

## 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* and *Campylobacter* performance standards.
7. Describe the regulatory requirements for the food safety standard related to fecal contamination.
8. 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 (i.e. *Salmonella/Campylobacter* performance standards)

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 Poultry Products Inspection Act (PPIA).

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.

*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 performance standards 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 operations.

Cross-connection between potable and non-potable water is not acceptable. The plumbing system must be installed and maintained to prevent adulteration.

*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 poultry 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.

*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 condition. 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, establishment 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 allow the spread of pathogenic organisms 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 their operations 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, poultry 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 poultry 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.

Poultry 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 actions should remain in effect until the establishment has taken corrective action and has proposed effective preventive measures.

## **SANITARY DRESSING – A SYSTEMS APPROACH**

### **Introduction**

There are two purposes of this section. First, we will provide some background information about sanitary dressing and the procedures in the poultry slaughter process and how this process may impact sanitary dressing. Second, we will provide some information on how the Off-line inspector verifies compliance using the instructions in FSIS Directives 6410.3 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 or ingesta. Sanitary dressing procedures minimize this type of contamination.

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

FSIS continues to find positive results in samples and we continue 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 *Salmonella* verification testing results have shown reduced *Salmonella* levels in poultry establishments since FSIS implemented *Salmonella* performance categories and other policies designed to lower levels of *Salmonella*. However, improvement in sanitary dressing and other process controls can reduce even further the levels of *Salmonella* and other enteric bacteria, such as *Campylobacter*, on poultry carcasses. 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. As set out in 9 CFR 381.65, establishments must handle poultry carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, ingesta, or foreign matter. Since these sources can contain pathogens, establishments should reduce the potential for exposure to any food safety hazard during removal of feet, GI tract, and internal organs. The design of the establishment's slaughter operation must include a means to measure how well the sanitary dressing procedures accomplish this purpose and actions if contamination does occur. 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 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 the product is not adulterated, as required by the SPS regulations, 9 CFR 416.1- 416.5. Examples of means to achieve this include:

- 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 treatment 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 must maintain written sanitary dressing and process control procedures under a few circumstances. All poultry establishments must develop and maintain records ensuring that carcasses contaminated with visible fecal material do not enter the chiller as well as records that document procedures to prevent contamination of carcasses and parts from enteric pathogens and fecal material throughout the slaughter process. If the establishment is operating under the New Poultry Inspection System (NPIS), additional record requirements apply (See FSIS Notice 53-14). Records may be part of their HACCP Plan, Sanitation SOP, or other prerequisite programs. If the sanitary dressing procedures are used to support decisions made in the hazard analysis in accordance with 9 CFR 417.5(a) (1), establishments must maintain records addressing the sanitary dressing and process control program. The records must demonstrate that the program is effective and thus decisions made in the hazard analysis can be supported on an on-going basis.

A food safety system includes all aspects of the operation, from the beginning of the product flow, receiving; to the end, 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 cages be washed down? Are animals hauled long distances? How does the condition of the animals effect or overwhelm establishment antimicrobial interventions? 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 to use a systems 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 not to wait until the poultry carcass chiller 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 observation of the implementation of a variety of plans and procedures (e.g., HACCP plan, Sanitation SOP, prerequisite programs, FSIS and establishment testing results) and through the review of 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 drums, thighs, and ground poultry. Any contamination incidents on the slaughter floor can impact in the microbial quality of the resulting 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 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 or cages, 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.

#### **Poultry Slaughter Process – Potential Contamination Points**

- A. **Live receiving or hanging:** This is the point in the slaughter process where poultry arrive at the establishment in transport cages, are unloaded, and are hung on shackles before stunning and bleeding.

