DRAFT FSIS Compliance Guideline For Controlling *Salmonella* and *Campylobacter* in Raw Poultry

December 2015

This guidance document is designed to help poultry establishments, including those that are small and very small, to:

- Comply with regulatory requirements related to HACCP and the control of *Salmonella* and *Campylobacter*
- Identify and implement pre- and post-harvest interventions to control *Salmonella* and *Campylobacter* as part of their food safety system
- Utilize microbial testing results to monitor the performance of their HACCP system and inform decision-making

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This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on the Food Safety and Inspection Service (FSIS) Web page: http://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidance-documents

This is the **fourth** edition of the Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Poultry. This update includes new recommendations regarding sanitation, lotting practices, pre-harvest practices, intervention use during slaughter and further processing, and using establishment sampling results to inform decisionmaking. Future editions will continue to reflect feedback received from all stakeholders.

This draft Compliance Guideline represents FSIS's current thinking on this topic and should be considered usable as of this issuance. Therefore, even though this is a draft document, FSIS encourages establishments slaughtering or producing raw poultry products to incorporate information in this guideline in their decisionmaking process. FSIS encourages further study and solutions by industry for controlling and reducing the spread of *Salmonella* and *Campylobacter* in raw poultry facilities. A final version of this guidance will be issued in response to public comments.

I. Purpose

This guideline for poultry articulates how industry can meet FSIS requirements regarding control of food safety hazards. The guidelines summarize points in the process at which *Salmonella* and *Campylobacter* can be prevented, eliminated, or reduced in the pre- and post-harvest production process and include summaries of scientific studies that can be used to support specific control parameters. The guidelines will be updated as needed to reflect the most current information available to FSIS and stakeholders.

This document includes recommendations rather than regulatory requirements.

This compliance guideline describes concerns and controls for each step in the poultry slaughter process. FSIS has written this guidance for poultry establishments, including small and very small poultry establishments, to help them comply with regulatory requirements (9 CFR 381.65, Part 416, and Part 417) and pathogen reduction performance standards. Establishments may also find the links listed in Section XI useful for further resources as well as background on technical concepts.

FSIS encourages establishments to reduce levels of *Salmonella* and *Campylobacter* on carcasses during poultry slaughter and further processing operations using best management practices outlined in this guideline. However, the interventions suggested in this guidance cannot overcome poor pre-harvest production practices, poor sanitary practices in slaughter and dressing, or poor slaughter and further processing facility sanitation.

Establishments should use this guideline to improve management practices. When an establishment makes changes at the appropriate locations, process control should improve. As a result, establishments should produce raw poultry products that have less contamination with pathogens, including *Salmonella* and *Campylobacter*. Generally, those interventions to prevent, eliminate, or reduce *Salmonella* will likewise reduce or prevent *Campylobacter*. The Agency strongly recommends that establishments consider both pathogens when designing food safety systems.

Again, the information in this compliance guideline is provided as guidance to assist poultry slaughter establishments, and is not legally binding from a regulatory perspective.

II. Request for comments

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and docket number FSIS-2014-0034. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to http://www.regulations.gov/.

III. Introduction and Background

FSIS regulated poultry slaughter and processing establishments are required to determine the "food safety hazards that can occur before, during, and after entry into the establishment" (9 CFR 417.2(a)) in their hazard analysis. Pre-harvest interventions, adequate sanitary dressing procedures at slaughter, and adequate sanitary conditions during further processing are a part of an integrated approach to reduce the public health impact of *Salmonella* and *Campylobacter*. These pathogens are a hazard that establishments producing raw poultry products should control through a HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. FSIS has determined that contamination of poultry carcasses and parts by fecal material and enteric pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP (SSOP) or other prerequisite program.[1] For this reason, if an establishment relies on its SSOP or other prerequisite program to address enteric pathogens, the establishment's HACCP system must identify why such SSOP or other prerequisite program results in the enteric pathogens not being reasonably likely to occur. The measures outlined in this document will be most effective at decreasing *Salmonella* and *Campylobacter* in raw poultry products when considered together.

> ***Key Point***
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> Federally inspected poultry establishments are required to conduct a **hazard analysis** as part of their Hazard Analysis and Critical Control Point (HACCP) system. The hazard analysis is required to include "food safety hazards that can occur before, during, and after entry into the establishment" (9 CFR 417.2(a)).

Reason for Reissuance

Two goals of the federal Healthy People 2020 (HP2020) initiative are to reduce foodborne illnesses that are caused by *Salmonella* and *Campylobacter*.[2] Specifically, this HP2020 goal is to reduce human illnesses from *Salmonella* by 25 percent and *Campylobacter* by 33 percent by the year 2020. The Agency has developed this revised guidance to provide updated information for establishments to use to control pathogens in raw poultry products with the goal of reducing human illnesses from consuming poultry contaminated with *Salmonella* and *Campylobacter*. In addition, the FSIS proposed performance standards for chicken parts and comminuted chicken and turkey are based on meeting the Healthy People 2020 goal.[3] This guidance can assist establishments to meet these proposed performance standards, which are associated with illness reductions.

[1] 79 FR 49565
[2] Healthy People 2020 is a broad-ranging set of public health goals to improve the health of all Americans. More information is available at http://www.healthypeople.gov/2020/default.aspx
[3] 80 FR 3940

Since issuance of the most recent version of the compliance guidance in 2010, there have been several outbreaks associated with consumption of raw poultry products, including chicken parts and comminuted (including ground) turkey products. In 2011, there were two *Salmonella* outbreaks associated with ground turkey products (specifically, turkey burgers and ground turkey) that resulted in a total of 148 illnesses and 40 hospitalizations. In 2012-2013 and 2013-2014, there were two *Salmonella* outbreaks associated with consumption of chicken parts that together resulted in over 700 illnesses and over 270 hospitalizations. Also in 2013, a *Salmonella* outbreak resulted from consumption of mechanically separated chicken that was sent to an institutional facility. This outbreak resulted in 9 illnesses and 2 hospitalizations.

In addition, four outbreaks associated with raw, heat treated stuffed chicken products occurred from 2013 through 2015. In 2013, an illness outbreak was associated with chicken Kiev, and an outbreak in 2014 associated with chicken Kiev resulted in six illnesses. In 2015, two outbreaks attributed to raw, heat treated, stuffed chicken products resulted in 20 illnesses (15 from one outbreak, and five from the other outbreak).

FSIS analyzed practices of establishments that manufactured product associated with these outbreaks and variously found problems with sanitation, intervention use, and cooking instructions validation at some or all of these establishments. FSIS considered these problems and outbreaks and is providing additional guidance specific to these issues.

FSIS reviewed questions submitted through askFSIS regarding Hazard Analysis and Critical Control Points (HACCP) Plan, Hazard Analysis, Prerequisite Programs, and process control, as related to pathogens such as *Campylobacter*. A summary of these questions can be found in Attachment 1. Based on askFSIS questions, FSIS revised the guidance to:

- Clarify that effectively designed and consistently implemented HACCP systems (including HACCP plans, SSOPs, and prerequisite programs) can reduce risk from pathogens
- Provide additional information on establishment sampling and testing for use in food safety decisionmaking, including informing whether establishments are maintaining process control
- Emphasize the role of maintaining sanitary operations and preventing contamination by implementing sanitary dressing procedures and minimizing cross contamination during slaughter and further processing.
- Discuss further the use of antimicrobial interventions to control pathogens.

FSIS did not receive any public comments in response to the **third** edition of the Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Poultry (2010). FSIS will review any public comments received in response to this draft and may update the compliance guideline in response. In addition, FSIS intends to conduct a review of Food Safety Assessments completed beginning in July 2014 at establishments that

produce raw comminuted chicken and turkey, and based on its findings may update a future version of this compliance guideline. FSIS will also analyze the results of the Poultry Checklist completed in 2014, and may update this guidance document.

Food Safety Systems and the HACCP Framework

Unlike the production of ready-to-eat (RTE) product in which a lethality treatment destroys pathogens of public health concern, slaughter and further processing operations do not have a treatment capable of destroying all pathogens in raw products. Under HACCP regulations, establishments are required to have food safety systems designed to ensure that poultry is processed in a manner that reduces possible contamination hazards during slaughter and processing. Slaughter establishments should have treatments in place to reduce the level of incoming contamination on the exterior of the birds throughout the operation. Establishments need to document the procedures and treatments they use to reduce contamination in their HACCP flow chart or applicable prerequisite program.

The Food Safety System

In the simplest of terms, the food safety system is a puzzle where, ideally, all the pieces fit together (Figure 1). Each piece is connected to the others and each affects the other. No one piece of the puzzle is more important than the others; all the pieces are important and work together to achieve process control. Like pieces in a puzzle, an establishment should consider how its food safety programs, including SSOPs and other prerequisite programs, work together and how they impact the entire food safety system. An establishment needs to have a clear understanding of how each of these pieces work together in order to make decisions about its food safety system and understand weak points in their process that may affect the establishment's ability to maintain process control and prevent, eliminate, or reduce pathogens to an acceptable level.

Figure 1 - The Food Safety System Puzzle

Process control is maintained by a procedure or set of procedures designed to provide control of the establishment's operating conditions that are necessary for the production of safe and wholesome food. The goal of process control in a raw poultry establishment is to minimize fecal contamination of the carcasses (in establishments that slaughter), remove bacterial pathogens that may be present and injurious to health, control the proliferation of any remaining micro-organisms, and prevent recontamination.

Process control procedures are likely to include:

1. Adequate sanitary dressing practices to prevent contamination and to minimize cross-contamination;
2. Decontamination of carcasses that become contaminated;
3. Antimicrobial intervention treatments; and
4. Implementation of other best practices described throughout this compliance guide, and incorporation of such best practices into the HACCP system (prerequisite program, SSOPs, or HACCP plan).

Establishments that fail to effectively utilize these procedures and treatments create the potential for contamination of carcasses and products and vulnerability of their food safety systems.

Key Points

An establishment may determine that a hazard is not reasonably likely to occur because the establishment maintains a prerequisite program that prevents the hazard from occurring.

