep a table or a chart of the results for at least the most recent 13 test results. IPP should consider the length of operations. In cases where the establishment has not been operating long enough to have 13 test results, there is not noncompliance for a lack of testing.

Generic *E. coli* tests are reported as a quantity or bacterial concentration. Bacterial concentration can be reported using either the Colony Forming Unit (CFU) or the Most Probable Number (MPN) based laboratory methods of analysis to evaluate the generic *E. coli* testing. These methods provide an estimate of the number of unit viable cells per sample, and are acceptable as valid measurements for bacterial limits. It is important to understand that these methodologies (laboratory procedures for sample analysis) are different and should **not** be used interchangeably.

An establishment using the “m” and “M” criteria must record each test result in terms of colony forming units per square centimeter (CFU/cm<sup>2</sup>) for excision and in colony forming units per milliliter (CFU/ml) for whole-bird rinses. Alternatively, an establishment using **statistical process control (SPC)** method may record results as CFU/cm<sup>2</sup> or MPN/cm<sup>2</sup> (sponge samples), and CFU/ml or MPN/ml (rinsate). IPP should match the units of measure with the testing technique used to ensure that results are reported correctly. They are to verify that the establishment records the results on a process control chart or table that shows at least the most recent 13 test results.

Establishments must keep records of the tables and charts with generic *E. coli* test results for 12 months. Establishments are not required to maintain a file of

laboratory reports received from either an in-house laboratory or an outside laboratory.

**7. Criteria for evaluation of test results – paragraph (a)(5)(i) and (a)(5)(ii) of section 310.25 and 381.94**

IPP should refer to the generic *E. coli* testing regulations. If the Agency does not have performance criteria published for the species being sampled or for the sampling technique being used, the establishment must use **statistical process control** values to document generic *E. coli* test results (paragraph (a)(5)(ii)).

Livestock baseline studies conducted to arrive at the performance criteria published in the regulations were performed on cattle and swine only, using excision testing. Therefore, when the sponge method is selected for sampling any species, the performance criteria do not apply. For example, if a livestock slaughter establishment uses sponge sampling, statistical process control must be used to evaluate generic *E. coli* test results, not the m/M criteria. Establishments that slaughter ratites must use statistical process control.

**8. Sample Integrity – paragraph (a)(2)(i) of section 310.25 and 381.94**

According to this section of the regulations, sample integrity must be addressed in the establishment's written sample collection procedure and should be followed; but if it is not followed, it is not an enforceable issue. If IPP observe circumstances that seem to jeopardize sample integrity (e.g., freezing the sample, not shipping the sample on the same day it is collected), the District Office should be notified through supervisory channels. Further investigation of the situation and any enforcement actions will be directed from the District Office.

**Using Statistical Process Control (SPC) to Evaluation Test Results**

SPC for generic *E. coli* is required with products that were not represented by the PR/HACCP Rule by a performance standard, because no relevant baseline studies were available at the time. As mentioned earlier, the generic *E. coli* results published in the Federal Register Notice (2005) can complement SPC by providing establishments with an additional measure of process control. The results below are for cattle and swine carcasses sampled using the sponge method of sample collection.

<b>Class of product</b>	<b>Method</b>	<b>80th percentile</b>	<b>98th percentile</b>
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Cattle carcasses	sponge	0.0 CFU/cm <sup>2</sup>	3.1 CFU/cm <sup>2</sup>
Swine carcasses	sponge	0.46 FU/cm <sup>2</sup>	400 CFU/cm <sup>2</sup>

SPC provides a powerful mechanism for establishments to monitor and interpret the data collected for ongoing HACCP verification. SPC can provide establishments with an early warning that their process may not be functioning as designed. This warning can allow establishments to take corrective actions or make other process modifications to bring their process back into control without actually failing the desired performance.

SPC, used when the regulations do not cite performance criteria, begins when the establishment conducts a series of preliminary generic *E. coli* tests during its own slaughter operations. They chart the results in cfu/cm<sup>2</sup> or cfu/ml to determine the typical range of generic *E. coli* counts found at their establishment under normal circumstances. After a company collects test results long enough to believe they have a true picture of their performance, they set an upper and lower control limit based on test results. There are no regulatory requirements for how statistical process controls are determined. Companies may use a variety of valid methods to determine limits for statistical process control. For example, establishments may calculate their own statistics, hire a consultant company, or use a software package to develop statistical process control values. Once the establishment determines the process control values and has set generic *E. coli* criteria to define process control, and as long as the data points on the company chart stay within the control limits set by the company, the process is considered in control.

### Using Performance Criteria (m/M Values) to Evaluate Test Results

Cattle and swine establishments that choose excision of three sites must use the m/M performance criteria published in the regulations for evaluating test results when they are available. Regulatory m/M criteria apply only to swine and cattle sampling when the excision sampling technique is used. When performance criteria are published in the regulations, the *E. coli* test results are compared to the regulatory criteria and may fall into one of three categories: acceptable, marginal (represented by “m”), and unacceptable (represented by “M”).

- Marginal results (“m”) are those that fall within the worst 20% of overall industry performance in terms of *E. coli* counts (results taken from baseline study). More than three marginal results in the last 13 tests are unacceptable.

- Results in the worst 2% of overall industry performance (results taken from the baseline study) are called the maximum or “M” value. Any single test result exceeding “M” is unacceptable.

The m/M values taken from the regulations are applied to a moving window of the last 13-documented test results. That means that the establishment considers all of the last 13 test results when determining if the process is in control. Every time a new test result is added to their records, the oldest test is dropped and the new test becomes one of the most recent 13 results.

For the slaughter process to be judged in control no more than three sample results can be above the “m” marginal line. If four sample results are above “m”, the process is out of control.