- B. **Stunning and Bleeding:** This is the point in the slaughter process where the bird is stunned, cut, and bled. Stunning methods used to make birds unconscious may be electrical, mechanical, or chemical. Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalding (9 CFR 381.65(b)).
- C. **Scalding:** This is the point in the slaughter process where the birds are placed in hot water in order to facilitate feather removal. Scalding is an important step that can reduce levels of *Salmonella* and *Campylobacter* on the carcasses, since much of the dirt, litter, and feces on carcasses is removed at this step. *Salmonella* and *Campylobacter* contamination consistently decrease when scalding is well controlled.
- D. **Feather Removal or Picking:** This is the point in the slaughter process designed to remove feathers and, in most cases, the uppermost layer of skin before evisceration.
- E. **Evisceration:** This is the point in the process where removal of the internal organs, and of any processing defects, from the poultry carcasses occurs in preparation for chilling. Evisceration includes multiple processes. It begins at the transfer point (i.e., re-hang) and ends when the carcass enters the chiller. It is the point in the slaughter process where the removal of the viscera (i.e., the edible offal that includes the heart, liver, and gizzard) occurs by automated or manual means.
- F. **On-line Reprocessing:** This is the point in the slaughter process where carcasses accidentally contaminated with digestive tract contents are reprocessed on-line. Establishments are required to incorporate procedures into their HACCP system for online reprocessing (OLR) and will no longer need a waiver to use approved OLR antimicrobial intervention systems. On-line inspectors in all poultry slaughter establishments other than ratites will still be responsible for identifying and condemning excessively contaminated carcasses in accordance with 9 CFR 381.91 that interfere with inspection or that the establishment is unable to make wholesome. Additional information can be found in FSIS Notice 50-14, Modernization Of Poultry Slaughter Inspection: Verification Of Online Reprocessing (OLR) and Offline Reprocessing (OFLR) Antimicrobial Intervention Systems. The lists of approved OLR antimicrobial interventions systems and the parameters of use for each system are attached to FSIS Notice 50-14 as Table 1 and in future revisions of FSIS Directive 7120.1. .

- G. Off-line Reprocessing and Salvage:** This is the point in the evisceration process where internally contaminated carcasses are reprocessed off-line according to 9 CFR 381.91(b) (1) and (b)(2). The final rule amended 9 CFR 381.91 to permit poultry slaughter establishments except for ratite establishments to use approved OFLR antimicrobial intervention systems to clean carcasses accidentally contaminated with digestive tract contents. Establishments must incorporate procedures for OFLR into their HACCP system. Carcasses removed from the line for reprocessing are subject to FSIS reinspection. On-line inspectors in all poultry slaughter establishments other than ratites will still be responsible for identifying and condemning excessively contaminated carcasses in accordance with 9 CFR 381.91 that interfere with inspection or that the establishment is unable to make wholesome. Additional information can be found in FSIS Notice 50-14, Modernization Of Poultry Slaughter Inspection: Verification Of Online Reprocessing (OLR) and Offline Reprocessing (OFLR) Antimicrobial Intervention Systems. The lists of approved OFLR antimicrobial interventions systems and the parameters of use for each system are attached to FSIS Notice 50-14 as Table 2 and in future revisions of FSIS Directive 7120.1.
- H. Product Reconditioning:** This is the point in slaughter and further processing where contaminated eviscerated carcasses and parts that have fallen on the floor, or otherwise have become contaminated off-line, are reconditioned in order to restore sanitary conditions.
- I. Chilling:** This is the point when eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 CFR 381.66(b)(1). There are two types of chilling systems: immersion and air. Air chilling is now defined in 9 CFR 381.66(e). FSIS Notice 51-14 Modernization Of Poultry Slaughter Inspection: Change In Chilling Requirements For Ready To Cook Poultry applies to all poultry slaughter establishments other than ratites.

## **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 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 and employee hygiene such as not cleaning hands, gloves, knives or equipment. The interventions will not achieve their intended effect if the incoming bacterial loads on feathers are so great that they overwhelm the antimicrobial treatments.

## **Determining and Documenting Noncompliance**

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

### **Indications of Potential Noncompliance**

Some observation findings 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.
- 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 poultry slaughtered.
- Feedback from on-line IPP indicating increased incidents of carcass contamination.