If an establishment does not effectively implement its prerequisite program (9 CFR 417.5(a)(1)), a hazard is not prevented, and therefore the HACCP system would not be designed to control the hazard

Hazard Analysis

The hazard analysis forms the foundation of the establishment's food safety system. 9 CFR 417.2(a)(1) requires that an establishment identify any food safety hazards that might occur in the production process, including hazards before, during and after entry into the establishment; assess which hazards are reasonably likely to occur; and develop measures to prevent, eliminate, or reduce to an acceptable level those hazards that are. The hazards associated with a particular product depend on the incoming materials, the production steps, and the characteristics of the finished product.

Each establishment must maintain documents supporting the decisions that it makes during the hazard analysis (9 CFR 417.5(a)(1)). This documentation must include information to support decisions regarding hazards that are not reasonably likely to occur.

Sanitation Standard Operating Procedure (SSOP) or Other Prerequisite Programs to Prevent Hazards

Establishments may address *Salmonella* and *Campylobacter* in their SSOP or other prerequisite programs. However, if an establishment relies on its SSOP or another prerequisite program to address enteric pathogens, the establishment's HACCP system must identify why such SSOP or other prerequisite program results in the enteric pathogens not being reasonably likely to occur.

Prerequisite programs are written procedures that describe particular activities of an establishment that can be used to support decisions made in the hazard analysis. Sanitation SOPs (SSOPs) and Good Manufacturing Practices (GMPs) are examples of prerequisite programs. Prerequisite programs have the following characteristics:

1. The program is written and describes procedures (including the critical operational parameters) that the establishment will implement to show the hazard is not reasonably likely to occur;

2. The program is designed to prevent the hazard from being likely to occur, and the establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant data that show that the hazard has been prevented);

3. The establishment maintains records that demonstrate that the program is being implemented as written (e.g., monitoring of the critical operational parameters);

4. The establishment maintains records to demonstrate the program effectively prevents the hazard (i.e., on-going verification of the decision that the hazard is not reasonably likely to occur);

5. The program describes actions the establishment will take when it fails to implement the program, or when it finds the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard per 9 CFR 417.3(b)).

If establishments determine that *Salmonella* and *Campylobacter* are hazards not reasonably likely to occur because of SSOPs or prerequisite programs, they are required to have records associated with their SSOPs or other prerequisite programs that show how the programs support their decisions on an ongoing basis as part of their HACCP decisionmaking documents. FSIS will verify that these records demonstrate both that the programs are being effectively implemented, and that the programs are actually preventing the food safety hazard from being reasonably likely to occur on an ongoing basis. When prerequisite programs are not effectively designed or not consistently implemented to a degree that results in inadequately addressing the pathogen, then the hazard analysis is not supported. When SSOPs or prerequisite programs inadequately address pathogens, FSIS considers the SSOPs or prerequisite

programs to be ineffective, and that an unforeseen hazard has occurred. In this case, FSIS would consider that the hazard is reasonably likely to occur. Some findings that indicate that an establishment's SSOP or prerequisite program is not adequately addressing pathogens include: human illness associated with product; FSIS sampling results on carcasses, parts, or comminuted products that indicate poor pathogen control (e.g., establishments moving in and out of category 3); or establishment sampling results that indicate poor process control.

In this case, because a ''deviation not covered by a specified corrective action'' or an ''unforeseen hazard' has occurred, an establishment that addresses *Salmonella* or *Campylobacter* in an ineffective SSOP or prerequisite program (but does not address pathogens in a HACCP plan) would need to take corrective actions, including reassessment, as set forth in 9 CFR 417.3(b). The reassessment will likely reveal that the hazard analysis is not supported, and that the hazard is reasonably likely to occur. The establishment would then need to develop and implement a HACCP plan that meets the requirements of 9 CFR 417.2(c). In this HACCP plan, the establishment must address the pathogen with a CCP.

If the process results in a high number of *Campylobacter or Salmonella* subtypes more commonly associated with human illness, the establishment should take appropriate action. If the process is addressed in the Sanitation SOP (SSOP), but the SSOP or its implementation failed to prevent direct contamination or adulteration of products, then the corrective actions listed in 9 CFR 416.15 must be met. If the process is addressed in another prerequisite program, the establishment needs to follow the actions listed in the program. The establishment should determine specifically why its food safety system is not appropriately and consistently minimizing the level and type of contamination on raw poultry products.

If an establishment cannot control *Salmonella* or *Campylobacter* subtypes commonly associated with human illness, the establishment should conduct a reassessment to evaluate the sufficiency of its food safety system design and implementation. The establishment should determine whether its Sanitation SOP or other prerequisite program is adequate to prevent *Salmonella* and *Campylobacter*. If not, the establishment should consider addressing *Salmonella* and *Campylobacter* control in a HACCP plan.

HACCP Plan to Control Hazards

If the establishment decides through its hazard analysis that *Salmonella* or *Campylobacter* is a food safety hazard reasonably likely to occur, 9 CFR 417.2 requires that the establishment's Hazard Analysis and Critical Control Point (HACCP) plan address these food safety hazards. The HACCP plan must meet all parts of 9 CFR 417.2(c), including having a Critical Control Point (CCP) to address the pathogen. A CCP 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. As an example, an establishment might have a CCP at a point during slaughter for applying a validated antimicrobial intervention to carcasses.

FSIS requires the establishment to develop critical limits for CCPs to control hazards that are reasonably likely to occur (9 CFR 417.2(c)(3)). Critical limits 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 critical limit 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. An example of critical limits (CL) are the critical operational parameters for an antimicrobial intervention applied to carcasses at a point during slaughter.

To determine whether critical limits are being met, establishments must monitor them. 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. Monitoring procedures usually involve either a measurement or an observation. For the example of a CCP of applying an antimicrobial intervention during slaughter, monitoring activities might include measuring the concentration, pH, and other critical operational parameters of the antimicrobial intervention, at a frequency sufficient to determine whether the CCP is under control. If a CL is not met, the corrective actions listed in 9 CFR 417.3 must be met. To document whether the establishment meets its CCP, the establishment records its measurements and corrective actions as part of a recordkeeping system.

Verification ensures that the HACCP plan is being implemented as written. Verification confirms the accurate monitoring of the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. 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. For the example of a CCP of applying an antimicrobial intervention during slaughter, verification activities might include direct observation of monitoring procedures and review of CL monitoring records and corrective actions records.

IV. Sanitation

Cleaning followed by sanitizing is essential to control pathogens in an establishment. Pathogens can attach to processing equipment or grow on food materials left behind on product contact surfaces. Properly cleaning an area requires removing debris before using a cleaning agent (detergent). Alkaline detergents are frequently used and vary in strength. Examples are sodium hydroxide, nitrous oxide, sodium silicate, and trisodium phosphate (TSP). Acid detergents are also used and vary in strength. They include hydrochloric, sulfuric, phosphoric, and acetic acids. Quaternary ammonia is a type of synthetic detergent. Regardless of type, detergents should be in contact with surfaces for a sufficient time to ensure effectiveness of the product. Establishments should follow manufacturers instructions regarding application and contact time for detergents.

Once a surface has been cleaned of all visible residues, sanitizers should be applied. There are several types of chemical sanitizers commonly used: quaternary ammonia, industrial strength bleach, iodine compounds, peracetic acid, steam, and ozone. There are areas within an establishment where it may be better to use one type of sanitizer over another. For example, to sanitize aluminum equipment, rubber belts, and tile walls, iodophores (e.g., betadine, iodine) are recommended. Active chlorine is best for other types of walls, wooden crates, and concrete floors. A listing of various detergents and sanitizers as well as their properties can be found in Dr. Scott Russell's presentation from the Post-Harvest *Salmonella* meeting. The listing is on the FSIS Web site: http://www.fsis.usda.gov/wps/wcm/connect/e1ec9a80-79eb-4e73-b293-e8ec3386b9ed/Slides_022306_SRussell.pdf?MOD=AJPERES

Each establishment's SSOPs, other prerequisite programs, or HACCP plans should address procedures that ensure that all slaughter and further processing equipment, employee hands, tools, and clothing and food contact surfaces are maintained in a sanitary manner to minimize the potential for cross contamination within and among lots of production. Establishments should develop and effectively implement SSOPs that address, at a minimum, the handling and cleaning of food contact surfaces, equipment, utensils, implements, and the processing areas. The SSOPs should indicate the frequency with which these items will be cleaned and the frequency at which establishment will verify their cleanliness and removal of product residues.

In addition to achieving pre-operational sanitation, maintaining operational sanitation can minimize cross contamination during poultry slaughter and further processing. Establishments are required to clean and sanitize both food contact and non-food-contact surfaces as frequently as necessary to prevent the creation of insanitary conditions (9 CFR 416.4). Operational sanitation extends to active practices as well as maintaining sanitary equipment. Sanitation procedures should prevent cross-contamination from equipment, personnel, traffic, air flow, tables, and floors to product. Establishment employees should regularly clean and disinfect knives or other product contact surfaces during use. When employees use knives during carcass trimming or cut-up operations, establishments should ensure that sanitation is maintained between

carcasses. Some ways that this may be achieved is by sanitizing knives in 180 degree water or antimicrobial-containing water between every carcass and using air or water knives instead of physical knives. Figure 2 shows an establishment employee washing hands and knife after cutting wings on each carcass. Figure 3 shows cut-up stations in which fat and other product build up accumulates on the knife sharpeners, which establishment employees use as needed. No water for cleaning is available at each station.

Employees are in continuous contact with the product. The production of wholesome products is difficult when employees do not maintain clean hands and clothing. Therefore, sanitation training and education, as well as supervision, are crucial. Sanitizing stations should be available and maintained for mandatory hand washes. It is important that all employees follow standard hygienic practices in accordance with 9 CFR 416.5(a), 416.5(b), and 416.5(c). Outer garments, head coverings, aprons, gloves, and protective shields should be worn, and cleaned or changed as necessary. Furthermore, jewelry, food (including candy and gum), and tobacco products should be restricted within the establishment. Care should be taken by employees when performing tasks, including sanitation procedures, to prevent cross-contamination. For example, exposed product should be covered prior to hosing floors to prevent splash-back from contacting product.