If the test result of the most recent sample is above “M”, the process is automatically out of control, regardless of the previous test results. Once another test result is entered in the chart or table, the “M” test simply becomes another result considered to be above the “m” line. It no longer carries the consequence of causing “automatic” process control failure.

After the slaughter process is judged to be out of control, a subsequent test result below the “m” line indicates that the establishment did something to correct a problem and bring the process back into control (this correction does not have to be documented anywhere). However, the process is not judged totally in control until the window of 13 tests also shows process control.

The following table from the regulations shows the m/M values for *E. coli* performance criteria set by the Agency.

Species	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum # permitted in marginal range (c)
Cattle	Negative	100 CFU/cm <sup>2</sup>	13	3
Swine	10 CFU/cm <sup>2</sup>	10,000CFU/cm <sup>2</sup>	13	3

The previous table establishes performance criteria only for excision testing of cattle and swine.



## Slaughter Food Safety Standard

FSIS has food safety standards that require establishments to have controls in place to prevent the contamination of carcasses with certain contaminants, such as fecal material. This section provides an overview for how these food safety standards are verified for livestock.

### *Enforcing Food Safety Standard for Livestock Postmortem*

**References:** [FSIS Directive 6420.2](#), Regulations: 9 CFR 310.17(a), 310.18, and part 417.

FSIS enforces food safety standards for fecal, ingesta, and milk contamination on livestock carcasses and on head meat, cheek meat, and weasand meat from beef through postmortem inspection activities at establishments that slaughter livestock. The establishment must meet the food safety standard for visible fecal, milk, and ingesta contamination on livestock carcasses at or after 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.

- For example, the establishment may locate the critical control point after the postmortem rail inspection station.
- In other cases, the establishment may have a CCP prior to the postmortem rail inspection station.

**Note:** Regardless of the location of the CCP, FSIS off-line inspectors will verify compliance with the zero tolerance standard at the rail inspection station.

When the on-line inspectors at the rail station find feces, ingesta, or milk on livestock carcasses, the establishment reexamines and reconditions the entire carcass (trimming all contamination). **On-line** inspectors are to **stop the slaughter line** for carcass reexamination and reconditioned by the establishment **unless:**

- The establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, **and**
- The IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.

Additionally, on-line inspection program personnel are to notify the IIC or, if unavailable, other off-line inspection program personnel when they believe that:

- An establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or
- An establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of carcasses contaminated with fecal material, ingesta, or milk for postmortem inspection at the rail inspection station indicates failure to control dressing processes).

Establishments that slaughter beef must also meet the food safety standard for no visible fecal, milk, or ingesta contamination on head meat, cheek meat, and weasand meat at the end of the harvesting process after all of the establishment controls and interventions have been implemented. This verification may take place at the time of packaging or when product is placed in a container for storage.

When verifying the food safety standard in beef slaughter establishments, inspection personnel should verify that the establishment is meeting all of the requirements, including no fecal, milk, or ingesta contamination on beef carcasses, and the head meat, cheek meat, and weasand meat from beef.

In beef slaughter establishments, if the on-line head inspector finds fecal, milk, or ingesta contamination, the contamination must be removed by the establishment before the head can be passed. Also, if the on-line inspector finds fecal, milk, or ingesta contamination on weasand meat during the harvesting step, the establishment must remove the contamination before the weasand meat can be passed. If fecal, milk, or ingesta contamination is repeatedly found, on-line inspection personnel are to notify the off-line inspection personnel. The off-line inspection personnel will perform verification activities to determine if the establishment's process and sanitary dressing procedures are controlling fecal, milk, and ingesta contamination during the head meat or weasand meat production process.

IICs and other off-line inspection program personnel will verify the adequacy of establishment procedures to ensure compliance with the food safety standard for fecal, ingesta, or milk contamination, **when notified by on-line inspection program personnel of an apparent problem or when there is a scheduled Zero Tolerance Task.**

Follow these steps when verifying establishment procedures for livestock carcasses:

1. **Off-line** inspection program personnel are to randomly select carcass units at the **postmortem rail inspection station** for examination on-line, at or after the postmortem rail inspection station, **regardless of the location of the CCP.** (This inspection should occur before the final wash. In situations where

this is difficult, such as those related to worker safety, the IIC should develop appropriate procedures with plant management in order for this inspection to be properly conducted).

2. Based on the expected slaughter volume for that day (number of animals), determine the number of carcass units to be examined, using the following table. If carcasses are split, each half carcass is ½ of a carcass unit. (Select two times as many half-carcasses.)

<b>Slaughter Volume (# of animals per day)</b>	<b># of Carcass Units (Unit = whole carcass)</b>
100 or less	2
101 to 250	4
251 to 500	7
More than 500	11

Note: It is not necessary to examine all of these units at the same time.

3. Examine the selected carcass units using the same technique that inspection program personnel use at the postmortem rail inspection station.

Follow these steps in beef slaughter establishments when verifying establishment procedures for beef head meat, cheek meat, and weasand meat:

1. Review the HACCP plan.
2. Examine the same amount of product as the establishment has listed in the HACCP plan for monitoring procedures. (Note: If the establishment does not have documents supporting the monitoring procedures and frequency, there is noncompliance with 9 CFR 417.5(a)(2).)
3. Select product after all of the establishment controls and interventions have been applied. Verification may occur at the time of packaging or when product is placed in a container for storage.

Off-line inspection program personnel who find feces, ingesta, or milk on carcasses in livestock slaughter establishments, and the head meat, cheek meat, and weasand meat of beef in beef slaughter establishments as part of the Zero Tolerance Task will

- a. Notify establishment of the contamination
- b. Issue an NR.
- c. Verify that the corrective action requirements of 9 CFR 417.3 are met.