Incidental contamination (e.g. 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 key 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. The slaughter process is a system, so 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)

*9 CFR 416.11 General Rules. Each establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOPs) in accordance with the requirements of this part.*

According to 9 CFR 416.11-14, the establishment is responsible for developing, implementing, and maintaining written Sanitation Standard Operating Procedures (SSOPs) that meet the requirements of Part 416. 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.

*9 CFR 416.15 Corrective Actions (b) Corrective Actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs or the procedures specified therein.*

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 NACMCF identified the purpose of the hazard analysis in the 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.

## 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. 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 HACCP team 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 HACCP team 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 establishment must take corrective actions every time a deviation from the critical limit occurs. The corrective actions consist of

- 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 HACCP team 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 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.

## ***Salmonella* and *Campylobacter* Verification**

### **Background**

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. Only the performance standards for livestock carcasses and certain raw ground meat products (9 CFR 310.25(b)) are still applicable. 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 published new performance standards in 2010 and 2011 for *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The Agency has identified *Campylobacter* as part of FSIS's pathogen reduction strategy and established *Campylobacter* performance standards for poultry carcasses.

- In 2014, FSIS published the Modernization of Poultry Slaughter Inspection; Final Rule (Federal Register Docket No. FSIS-2011-0012; August 21, 2014) to facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter inspection, make better use of Agency's resources, and remove unnecessary regulatory obstacle to innovation. In this publication, FSIS informed industry that it was removing the codified *Salmonella* pathogen reduction performance standards for poultry (9 CFR 381.94(b))
- In January 2015, the Agency identified new *Salmonella* and *Campylobacter* performance standards for raw chicken parts and NRTE comminuted poultry products. (FRN Docket No. FSIS-2014-0023; January 26, 2015). It also announced that it will use the results of routine sampling throughout the year, using a moving window approach, to assess whether the establishment's processes are effectively addressing pathogens on poultry carcasses and other products derived from these carcasses. In this publication, FSIS is also implementing an exploratory sampling of raw pork products for pathogens of public health concern, as well as indicator organisms.

*Campylobacter* species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the second most frequently reported cause of food borne illness, and *Campylobacter jejuni* is the most common strain causing illness.

*Salmonella* and *Campylobacter* contamination of raw poultry products occurs during slaughter operations, as well as during the live-animal rearing process (e.g., on-farm contamination can coat the exterior of the bird and remain attached to the skin). Contamination can be minimized with the use of proper sanitary dressing procedures and by the application of antimicrobial interventions during slaughter and fabrication of the carcasses into parts and comminuted product. In addition, if raw poultry is improperly handled during food preparation, *Salmonella* and *Campylobacter* can cross-contaminate other foods or food contact surfaces.

*Salmonella* and *Campylobacter* can be transmitted to humans by eating foods contaminated with animal feces. The goal of the newly revised *Salmonella* and *Campylobacter* testing program is to protect the consumer from contaminated products by verifying that each establishment meets the new performance standards.

### ***Salmonella* and *Campylobacter* Verification Testing – The Role of the Inspector**

The *Salmonella* and *Campylobacter* verification sampling is conducted in establishments by FSIS inspection program personnel (IPP). IPP will collect

samples using on-going scheduled sampling (routine sampling) using a moving window approach to assess process control for all *Salmonella* performance standards.

IPP collect the following poultry samples, using a moving window sampling approach, to be analyzed for **both *Salmonella* and *Campylobacter*** as described in Directive 10,250.1, Notice 22-15, and FSIS Notice 31-15.