Figure 2

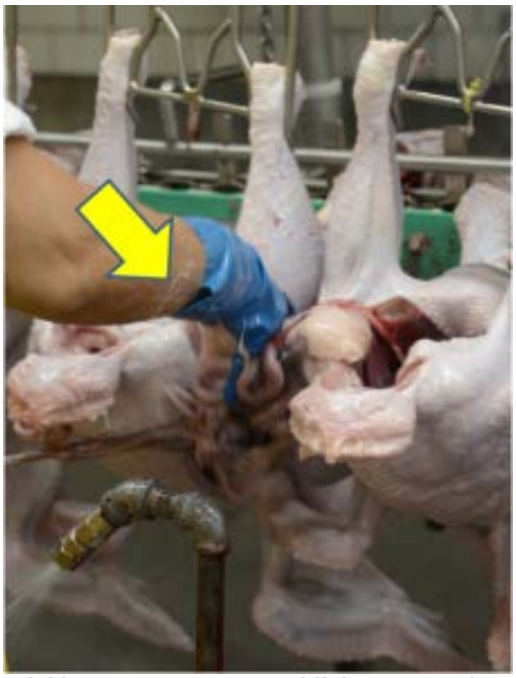
Best practice: Establishment employee washes hands and knife with water treated with an antimicrobial after cutting wings on each carcass. This set up and practice reduces cross-contamination.

Figure 3

Not recommended: Cut-up stations do not have water for cleaning knives. Knife sharpeners are available at each cut-up station and are used as needed. This set up and practice increases cross-contamination.

Figure 4 shows an establishment employee performing manual evisceration. The employee's arm is uncovered and is not being washed sufficiently to prevent cross-contamination, as shown by the organic material present on a bare arm, which may then enter another carcass.

Figure 4



Not recommended: Organic material is present on an establishment employee's arm (yellow arrow). Water is available for washing, but the employee is not washing with sufficient frequency to prevent cross-contamination during manual evisceration. Plastic sleeves are more sanitary and easier to wash than bare arms

Sanitation requirements regarding dressing rooms, lavatories, and toilets should be followed per 9 CFR 416.2 (h)(1) and 416.2 (h)(2). In addition, keeping track of employee foreign travel and health protects employees, product, and consumers. Keeping the processing areas clean and employee areas clean and in good repair set a personal tone for the operation. These are management choices but can indirectly affect the product.

The sections on Slaughter and Further Processing provide additional guidance regarding maintaining sanitation during those processes.

V. Lotting practices

If products are associated with a human illness outbreak, multiple lots might be implicated, and FSIS might request that multiple lots be recalled. Proper lotting may be instrumental in reducing the impact of any potential future product recalls. Establishments are required to inform the FSIS District Office of the type, amount, origin, and destination of any adulterated or misbranded product (9 CFR 418.2). In such a situation, the establishment should be able to provide a scientific basis that justifies why other lots of raw poultry product originating from the same source materials (e.g., carcasses) as the product associated with the outbreak should not be considered contaminated or adulterated. Lots should be designed so that if product in a lot was associated with human illness, the product in other lots is microbiologically independent and is not implicated.

> ***Key Point***
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> Source material from more than one supplying establishment may expand the implicated lots following a human illness outbreak of *Salmonella* or *Campylobacter*

When designing lotting practices, establishments should consider not only their own processes but also determine how their use of raw poultry source materials contributes to or limits pathogen contamination between production units. Source materials include any raw poultry products used in further processing at the establishment. (Depending on the finished product, source materials can also include other ingredients such as vegetables and spices.) These can include source materials that are produced within the establishment or that are received from other establishments. Some examples of poultry source materials include carcasses for further processing, parts that are to be tenderized, poultry parts that are to be ground, carcass frames that go into a mechanical separator, and mechanically separated product that is to be blended with other ingredients (including other source materials such as ground poultry). In a 2015 outbreak of stuffed chicken products, the volume of implicated product expanded significantly (from 58,000 pounds to 1.7 million pounds) because the company used contaminated source materials to produce multiple lots of product without microbiological independence.

Suggestions for defining microbiologically independent lots are:

- Product from one flock or supplier may be considered as an independent lot provided that carcasses, parts, or comminuted product from one flock or supplier is handled so as not to cross-contaminate carcasses, parts, or comminuted product from other flocks or suppliers. For example, to maintain separate lots, following the grinding of product from one supplier, establishments should sanitize the lines and equipment before the product from the next supplier is processed. For each lot, establishments should maintain records on trace back information through to the originating slaughter establishment (if applicable), grow-out houses, hatchery, and breeding flock.

- Defining lots based on microbiological testing would be acceptable if the sample collection and testing method is designed to have a high confidence of detecting positive results when *Salmonella* or *Campylobacter* is present in a production lot.

- Processing interventions that limit or control *Salmonella* or *Campylobacter* contamination can help to define the lot.

- Sanitation SOPs or any other prerequisite programs (including testing programs) used to control the spread of pathogen cross-contamination among source materials during production can help to define the lot.

Note that the following may lead to cross-contamination of raw poultry source materials during production and may expand the implicated lot in the event product is associated with an outbreak:

  - improper sanitary dressing procedures;
  - insanitary product contact surfaces on equipment, such as machinery and employee hand tools; and
  - improper employee hygiene.

Key Points

Reworked affected product or carryover source materials from previous production may expand the implicated lot following an outbreak.

Both intentional carryover of source material and accidental carryover (resulting from inadequate equipment sanitation) may contaminate future lots with *Salmonella* and *Campylobacter*

Additional considerations regarding lotting practices are discussed in the Microbiological sampling section.

VI. Intervention use

Establishments may choose to implement antimicrobial interventions to prevent or control *Salmonella* and *Campylobacter*. For interventions used that are part of an establishment's HACCP system (HACCP plan, SSOP, or other prerequisite programs), establishments must maintain scientific support for their effectiveness and implement the interventions according to their support. Because interventions applied as part of an establishment's HACCP system affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these interventions as supporting documentation for its hazard analysis (9 CFR 417.5(a)).

Guidance on identifying and selecting critical operational parameters for antimicrobial interventions and validation is available in the FSIS Compliance Guideline HACCP Systems Validation. The guidance document discusses how to apply those parameters within an establishment as part of a HACCP system.

When selecting an antimicrobial intervention, establishments must ensure that antimicrobial interventions and levels used are safe and suitable. FSIS Directive 7120.1, Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products, includes a list of antimicrobial agents that have been deemed safe and suitable when applied to certain products. This FSIS Directive is updated monthly. Together, 9 CFR 424.21 and FSIS Directive 7120.1 provide a complete list of substances that have been reviewed and can be used in the production of meat, poultry, and egg products. However, FSIS Directive 7120.1 by itself is not sufficient scientific support for establishments' use of interventions because it does not contain efficacy data or all of the critical operational parameters. FSIS does not endorse the use of any particular antimicrobial agent included in FSIS Directive 7120.1.

> ***Key Point***
>
> FSIS Directive 7120.1 **by itself** is not sufficient scientific support for an establishment's use of interventions.

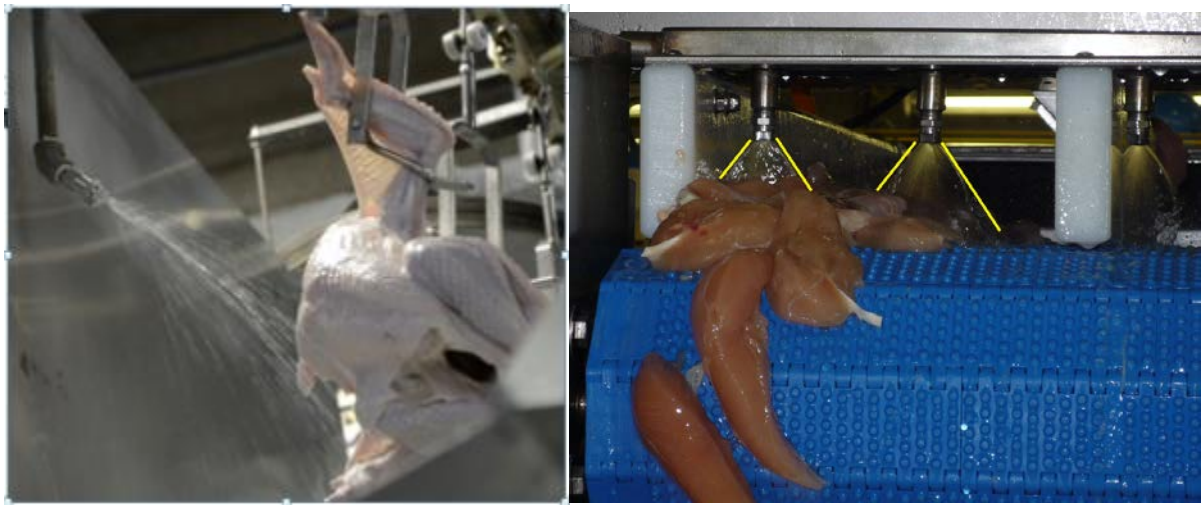
If a company or establishment wishes to use a substance (e.g. an antimicrobial processing aid applied as a dip or spray) in the production of meat or poultry products that is not listed in FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat Poultry and Egg Products*, or desires to apply it to a different product or use it at a different level than that for which the substance has been listed, it would need to submit for review a protocol to FSIS describing the proposed function of the substance in the specific poultry or meat product and conditions of use. An example of applying a substance to a different product than it was approved for would be applying an antimicrobial listed for use on the surface of poultry products to ground poultry. Per the Memorandum of Understanding between FSIS and the Food and Drug Administration (FDA), FSIS consults with FDA in reviewing the safety and suitability of substances used in the production of meat and poultry products. These can be substances used during processing or pre-harvest. FDA reviews submissions for

safety, and FSIS reviews submissions for suitability. If FSIS has no objection to the use of a proposed substance and conditions of use, and FDA expresses no concern on the basis of safety, the substance will be added to the next update of FSIS Directive 7120.1.

FSIS has found that some poultry establishments measure critical operational parameters at the point where chemicals are mixed rather than where they are applied. Values of these parameters can differ between these two locations. For this reason, values of such parameters as pH, temperature, and concentration should be measured at the point they are applied to the product, rather than where they are mixed or prepared.

With any antimicrobial intervention, carcass/product coverage is important. Figure 5 below shows examples of incomplete coverage of poultry carcasses and parts. An establishment can use simple verification procedures to ensure an antimicrobial intervention achieves carcass/product coverage. For example, the establishment could apply the intervention using fluorescein instead of the antimicrobial to evaluate carcass/product coverage. Alternatively, the establishment could apply spray cream before the intervention and evaluate the carcass/product for full coverage after the intervention. When applying antimicrobial interventions to ground product or to parts that are macerated (or otherwise not smooth), establishments should consider how they will ensure that the intervention will be thoroughly mixed in and cover surfaces where bacteria may be present.

Figure 5



Not recommended: Incomplete coverage is because of inadequate reach of antimicrobial spray in both images. On the left, only part of the carcass is receiving the spray. On the right, no spray is applied to the underside of products. In addition, not all pieces on the conveyor belt are being treated because the arc of the spray (just inside the yellow lines) is too narrow to cover all product that could pass on the conveyor. Spray is also not being applied to all pieces due to product piling up and overlapping on the conveyor belt.

This compliance guideline describes pre- and post-harvest interventions that establishments can use to create a food safety system that achieves consistent process control. The guide references available relevant studies. Antimicrobial intervention methods should be designed to reduce microbial contamination on carcasses and products of further processing (e.g. parts, comminuted) and commonly involve the application of organic acids, chlorine derivatives, or other antimicrobial interventions. At slaughter, interventions work best to reduce pathogens on source materials that have not become contaminated with fecal material, digestive tract contents, bile, or foreign matter.

Note: This guideline uses the term “free available chlorine” when referring to parts per million (ppm) chlorine. Free available chlorine is the concentration of hypochlorous acid (HOCL) and hypochlorite ions (OCL) existing in chlorinated water. (Reference: Handbook of Chlorination and Alternative Disinfectants, Geo. Clifford White, Fourth Edition 1998. Wiley Interscience).

VII. Using Microbiological Sampling and Testing

The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides guidance to help small and very small poultry establishments to meet the sampling and analysis requirements under the final rule to modernize poultry slaughter inspection. It is designed to assist establishments as they develop a microbiological sampling plan; utilize microbial testing results to monitor process control; and make decisions on process control throughout the poultry slaughter process (79 FR 49566) so that the establishment meets the minimum requirements under the final rule. While this compliance guide provides guidance on how to meet the minimum requirements under the final rule, a prudent establishment would develop an integrated sampling program that addresses multiple points throughout the poultry production process and includes sampling at points during further processing as well as during slaughter. This section provides guidance for developing and using sampling and testing data in further processing.

Microbiological testing provides a measure of the extent of control at the step being evaluated and the steps preceding it. By performing microbiological analyses at several points within a process, it is relatively easy to identify the segment of the process where control has been lost. In addition, end-product testing can provide an integrated measure of the performance of the entire process.

FSIS regulated establishments may perform microbiological testing (or contract with an outside laboratory) for various reasons, including, but not limited to:

1. Fulfill regulatory requirements,
2. Support on-going verification of the establishment's HACCP plan (9 CFR 417.4 (a)(2),
3. Support decisions made in the establishment's hazard analysis (9 CFR 417.5(a)(1) and 417.5(a)(2),
4. Evaluate the effectiveness of the establishment's sanitation program (9 CFR 416.14), and
5. Comply with customer's purchase specifications or requirements.

One way an establishment could ensure that the food safety system is effective is to use process mapping. Process mapping (also known as carcass mapping or biomapping) can be used as a baseline for assessing the effectiveness of certain interventions as well as the effectiveness of the overall food safety system. Process mapping is defined as conducting microbial sampling at selected points in the process where contamination levels can be assessed. The assessment measures microbiological loads on carcasses against a specific target organism or class of organisms. Process mapping shows areas where immediate improvements can be made, or where there is a need for process adjustments. A process mapping (testing) protocol could contain procedures for obtaining multiple samples from a single flock after each processing step. Plotting these test results creates a map of the microbial

reduction at each intervention step in the system. The plot shows where process control is most effective, least effective, or needs modification. FSIS strongly recommends that plants use process mapping techniques to develop their own sampling programs for *Salmonella* or other indicator organisms.

Effective sanitary dressing and process control procedures are crucial to an establishment's ability to produce a clean, safe, wholesome, and unadulterated product. Carcass contamination is a vehicle for the transfer of pathogens.

An establishment can verify the effectiveness of its process control procedures by conducting on-going verification activities such as microbiological sampling and testing. Microbiological sampling programs within establishments can include testing for indicator organisms such as Aerobic Plate Count (APC), total coliform, Enterobacteriaceae, and generic *E. coli*. Indicator organisms are less costly to sample than pathogenic bacteria and easier to detect and quantify. They are a valuable tool used to monitor actual in-plant processes and to determine whether a process is in or out of control. Establishments may choose from a variety of indicator organisms, including pathogenic organisms themselves, to measure microbial contamination and determine process control.

General Considerations for Establishment Ongoing Verification Testing

Process verification testing is utilized to "verify" (i.e., confirm) that the process is performing as anticipated. Process verification differs from validation in that validation utilizes an initial predetermined number of repetitions and tests, while verification involves ongoing, periodic testing. Process verification testing is intended to demonstrate that the validated process is functioning as designed, and that the results obtained during verification testing are not significantly different than those observed during the validation testing performed. Verification testing works as one of the pieces of the food safety system puzzle to help inform the establishment of any weak points that may exist in its process and that, consequently, may lead to a loss of process control.

Official establishments are responsible for ongoing verification of their entire HACCP system. Therefore, establishments could choose to sample at multiple points in the process in order to verify that each component of the HACCP system is continuing to function as designed. Simply testing only finished product will not typically provide the establishment with sufficient information to detect and correct vulnerabilities at specific steps in their HACCP system.

Establishments are required to support their verification procedures and frequencies, including the statistical design. FSIS has identified a number of key considerations for

Key Points

An establishment can sample at multiple points in its process to verify that each component of the HACCP system is continuing to function as designed.

Simply testing finished product will not typically provide sufficient information to detect and correct vulnerabilities at specific steps in their HACCP system.

establishments when designing their verification activities. The Agency encourages establishments to carefully consider the following issues.

Statistical Process Control

Statistical process control provides a powerful mechanism for establishments to monitor and interpret the data collected for ongoing HACCP verification. Statistical process control 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 failing a performance standard or the individual establishment-identified pre-determined performance criteria. Statistical process control can also provide establishments with reasonable assurance that their HACCP system is functioning as designed, and that they are likely to meet applicable performance standards.

A number of methods and approaches are available for establishments to follow. Establishments should consider available guidance and develop a statistically valid approach for interpreting sample results (Saini et al. 2011; De Vries and Reneau 2010). The basic approach is to:

1. Collect samples for one or more indicator bacteria at one or more points in the process (such as at rehang, post-chill, after cut-up, etc.) while also collecting samples for the pathogen of interest on incoming and final product. The same combinations of indicator bacteria and sample collection points should be used during ongoing monitoring as the establishment used for the initial validation step. Using multiple indicator bacteria, collected at multiple points, will give the establishment more ongoing information about process performance (Saini et al. 2011). The initial data collection step could be combined process mapping performed for HACCP validation. The number of samples and the collection design should be large enough to establish statistical limits.

2. Compare pathogen levels on incoming and final product to determine whether the process is achieving the desired level of reduction of microbial load (measured in log). If the process is functioning correctly, then the results for indicator species represent the process when it is functioning correctly. If the process is not functioning correctly, make adjustments to the process and repeat step 1.

3. If the results for pathogens demonstrate that the process is functioning correctly, use the sample results for indicator bacteria to establish a maximum acceptable limit for each indicator and collection point. Common statistical techniques include setting the limit 2 or 3 standard deviations above the mean. Lower limits may be more likely to identify a potential process issue when none exists while higher limits may be less likely to identify potential process concerns that do exist (De Vries and Reneau 2010).

4. Define the actions to take if results are above the limits set in step 3. This plan should include what the action will be, who will take the action, how it will be recorded, and how it will be verified. Establishments should respond to the results to assess process control and the food safety system as a whole.

In cases where an establishment does not have the resources or capacity to develop and implement its own statistical control limits or procedures, establishments can utilize the results from FSIS nationwide poultry surveys, provided in Tables 1 (chicken) and 2 (turkey). These results come from nationwide surveys conducted between 2007 and 2012.[4] During these surveys, FSIS collected samples from multiple points in the production process: both chicken and turkey carcasses at rehang and post chill; chicken parts after cut-up with skin on; chicken parts after cut-up with skin off; chicken necks; and chicken giblets. The tables show the median enumeration values for four common indicator bacteria: generic *E. coli*, APC, Enterobacteriaceae, and total coliforms. The median indicates that 50% of the samples in the FSIS surveys had enumeration values below the ones in the table, and 50% had values above the ones in the table. Rehang sampling information reflects incoming contamination of the exterior of the carcass that was introduced pre-harvest (including at transport). Establishments should use test results for indicator organisms at rehang to inform them of their process control.

Table 1 - Indicator Organism Median Values for Chickens

	Median (CFU/mL)			
	Generic E. coli	**APC**	**Enterobacteriaceae**	**Total Coliform**
Carcass – *Rehang*	540	28,000	1,600	940
Carcass – *Post Chill*	20	260	20	20
Skin-on Parts*	20	10,000	160	50
Skin-off Parts*	20	53,000	450	110
Necks	95	16,000	275	165
Giblets	20	1,900	60	40
Comminuted	Not available from FSIS sources			

* Excluding necks & giblets

Table 2 - Indicator Organism Median Values for Turkeys

	Median (CFU/mL)			
	Generic E. coli	**APC**	**Enterobacteriaceae**	**Total Coliform**
Carcass – *Rehang*	22	1,800	50	40
Carcass – *Post Chill*	<1.2	18	<1.2	<1.2
Skin-on Parts*	Not available from FSIS sources			
Skin-off Parts*				
Necks				
Giblets				
Comminuted				

* Excluding necks & giblets

[4] FSIS Young Chicken Survey; FSIS Young Turkey Survey; FSIS Raw Chicken Parts Survey

If an establishment uses the data from these tables, it is important that its sampling methodology be comparable to the FSIS method. When establishments compare their sample results to the ones in the tables, a sample value that is higher than the corresponding one listed in the table indicates the establishment may not be maintaining process control and may be less likely to meet applicable performance criteria. Sample values lower than the one listed in the table indicate that the establishment is maintaining process control, unless there is evidence that there are other problems in the establishment's procedures or production environment, such as evidence that the establishment's product has been associated with illnesses. When illnesses are associated with a particular establishment, achievement of a lower frequency of contamination, along with a lower level of contamination, has been demonstrated to be essential in reducing or eliminating illness from the establishment's products and protecting public health.