- Poultry carcasses
  - young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9CFR 381.170(a), and
  - young turkey carcasses
  
- NRTE comminuted poultry

NRTE comminuted poultry is any non-breaded, non-battered, raw NRTE chicken or turkey product that has been processed to reduce the particle size which may or may not contain added ingredients. NRTE comminuted poultry includes:

- (1) ground (Ground product group category) – ground chicken or turkey for any purpose (e.g., packed for consumer or for any type of further processing); or
- (2) mechanically separated (Mechanically Separated product group) – mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or
- (3) hand or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Chicken or turkey product, other than ground or mechanically separated falls under the Other Non-intact product group. These products include:
  - NRTE comminuted chicken product may be derived from any age chicken, including young chickens (broilers, fryers, and roasters), fowl, capons, and roosters, as defined in 9 CFR 381.170(a)(1); and
  - NRTE comminuted turkey product may be derived from any age turkey, including young turkeys, yearling turkeys, and old turkeys, as defined in 9 CFR 381.170(a)(2).

## The Performance Standards

The *Salmonella* and *Campylobacter* performance standards apply to establishments overall process control, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* and *Campylobacter* samples.

*Salmonella* and *Campylobacter* performance standard verification samples are taken as part of a moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis. When assessing process control under a moving window approach, FSIS intends to evaluate, over a certain period of time, a number of sequential results from a single establishment. Thus, given the fixed timeframe of one year (52 weeks) for which an establishment has been sampled, FSIS would assess the first moving window by evaluating the number of samples taken within the 52-week period. The charts below shows the maximum acceptable percent positive results or number of positives results allowed in the moving window before the establishment fails to meet the performance standard. A test is considered positive when any *Salmonella* or *Campylobacter* organisms are found.

**Salmonella/Campylobacter Performance Standards for Poultry**

Product	Maximum Acceptable % Positive		Performance Standard	
	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>
Broiler Carcasses <sup>^</sup>	7.5	10.4	5 of 51	8 of 51
Turkey Carcasses <sup>^</sup>	1.7	0.79	4 of 56	3 of 56
Comminuted Chicken <sup>*</sup>	25.0	1.9	13 of 52	1 of 52
Comminuted Turkey <sup>*</sup>	13.5	1.9	7 of 52	1 of 52
Chicken Parts <sup>*</sup>	15.4	7.7	8 of 52	4 of 52

<sup>^</sup> The maximum percent positive for *Salmonella* and *Campylobacter* under the performance standards for young chicken and turkey carcasses is listed in FSIS Directive 10,250.1

<sup>\*</sup> Developed proposed performance standards published in the FRN Docket No. FSIS-2014-0023

**Generic *E.coli* Testing for Ratite Slaughter Operations**

Each official establishment that slaughters ratites 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 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.

**Note:** Establishments that slaughter ratites will continue testing samples for generic *E. coli* as an indicator for process control in accordance to 9 CFR 310.25(a). In contrast, those establishments that slaughter poultry other than ratites are required to meet the new regulatory requirements, as per 9 CFR 381.65, to demonstrate the effectiveness of their process control procedures.

### **Microbiological Sampling for Poultry Slaughter other than Ratite Operations**

The purpose of the new sampling requirements is to ensure that establishments monitor and evaluate the effectiveness of their procedures to prevent contamination of carcasses by enteric pathogens and visible fecal material on an ongoing basis. Fecal contamination is a principal source of pathogenic organisms that contaminate poultry carcasses. Under the Modernization of Poultry Slaughter Inspection final rule establishments that slaughter poultry, other than ratites, are required to perform microbiological sampling and analysis, for example, testing for *Salmonella*, *Campylobacter*, or indicator organisms such as aerobic plate count (APC), total coliform, Enterobacteriaceae, and *Escherichia coli*, Biotype I, also known as generic *E. coli*.

Because establishments have differences in their operations, each establishment has the flexibility to develop a sampling plan and determine the microbial organism that will accurately monitor the effectiveness of its process control procedures.

Microbiological test results that represent the level of microbiological contamination at key steps in the slaughter process are necessary for the establishment to provide comprehensive objective evidence to demonstrate process control. Process control consists of the programs and procedures that an establishment implements to ensure its process prevents contamination of poultry carcasses and parts, including contamination with pathogens and fecal material. Process control also ensures that the resulting product meets applicable standards or definitions.