As establishments consider the information in these tables, they should identify whether the products are different than those in the tables to determine whether the results in the tables are applicable. Specific hazards are associated with different HACCP processes. The HACCP regulations require establishments to consider the relevant hazards associated with the specific process in their hazard analyses. The regulations also require establishments to design and implement a food safety system that reduces hazards associated with the process to acceptable levels.

A prudent establishment should consider available information provided by FSIS, including the proposed *Salmonella* and *Campylobacter* performance standards for chicken parts and comminuted poultry proposed by FSIS,[5] to develop its own internal controls for pathogens in these products. FSIS has found that its category approach (Category 1, 2, and 3) to assess process control has worked to identify whether individual establishments are maintaining consistent control. Establishments developing their own internal pathogen controls should consider how they may apply this concept.

Recommended Best Practices, Statistical Process Control

1. When defining process control limits, verify that the establishment is maintaining process control, so that values within the control limits will be representative of performance when the system is functioning as designed
2. Lower statistical control limits may be more likely to indicate that process control issues are present when they are not, while higher limits may be more likely to miss potential process vulnerabilities
3. For chicken parts and comminuted poultry, consider using the performance standards proposed by FSIS to establish internal pathogen controls

[5] 80 Fed. Reg. 3940 (January 26, 2015); 80 Fed. Reg. 12618 (March 10,2015).

Designing a sampling program

When a microbiological sampling program is properly designed and implemented, it can provide valuable information about an establishment's process control. When not properly designed and implemented, the test results can provide inaccurate and unreliable information that may not represent the establishment's actual process control. This use of inaccurate or unreliable test results could lead to inaction or an inappropriate course of action and can lead to false assurances of product safety.

There are a number of factors that need to be considered when designing a sampling plan. Sample collection and analysis involves multiple steps, all of which must be successfully performed and documented to maintain the identity and integrity of the sample. Before starting sampling, an establishment needs to consider the design of their sampling program. A well-designed microbiological sampling program should clearly define the:

- intended purpose of the testing program;
- organisms of concern that will be the target of testing;
- product that will be subject to testing;
- locations within the process where samples will be collected;
- sample collection procedures;
- procedures for ensuring sample integrity;
- testing method for sample analysis;
- laboratory performing the analysis;
- method for evaluating test results; and
- actions taken based on the test results.

Establishments can find information on criteria for selecting a commercial or private microbiological testing laboratory to analyze establishment samples in FSIS's Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory.

How can microbiological sampling data be used?

Following successful validation of its HACCP system, an establishment uses the validation data to implement its system and solidify its monitoring and ongoing verification procedures and frequencies. Establishments are required to support the monitoring and verification procedures selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Microbiological verification data should include samples collected at a number of points throughout the process (e.g., samples of starting materials, interim product, and finished product) for the same lot. Selecting samples in this way allows the establishment to determine whether the food safety system is reducing contamination, and whether the HACCP system is working as designed, similar to

process mapping. Samples at intermediate points provide additional information about intermediate process steps.

Target organisms

Establishments should consider the advantages and disadvantages of testing for the presence of selected indicator bacteria and pathogens for ongoing HACCP verification. Indicator bacteria are used because they are often present in the finished product at some level, in contrast to pathogens which may or may not be present. As a result, poultry slaughter facilities can establish a non-zero level of the indicator species that may be easier for the laboratory to reliably measure and for the establishment to interpret. Sampling and testing costs for indicator species may also be lower than costs for pathogens. However, while elevated levels of indicator bacteria are usually interpreted to mean pathogens are more likely, this relationship is not perfect. In other words, high levels of indicators do not always mean that the pathogen is present, and low levels do not guarantee the pathogen is controlled. Only pathogen testing can effectively verify that pathogens are controlled to acceptable levels in finished product.

There are no identified index organisms that directly reflect the presence or absence of pathogens in poultry (e.g., *Salmonella* and *Campylobacter)*. Therefore, FSIS recommends that an establishment test for pathogens at least intermittently and compare its results against the presence or absence of other non-pathogenic organisms (i.e., the indicator organisms the establishment is using) to assess whether it is maintaining process control.

The indicator organisms can provide evidence of control, while periodic testing for pathogens may verify that the establishment is reducing pathogens to acceptable levels. Establishments conducting their own ongoing verification sampling of finished product for *Salmonella* and *Campylobacter* can use the FSIS performance standards as indicators of process control.

Antimicrobial Interventions and drip time

Antimicrobial interventions used during processing steps may make it more difficult to detect remaining bacteria in the collected sample. For example, consider poultry carcasses exiting a chiller tank where antimicrobial interventions are used. Contaminated carcasses may have bacteria that survived the chiller tank. However, those bacteria may not be detected through sampling if the carcass is not allowed adequate drip time before collecting the sample. Adequate drip time will allow excess antimicrobial to drip off the carcass. Immediate sample collection will include a significant amount of residual antimicrobial, which can and will make it harder for the laboratory to detect live bacteria. If the carcass is allowed adequate drip time, the sample will contain less residual antimicrobial, and the laboratory will be more likely to detect live bacteria. At this time, FSIS generally recommends establishments wait at least 60 seconds after application of antimicrobial interventions before collecting a

sample to reduce the amount of antimicrobial carryover. Allowing more than 60 seconds of drip time will further reduce antimicrobial carryover. Tipping over the carcass to allow drainage of chiller water that has accumulated in the body cavity should also result in greater accuracy of the test result. Establishments could also consider whether a neutralizing agent is available which could stop the action of any residual antimicrobial intervention, making it possible to more accurately detect live bacteria remaining on the sample.

Sample Collection Method

The sample collection method can significantly affect the ability to detect bacteria on carcasses. For example, non-destructive collection methods (such as rinses and sponge samples) are less likely than destructive methods (such as collecting product) to collect bacteria that are in feather follicles, crevices, or skin folds as well as bacteria present in biofilms on the poultry skin. Furthermore, if pathogens are introduced into the interior of the poultry product, such as through injection or needle tenderization, these bacteria may not be collected in non-destructive samples. Comminuted or ground product cannot be sampled using non-destructive collection methods. For these types of products, a destructive method of sampling is used to collect a specific volume or weight of product for further analysis. Sampling product itself allows the entire sample to be submerged in enrichment broth that encourages the growth of the bacteria of interest. As the bacteria replicate, some of the cells will leave the product and enter the liquid, where they may be detected.

Proper sample collection techniques and procedures are necessary to ensure the accuracy of test results. Sample handling and collection procedures should be designed for the type of product to be sampled (e.g., parts or comminuted), the sample collection method (e.g., parts rinse, comminuted product sampling), and the type of sample collected (e.g., rinsate sample, finished product samples, excision sample of skin). Individuals who will collect samples need to receive training on proper sample collection procedures.

It is important for the establishment to be able to collect and ship samples properly. On-site assistance or information on proper sample collection (aseptic techniques) and prompt shipment of samples to the laboratory from the establishment are also important. The final result of the analysis will be neither accurate nor meaningful if a laboratory has not implemented procedures to prevent mishandling of samples or alteration of records.

To effectively use quantitative data to evaluate process control, the collection, handling, storage, and transportation of samples should be carefully controlled to prevent temperature abuse, sample leakage, and other events that could affect sample integrity and lead to unreliable test results. Procedures for maintaining sample integrity are particularly important when samples need to be transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) where they

may not be under the direct control of the establishment or the laboratory for a period of time.

Examples of non-destructive sample collection techniques that an establishment may choose to use to collect poultry carcass samples are included as attachments to the FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry. (Non-destructive techniques do not result in destruction of the product being sampled. A parts rinse sample collection is an example of a non-destructive sampling technique.)

Recommended Best Practices, Ongoing Verification Testing

1. Establishments must provide support for their verification procedures and frequencies.
2. Both indicator bacteria and pathogens can provide useful information.
3. Allow at least 60 seconds before sampling after application of any antimicrobials, to prevent excessive antimicrobial carryover in the collected sample.
4. Destructive sampling methods are significantly more likely to detect bacteria than non-destructive methods.

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Written microbiological sampling program

The establishment should incorporate its microbiological sampling plan into a written program. The microbiological sampling program should be incorporated into the establishment's HACCP plan, Sanitation Standard Operating Procedures (Sanitation SOP), or other prerequisite program. The following elements should be included in the written sampling program:

1. A description of the sample collection procedures, including how sampling that is representative of all lines and production shifts is achieved, how samples are handled to ensure sample integrity, how the establishment ensures that samples are collected per the written program, and the establishment employees designated to collect the samples for testing.

2. Information on the method used to analyze the samples and identify the laboratory performing the analysis. The method used should be an Association of Analytical Chemists (AOAC) official method or one validated by another recognized independent testing body.

3. The microbiological organisms (i.e., *Salmonella, Campylobacter*, or indicator organisms) that it will test for to monitor the effectiveness of its process control procedures,

4. The locations within the process where samples are collected,

5. The frequency of sample collection, and

6. Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline HACCP Systems Validation.

Selection of products for sampling

The samples are to be selected and collected in a manner and at a frequency that will ensure that the samples are representative of the establishment's production. If more than one shift is operating at the plant, a sample can be taken on any shift. All shifts should be sampled with sufficient frequency to assess process control of all shifts.

The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides information on methods for selection of carcasses for sampling during the slaughter process. The same selection techniques can also be applied to further processed products.

Different methods of selecting the specific products for sampling could be used, but all require the use of random numbers. Examples of methods include random number tables, calculator- or computer-generated random numbers, or drawing cards.

Pre-sampling preparation and aseptic technique

Extraneous organisms from hands, clothing, sampling equipment, and the processing environment may contaminate samples and lead to erroneous analytical results. Aseptic sampling techniques should be followed to ensure accurate results that are representative of the product and process are obtained.

Before beginning sample collection, it is important to assemble sampling supplies, such as sterile gloves, sterile sampling solutions, and sanitizing solution.

An area should be designated as a staging site for preparing the sampling supplies. A sanitizable surface, such as a stainless steel table or wheeled cart, can be used. A small plastic tote may also be useful for transporting sampling supplies to sample collection sites.

Sterile gloves should be used when handling sterile sampling equipment (e.g., sampling sponge) or when collecting samples of products that are not in finished packaging during the sample collection process. Care should be taken to prevent contamination of the external surface of the gloves prior to or during the sample collection process. Step-by step instructions on aseptic gloving are included as an attachment to the FSIS

Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry.

Sample analysis

To obtain the most accurate results, establishments should ensure the following:

- The collected sample should be either analyzed in-plant the same day as it is collected or by the following day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis. If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the comminuted product selected for sampling (or the parts rinsate) should be held under refrigeration until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant. If a sample cannot be collected and analyzed by the day after it is taken, the sample should be held under refrigeration until this is possible.

Key Points

To obtain the most accurate results, samples should be analyzed as soon after collection as possible.

If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery service to the laboratory.

- Samples should be held at refrigerated temperature, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs. Frozen samples should be discarded since the sample results may not be accurate.

Microbiological Testing Method

It is the responsibility of the establishment to ensure that its microbiological testing meets its food safety needs. An establishment needs to determine whether sample analysis will be performed by an outside (third party) laboratory or in their own microbiological testing laboratory onsite (if available).

Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, establishments may choose to have samples analyzed by an outside laboratory. FSIS has available the compliance guideline, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document should be particularly useful to very small establishments when they are selecting a commercial or private laboratory to analyze their microbiological samples. Establishments should clearly communicate their needs to the testing laboratory and direct the laboratory to any necessary testing protocols or other guidance, including this document, on the FSIS Web site. Establishments that select a laboratory that does not apply appropriate testing methods or effective Quality

Control/Quality Assurance (QC/QA) practices may not receive reliable or useful testing results.

To prevent cross contamination, FSIS recommends that a microbiological testing laboratory be segregated from manufacturing areas, and that access to the laboratory space be limited. If the establishment will be performing testing for pathogens onsite, then it should have the following additional safeguards in place to ensure food safety and security:

- Follow requirements for Biosafety Level II laboratory operation as outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL) available at: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf;
- Restrict access to the laboratory to trained staff; and
- Ensure that the laboratory is operating under the supervision of a qualified microbiologist or equivalent.

NOTE: Establishments can (and often do) analyze samples for non-pathogenic organisms such as generic *E. coli* and aerobic plate counts (APC) on-site. The test method used should be validated for the target organism and for the sample matrix (e.g., ground poultry, rinsate solution) being analyzed to ensure accuracy of the results. It should also be a method validated by a recognized independent body, such as the Association of Analytical Communities (AOAC).

Recordkeeping

Upon implementation of the sampling program, the establishment should maintain daily records sufficient to document the test results; the implementation and monitoring of sample collection; and the testing procedures, including support for the adequacy of the testing frequency. Daily records should include information such as the:

- Time, date, and location of the sample collection.
- Sample collector's name.
- Name or description of the product or sample source.
- Lot information and producer.

All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include information such as date the sample was shipped to the laboratory for analysis. The outside laboratory should document the:

- Date received;
- Condition of the sample upon receipt, including sample temperature, if applicable;
- Date the analysis was started and completed; and the
- Analytical result.

Test results should also be recorded and linked to the sample collection records by a sample number, form number or some other unique identifier. These records should be maintained in a way that ensures the integrity of the data. These records can be maintained in an electronic format, provided there are measures in place to ensure the security of the information. These records should be readily accessible for review by plant and FSIS inspection program personnel upon request.

Charting and Interpreting Test Results

Specific techniques of statistical process control include the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements. A sample result above the upper control limit may indicate the presence of a special cause of variation that should be identified and addressed each time it occurs. Results within control limits indicate simply that the process is in control. Control charts are used to (1) analyze and understand variables that affect the process, (2) determine process capabilities, and (3) monitor effects of the variables on the difference between target and actual performance. In most situations, more than one type of control chart would be applicable; detailed information on the use of control charts can be found in texts on statistical process control, under the topic “control charts”.

The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides examples of hypothetical control charts that demonstrate how test results can charted over time and used to verify process control effectiveness.

The test results should be charted and evaluated in a “moving window” format: the test results should be plotted and evaluated in a series over time. Every time a new test result is recorded, the oldest test in the series is dropped from the moving window. For example, an establishment may choose to evaluate their test results in a moving window of 13 tests. The establishment would use this series of 13 tests to evaluate their process control over the period of time represented by the series of 13 tests. The control chart would be updated with each new test result reported, adding the new test result and removing the oldest test result on the chart. The test results for samples collected at various points in the process should be plotted and evaluated in a series over time. The results should be evaluated to determine the effectiveness of process control measures in reducing microbiological levels between these points.

Actions in Response to Test Results

As discussed in the *Statistical Process Control* section, an establishment should describe the actions it will take if the test results obtained through their sampling are above the limits they have set. This description should include what the action will be, who will take the action, how the outcome of this action will be documented, and how it will be verified.

Establishments should use the information provided in these guidelines to improve management practices and to assist in investigating when there is a loss of process control. When an establishment makes changes at the appropriate locations, process control should improve. As a result, establishments should produce raw poultry products that have less contamination with pathogens, including *Salmonella* and *Campylobacter*. Generally, those interventions to reduce or prevent *Salmonella* should likewise reduce or prevent *Campylobacter*.

If the establishment determines that the trends in its test results indicate a loss of process control, the establishment should take action to investigate the cause. As discussed in the previous section on process control, an establishment should consider how the pieces of the "food safety puzzle" work together, and how they impact the entire food safety system. To do this, the establishment should evaluate its process control procedures and sanitary dressing practices to determine whether a root cause can be identified and to take steps to correct the problem. This determination should include a review of its process monitoring records as well as evaluation of the process during normal operations. The establishment should consider any implementation problems or changes in its practices, including but not limited to:

1. Procedures for routine cleaning and sanitizing of equipment, including hand tools that are used to remove contamination or to make cuts into the carcass;

2. The design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent the contact between carcasses and parts and prevent contamination of carcasses during operation;

3. Employee hygiene practices, ensuring that employees frequently wash hands and aprons that come in contact with carcasses; and

4. The implementation of antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, dips, drenches, or brushes, in accordance with the limits selected by the establishment.

Following its investigation, the establishment should respond appropriately to its findings through the use of decontamination procedures and antimicrobial intervention treatments as necessary to address any contamination that may have occurred on the carcasses and parts. The establishment should also take steps to initiate any necessary equipment repair or recalibration and employee training when identified.

Scheduled Slaughter & Processing

Maximizing the amount of finished product that is negative for *Salmonella* and *Campylobacter* can be achieved by implementing a scheduled slaughter and processing plan based on the status of incoming birds.

Scheduled slaughter and processing depends on lotting definitions that ensure lots are microbiologically independent. To implement a scheduled slaughter and processing

plan, establishments must determine the *Salmonella* and *Campylobacter* status of poultry flocks before their entry into the establishment. Using this information, establishments can then schedule pathogen-negative flocks for slaughter and processing separately from pathogen-positive flocks. "Separately" can be defined as different slaughter and processing establishments, different production lines in the same establishment, or at different times on the same production line (negative before positive and lines should be cleaned and sanitized before negative flocks or products). Establishments can also choose to utilize additional or lethality treatments, such as cooking, for pathogen-positive flocks.

> ***Key Point***
>
> Scheduled slaughter and processing is not a substitute for pre- and post-harvest interventions to control *Salmonella* and *Campylobacter*. The primary objective is to prevent transfer of pathogens from positive flocks to negative ones during slaughter or processing.

Microbiologically Independent Lotting Practices

Establishments can develop their own lot definition. Section V of this compliance guide provides additional information and recommendation on lotting. However, the benefit of scheduled slaughter and processing will be maximized by defining and processing lots in a microbiologically independent manner. Production lots can become contaminated through contamination on the source material, addition of a contaminated ingredient, or transfer of contamination by equipment or by other insanitary operations. Establishments must therefore consider their entire processes, including storage, to determine how concepts of microbiological independence apply to their establishment.

The following principles and examples may be useful to establishments when determining what microbiological independence means to them:

- Slaughter and processing equipment should be considered contaminated until it is cleaned and sanitized according to establishment SSOPs. All poultry products in contact with a piece of equipment after the equipment becomes contaminated, and before it is sanitized, are microbiologically linked.

- Contamination can be transferred between poultry products if they come into physical contact during processing and storage. Therefore, any product that is commingled or combined will be microbiologically related.

- If an ingredient is contaminated, all lots it is added to will be microbiologically related.

Step One: Determine Salmonella and Campylobacter Flock Status

The first step in scheduled slaughter and processing is to obtain accurate and reliable information about the *Salmonella* and *Campylobacter* prevalence in the live birds at preharvest. Status should be determined as close to slaughter as possible in order to increase the likelihood that *Salmonella* and *Campylobacter* will be detectable through drag swabs, boot samples, or litter samples. However, the results need to be available

to the establishment early enough to take action. This typically means sampling between 2 and 5 days before transport to slaughter.

Further information on sampling in the growout house is found in Determining Flock Pathogen Status Prior to Harvest, in the Pre-Harvest section of this guidance.

Step Two: Separate Slaughter and Processing

Birds from *Salmonella* and *Campylobacter* negative farms or houses should be transported, slaughtered, and processed separately from positive birds. Separately can mean at different establishments, on different lines within the same establishment, or at different points in time on the same line (negative birds before positive ones). Status should also be maintained throughout slaughter and processing, including if carcasses or parts are moved to other establishments for further processing. For example, if a negative flock is slaughtered separately from a positive flock, but the carcasses and parts are commingled during storage or further processing, all of the product should be considered positive. (Microbiological independence is not in place.)

> ***Key Point***
>
> Status should be maintained throughout slaughter and processing, including if carcasses or parts are moved to other establishments for further processing

In cases where positive and negative flocks are slaughtered and processed on the same line, establishments will need to evaluate their process to determine where to establish independence between lots. If there is no clear break, the establishment should consider carcasses or other raw poultry components to be positive until the next cleaning and sanitizing is performed. For example, all carcasses in the chiller tank at the time the first carcass from a positive flock enters the tank should be considered positive, even if some of the carcasses originated from negative flocks. Then, the establishment should consider all carcasses passing through the tank to be positive until the production line is cleaned and sanitized.

Step Three: Further Processing or Cooking

Establishments can also choose to utilize additional interventions for birds and poultry products derived from positive flocks. Use of interventions could be based on the establishment's knowledge of the log reduction achievable through the interventions and processes used. Alternatively, positive birds and products could be sent to cooking or another lethality treatment in order to achieve full lethality for any *Salmonella* or *Campylobacter* present in the bird.