## Inspection Program Personnel (IPP) Responsibilities

In poultry slaughter establishments (other than ratite), IPP are to conduct verification tasks, as outlined in Directive 5000.1 following the verification instructions in Notice 64-14. The PHIS verification task that IPP perform depends on how the establishment has incorporated its written procedures for preventing contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation in its HACCP system. For instance:

- If the establishment's written procedures are part of its HACCP plan, IPP are to verify HACCP regulatory requirements by performing the **Slaughter HACCP verification task** when it has been scheduled in PHIS.
- If the establishment's written procedures are part of its Sanitation SOPs, IPP are to verify that the establishment meets all Sanitation SOP regulatory requirements by performing the **Operational SSOP Review and Observation task** when it has been scheduled in PHIS.
- If the establishment's written procedures are part of another prerequisite program or other control measures, IPP are to verify the implementation of such program by performing the **Slaughter HACCP verification task** when it has been scheduled in PHIS.

IPP are to perform the appropriate PHIS verification task on a **routine** basis at the frequency specified in the establishment's task list. IPP are also to initiate a **directed** verification task if they observe noncompliance with the requirements in 381.65(g) and (h) while performing other tasks or when instructed to do so by supervision or other policy issuances.

## **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 poultry.

### ***Enforcing the Food Safety Standard for Poultry Postmortem***

**References:** FSIS Notice 64-14, 381.65(f), and Part 417.

FSIS enforces a food safety standard for visible fecal material on poultry carcasses through postmortem inspection and reinspection activities at poultry slaughter establishments. This food safety standard also is reflected in the regulations. FSIS views preventing carcasses with visible fecal contamination from entering the chilling tank as critical to preventing the cross-contamination of other carcasses.

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, Sanitation SOPs, or other prerequisite programs.

IPP assigned to establishments that operate under Streamlined Inspection System (SIS), New Line Speed Inspection System (NELs), New Turkey Inspection System (NTIS), or Traditional Inspection systems are to perform scheduled and unscheduled Poultry Zero Tolerance verification tasks off line to verify that the establishment is preventing carcasses with fecal material from entering the chiller (9 CFR 381.65(f)).

These checks are performed at either the same location as pre-chill testing in establishments inspected under the finished products standards (FPS), or the inspection station where Acceptable Quality Level (AQL) testing is conducted in a plant under traditional inspection, regardless of the location of the plant's CCP.

To perform a fecal contamination check, inspectors are to:

- Select 10 carcasses randomly (using an established FSIS method), and
- Examine the selected carcasses off line using the following inspection procedure:
  - For the outside back – While holding the carcass, with the back of the carcass toward the observer, start at the hock area and observe the

- hocks, back part of the legs, tail area, back of the carcass and top side of the wings.
- For the outside front – Turn the carcass and observe the bottom side of the wings, breast, and front part of the legs.
  - For the inside – Observe the inside surfaces of the carcass and the abdominal flaps and fat.
  - For the neck flap area – Observe the neck flap and the thoracic inlet area.

At least two fecal checks will be performed for each line on each shift.

The off- line inspectors will perform the Zero Tolerance verification task using the technique described in FSIS Notice 64-14.

If no visible fecal material is found on a check, the findings will be documented in PHIS.

If fecal material is found, the CSI will:

- Notify the establishment of the contamination
- Complete a Noncompliance Record (NR)
- Verify that the corrective action requirements are met.

**Note:** When IPP determine zero tolerance noncompliance while performing the zero tolerance verification task, they may verify the establishment's corrective actions per 417.3(a), 417.3(b) or 416.15(b) and 417.3(b) either while performing the zero tolerance verification task or during the slaughter HACCP task or Operational SSOP Review and Observation task.

Additionally, 9 CFR 381.65(g) all poultry establishments must demonstrate control of enteric pathogens and fecal contamination by microbiological testing. Establishments must ensure that carcasses with visible fecal contamination do not enter the chiller, per 9 CFR 381.65(f). Written procedures must be developed, implemented and maintained to document compliance with these regulations.