Recommended Best Practices, Scheduled Slaughter & Processing

1. Use microbiologically independent lotting practices to minimize commingling or cross-contamination
2. Determine the presence or absence of *Salmonella* and *Campylobacter* before flocks are transferred to slaughter
3. Slaughter and process negative flocks separately from positive flocks (different establishment, different line, or on sanitized equipment)
4. Consider the use of additional interventions or cooking for positive flocks and poultry products

PRE-HARVEST

VIII. Pre-Harvest Interventions and Management Practices

Pre-harvest interventions and practices can prevent or reduce *Salmonella* and *Campylobacter* contamination in live birds, increasing the effectiveness of post-slaughter interventions and establishment controls. This section identifies available pre-harvest interventions/practices, and how slaughter and processing establishments can encourage their use by poultry producers. This section covers poultry production from breeder stock through transport to the slaughter establishment. Live receiving and subsequent slaughter steps are covered in the following section.

Food Safety Hazards

Colonization of the poultry gastrointestinal tract with *Salmonella* or *Campylobacter* is a food safety hazard that can occur at pre-harvest (i.e., at growout, the hatchery, or at the breeder farm). Colonization can then result in fecal shedding of bacteria, which can contaminate skin and feathers during many steps from breeder farm to arrival at the slaughter establishment. External contamination can also occur during slaughter from rupture of the gastrointestinal tract and transfer of pathogens on contaminated equipment. FSIS-regulated establishments can, as part of their overall HACCP system, address these hazards through purchase specifications or other agreements to require that their suppliers implement certain pre-harvest management controls.

Pre-Harvest Interventions & Management Practices

FSIS recommends that establishments use two main practices for managing pre-harvest colonization of poultry with *Salmonella* and *Campylobacter*. Together, these practices are expected to reduce the number of birds colonized with or shedding pathogens, reduce the number of these pathogens in colonized birds, and reduce the likelihood that contamination will be transferred from colonized to uncolonized birds.

First, FSIS recommends that slaughter and processing establishments receive birds from growout farms, hatcheries, and breeder flocks that implement the recognized pre-harvest interventions described in this section. Implementing these interventions can decrease the *Salmonella* and *Campylobacter* contamination on birds received by slaughter and processing establishments (Cox and Pavic 2010; Volkova et al. 2011). Establishments may include incentives in their grow-out contracts for growers to raise birds that are delivered to slaughter and processing free of *Salmonella* and *Campylobacter*. Reducing or eliminating *Salmonella* and *Campylobacter* on incoming birds can reduce contamination of finished products and increase the likelihood that the establishment will meet FSIS performance standards for *Salmonella* and *Campylobacter*.

Second, if an establishment does not require that pathogen-free birds and poultry products arrive at slaughter, FSIS recommends that slaughter and processing

establishments test incoming birds and poultry products before entry into the establishment and make processing decisions based on those results. Further information about using pre-harvest sampling data for decisionmaking is found in the Scheduled Slaughter and Processing section. Using these results, an establishment could decide to implement a scheduled slaughter and processing plan based on the presence or absence ("status") of *Salmonella* and *Campylobacter* (Katsma et al. 2007). Separate slaughter and processing could include slaughtering negative flocks or flocks with lower pathogen levels at designated establishments, on different lines within the same establishment, or slaughtering and processing them first after a clean-up, prior to slaughtering and processing positive or more highly contaminated flocks. Other decisions could be to utilize additional chemical interventions or divert products from positive flocks to lethality treatment (such as cooking). Further information is provided in Section VII.

Pre-harvest Recommendations to Control *Salmonella* and *Campylobacter*

FSIS recommends that official establishments obtain birds produced from a system of breeder flocks, hatcheries, and growout houses that use the pre-harvest best practices and interventions described here.

This section provides information on interventions intended to prevent exposure to pathogens and on products intended to reduce the incidence or levels of *Salmonella* and *Campylobacter* in birds that are exposed to these pathogens. Interventions to prevent exposure and colonization are typically more effective than treatment of *Salmonella* and *Campylobacter,* as it is more difficult to eliminate *Salmonella* and *Campylobacter* from infected flocks. There are numerous routes of exposure to *Salmonella* and *Campylobacter* during pre-harvest including:

Key Points

Interventions to prevent exposure and colonization are preferable as it is more difficult to eliminate *Salmonella* and *Campylobacter* from flocks once infected.

Preventative interventions lose effectiveness if the flock is already infected. Consider using multiple interventions throughout pre-harvest.

- transmission through the egg from the breeder flock to chicks (vertical transmission) and transmission between birds during hatch and growout;
- exposure to contaminated water, feed, and bedding in the growout house;
- environmental exposures due to poor biosecurity practices and inadequate pest control.

FSIS is not aware of a single pre-harvest intervention that eliminates *Salmonella* and *Campylobacter* as a pre-harvest hazard. Instead, FSIS recommends that as many interventions are employed as practical — a "multi-hurdle" approach. A multi-hurdle pathogen reduction approach means that multiple sequential pathogen interventions can have an additive effect to reduce pathogens. Implementing multiple interventions and controls beginning at pre-harvest extends the multi-hurdle approach to *Salmonella* and *Campylobacter* prevention and control across each bird's life. Using interventions with differing modes of action can further improve the extent of pathogen reduction when using a multi-hurdle

approach. In this guidance, FSIS is providing available effectiveness data for pre-harvest interventions, as identified in scientific literature. However, because many factors during the pre-harvest period can contribute to pathogen colonization of individual birds, spread of pathogens between birds in a flock, and excretion of pathogens by birds, use of a particular intervention may have different efficacy than specified. Thus, the concept of a multi-hurdle approach is important to keep in mind.

Establishments should consider requiring suppliers to use the interventions listed here. Establishments can use these pre-harvest controls as part of their HACCP system (through purchase specifications or other agreements) and to support their decision-making. FSIS will work with other federal agencies such as USDA-Animal and Plant Health Inspection Service (APHIS), FDA, and USDA-Agricultural Research Service (ARS), to develop additional information on pre-harvest interventions.

This guide breaks the pre-harvest interventions into six sections focused on physical, biological, and hygienic approaches to reduce pre-harvest exposure to *Salmonella* and *Campylobacter*: Breeder Flock & Hatchery, Growout House, Bedding, Feed, Water, and Transportation. Establishments should consider combining exposure-reducing interventions with one or more of the products available for pre-harvest control of *Salmonella* and *Campylobacter* in poultry (Table 3).

These products have different modes of action, but all produce the same result: reduced incidence of pathogen colonization and reduced pathogen levels in colonized birds. Efficacy depends on the specific product, and most should be used in consultation with a veterinarian. Using both types of pre-harvest approaches — those to reduce exposure and those that reduce incidence of colonization and levels of pathogens — will minimize pathogens on birds at harvest.

Using interventions and best practices recommended in this guidance should help to provide for animal welfare and bird health at pre-harvest, thereby reducing stress in poultry and reducing *Salmonella* and *Campylobacter* in birds presented at slaughter. Evidence suggests that stress at pre-harvest can have adverse effects on food safety (Rostagno, 2009). Understanding the mechanism by which stress alters normal intestinal characteristics and induces susceptibility to enteric infections may help in developing additional pre-harvest strategies to reduce pathogen contamination in poultry.

NOTE: In this section, the term “young chickens” refers to all chickens raised for slaughter to distinguish it from chicken breeder stock. The term here is not limited to “broilers” as defined in 9 CFR 381.170(a)(1)(iii). In this section, “young turkeys” refers to all turkeys raised for slaughter to distinguish it from turkey breeder stock.

Table 3. Pre-harvest products to reduce colonization and number of *Salmonella* and *Campylobacter* in poultry.

Definition	Notes on Use
Vaccines: increase immunity to *Salmonella* by exposing the immune system to a controlled preparation. Live-attenuated vaccines produce broader immunity than other types, such as inactivated or subunit vaccines. Additional vaccine types utilize bacteriophages (viruses that infect bacteria) and autogenous vaccines (developed from bacteria isolated from the farm environment).	Only *Salmonella* vaccines are currently available. Approved live-attenuated[6] vaccines are available for use in breeder flocks and in young chickens and young turkeys and are administered orally or by injection. Other vaccine types, such as inactivated vaccines, may require multiple doses or take longer to produce the immune benefits, limiting but not excluding their usefulness in chicks due to the short growout period. Special approvals from APHIS are required for long-term use of autogenous vaccines or for use with multiple flocks. Some vaccines were found to show a 9% reduction in *Salmonella* prevalence, a 1-2 log reduction, or a 2-3 log reduction of *Salmonella* recovered from poultry challenged after vaccination.
Competitive Exclusion & Probiotics: preparations of beneficial bacteria that compete with *Salmonella* and *Campylobacter* in the gut for space or nutrients. Also known as direct-fed microbials.	Some products can be used on the day of hatch to establish healthy gut flora in chicks. Other products can be added to water and feed for both breeders and young chickens and used to boost competition against pathogens throughout the bird's lifetime or when otherwise indicated (e.g., stress). Antimicrobial use should be limited to avoid killing the beneficial bacterial species. One study on the effectiveness of a competitive exclusion culture in poultry found up to a 92% reduction of *Salmonella* following a *Salmonella* challenge.
Prebiotics: specific nutrients that will allow beneficial bacterial species to more effectively compete against *Salmonella* and *Campylobacter*.	Can be added to the feed of both breeders and young chickens. The most common supplements include yeast extracts such as beta-glucans and mannan oligosaccharides A study on the effectiveness of a prebiotic in poultry found a 34% reduction of *Salmonella* prevalence following *Salmonella* challenge.
Organic Acids: increase the acidity of the gut, which can kill	Can be added to both feed and water for breeders and young chickens. Adding to water during feed

[6] Live *Salmonella* vaccines administered to poultry presented for slaughter may have the potential to introduce a hazard into the establishment. Establishments should support how their use of such vaccines does not affect safety of poultry products derived from vaccinated poultry and does not interfere with FSIS inspection procedures.

Salmonella and *Campylobacter*. Because each bacterial species has a different susceptibility to organic acids, this mechanism also increases the ability of beneficial bacteria to compete against pathogens.	withdrawal is particularly important. After feed is withdrawn, birds may be more likely to peck at litter and may ingest pathogens. Organic acids in the water will lower the pH in the crop and reduce pathogen colonization and growth. A review article found that use of most organic acid products resulted in up to a 1 log reduction of *Salmonella*.

(References: Berge and Wierup 2012; Callaway et al. 2008; Cox et al. 2012; Desin, Köster, and Potter 2013; Feberwee wt al. 2001; Hume et al. 1998; Khan et al. 2003; Penha et al 2009; Spring et al. 2000; Wales et al. 2013)

Breeder Flock & Hatchery

Breeder flocks and hatcheries can be the original source of *Salmonella* and *Campylobacter* colonization for young chickens because infection can be transmitted through the egg (vertical transmission). Establishments should obtain broiler and turkey chicks from breeder flocks and hatcheries that follow National Poultry Improvement Plan (NPIP) procedures and recommendations. Because of the possibility of vertical transmission, establishment parent companies and independent growers should consider placing broiler and turkey chicks from breeder flocks free of *Salmonella* and *Campylobacter* onto grow out farms (Liljebjelke et al. 2005; Cox et al. 2012; Crespo et al. 2004). (Note that pathogen-free breeder stock is not a requirement for participation in NPIP.) Broiler breeders also demonstrate variability in innate immunity to *Salmonella* and *Campylobacter* — some chicken breeder stocks have been shown to be more resistant to colonization (Swaggerty et al. 2009). Utilization of these parental breeding stocks can produce broiler chicks that are more resistant to on-farm colonization.

Consider the use of one or more of the products listed in Table 3 to prevent or reduce colonization with *Salmonella* and *Campylobacter*. Several of the probiotic, prebiotic, and organic acid products can be administered to both breeder flocks and young chickens, often through feed and water. Of special note for breeder flocks are vaccines for *Salmonella*, which can reduce the likelihood of vertical transmission to chicks (Desin, Köster, and Potter 2013). Compared to the short growout period for young chickens, breeder flocks may remain productive for several months or longer. As a result, a greater number of vaccine options are available in breeders compared to young chickens and turkeys. For example, inactivated vaccines require multiple injections, something which may not be practical for broiler flocks, but could be valuable for breeder stock. In addition, autogenous vaccines require weeks of production time and special approvals for use for multiple flocks, limiting their cost-effectiveness in young chickens.

Competitive exclusion and probiotics can be administered to chicks on the day of hatch to inoculate the gastrointestinal tract with beneficial bacteria (Table 3). Inoculation with beneficial bacteria at the hatchery should be followed with use of appropriate prebiotics

and organic acids at the growout house to maintain beneficial bacteria through growout. Chicks should be transported from the hatchery to the growout house in new or cleaned/sanitized, and ideally lined, containers (Cox and Pavic 2010). Limit the number of individuals handling the chicks from the truck to the interior of the growout house to minimize chances for exposure.

Recommended Best Practices, Breeder Flock and Hatchery

1. Obtain chicks from pathogen-free breeder flocks and from breeders and hatcheries following NPIP procedures
2. Use breeding stock with innate resistance to *Salmonella* and *Campylobacter*
3. Consider using one or more of the products listed in Table 3
4. Transport chicks to growout in new or sanitized containers

Although the following sections focus on young chickens and turkeys, the practices apply to chicken and turkey breeders as well to minimize pathogens in those flocks.

Growout Houses

Farms and houses should be designed to facilitate cleaning and disinfection between flocks (Cox and Pavic 2010; Volkova et al. 2011). All poultry farms should develop and implement written biosecurity and hygiene plans. Poultry health should be monitored under the supervision of a veterinarian.

Available evidence suggests that the following practices are correlated with decreased likelihood of *Salmonella* and *Campylobacter* in birds presented for slaughter (Cox and Pavic 2010; Newell et al. 2011; Volkova et al. 2011):

- housing a single species (e.g., only chickens or only turkeys) on the farm and reducing the total number of animals;
- keeping birds of different ages in different houses (“all-in, all out”);
- limiting the number of people with access to growout houses and using disinfecting boot dips or disposable foot coverings and disposable coveralls when entering the house (a study by Gibbens et al. (2001) found that correct use of a boot dip and using house-specific boots and overalls reduced flock colonization of *Campylobacter* by 50%);
- removing vegetation around buildings, installing screens on windows and other openings, and increasing physical integrity of buildings to prevent access by rodents, birds, or insects (intervention studies found the use of fly nets decreased *Campylobacter* in poultry flocks from 51.4% to 15.4% (Hald et al. 2007); and
- using pest control measures including bait and traps.

In addition to reducing exposure to *Salmonella* and *Campylobacter* with the measures described above, consider the use of one or more of the products in Table 3 to reduce colonization and the number of pathogens in exposed birds. Most probiotics, prebiotics, and organic acids can be used with both breeder and broiler flocks as feed or water additives. Vaccines remain an option for broiler flocks; however, manufacturer information should be used to determine whether immune protection can be achieved during the short growout period.

Approved live-attenuated vaccines are available for use in young chickens and turkeys. Live vaccines may introduce *Salmonella* into flocks presented for slaughter, thereby introducing a human health hazard into the establishment. Establishments must be able to support that use of a live vaccine will not affect product safety, and that the vaccine will not be as or more likely to be detected on poultry using the standard FSIS MLG method . For this reason, FSIS encourages establishments to submit for FSIS New Technology review their proposed use of live *Salmonella* vaccines in poultry intended for slaughter.

Key Points

Pre-harvest interventions must **not**:

1) affect product safety,

2) jeopardize the safety of Federal inspection program personnel,

3) interfere with inspection procedures, including FSIS sampling, or

4) require a change in the Agency's regulations.

Recommended Best Practices, Growout House

1. Ensure physical integrity to prevent access by birds, rodents, and insects
2. Implement on-farm biosecurity and hygiene plans
3. Minimize the number of people with access to the growout house
4. Require the use of disposable foot coverings or boot dips
5. Consider use of products in Table 3

Bedding

Set new, dry, *Salmonella* and *Campylobacter* free bedding between flocks when possible. If bedding is not changed between each flock, remove saturated bedding (including litter under water lines) and allow bedding to dry for 10-14 days (consider testing to verify the bedding is pathogen-free) (Volkova et al. 2011). Producers should also consider testing to verify the bedding is pathogen free. Commonly used testing methods include boot or drag swabs, which provide a measure of litter contamination throughout the growout house. Studies generally find that boot swabs are the most sensitive to contamination (Mueller-Doblies et al. 2009).

Control litter moisture as much as possible, ideally maintaining a water activity below 0.84 (moisture content between 20-25%) and remove wet spots as frequently as

possible. Proper maintenance of the water distribution system will also prevent leaks and help keep the litter dry. Litter treatments are available that have been shown to reduce, but not eliminate, transmission between birds and flocks (Cox and Pavic 2010). Furthermore, some studies suggest that careful re-use of bedding may actually protect flocks against pathogens by providing a source of beneficial bacteria, which also compete with pathogens in the litter (Roll et al. 2011). Careful re-use can include testing for pathogens, removing caked or saturated bedding, and application of litter treatments between flocks.

Recommended Best Practices, Bedding

1. Change bedding between flocks or test, using boot or drag swab methods, to ensure bedding is pathogen-free
2. Allow bedding to fully dry between flocks
3. Minimize water content in bedding while birds are in the house

Feed

Use feed that is free of *Salmonella* and *Campylobacter*. In particular, obtain feed from manufacturers that follow good manufacturing practices to reduce or eliminate pathogens, such as those certified by the Safe Feed/Safe Food program administered by the American Feed Industry Association. Safe Feed/Safe Food producers may also conduct finished product testing to verify the product is negative of certain hazards. Clean and disinfect feeders between flocks and keep in good repair. Consider adopting the use of feed additives that are effective in young chickens (Table 3).

Protect feed from contamination during transportation and storage. Transport the feed to the farm in accordance with the Sanitary Food Transportation Act of 2005, which includes provisions for cleaning before transport of feed and measures to prevent contamination or tampering during transportation. Store feed on-farm in a manner that reduces the likelihood of contamination through contact with pests, fomites, or the environment (Berge and Wierup 2012). If feed is stored on-farm in a manner that could result in contamination (such as open bins or bags), poultry producers should conduct periodic sampling to determine whether contamination has occurred during storage. Some research indicates that pelleted feed is more resistant to contamination during storage than mash, and that the addition of organic acids to the feed may also protect against contamination. The Association of American Feed Control Officials provides additional recommendations on the production and distribution of animal feed, including Best Management Practices for Manufacturing, Packaging & Distributing Animal Feeds and Feed Ingredients (AAFCO).

Time feed withdrawal appropriately, recommended between 8 – 12 hours before slaughter (Cox and Pavic 2010). Withdrawing feed before slaughter can ensure that birds have an empty gastrointestinal tract during transport, slaughter, and evisceration, which can reduce external contamination with fecal material. However, some research

indicates that early withdrawal may lead the birds to peck at the litter in the growout house and decrease the acidity of the crop, increasing the likelihood that the bird will ingest pathogens and be contaminated at slaughter (Berge and Wierup 2012). Consider providing water with organic acids (Table 3 and discussed below) during feed withdrawal to prevent colonization of the crop. Extended feed withdrawal may also make internal organs more fragile, increasing the likelihood that the crop or other organs will tear during processing and contaminate the carcass (Cox and Pavic 2010). Most studies support a feed withdrawal period of 8-12 hours to prevent organ tearing (Rostagno et al. 2006; Cox and Pavic 2010).

Recommended Best Practices, Feed

1. Clean feeders between flocks
2. Use feed that is pathogen free
3. Consider use of appropriate feed additives (Table 3)
4. Protect feed from contamination during transport and storage
5. Pelleted and acidified feed may be more resistant to contamination during storage
6. Time feed withdrawal appropriately (between 8 – 12 hours) and supply water with organic acids during feed withdrawal

Water

Provide abundant, potable water (Cox and Pavic 2010). If water is not from a chlorinated or municipal source, routine testing is recommended to ensure that the source is free of pathogens. Clean the water distribution system between flocks, ensuring that biofilms, which may be reservoirs for pathogens, are removed when possible. Ensure that the system is free of cracks and leaks to minimize waste and to keep bedding dry.

A number of the products listed in Table 3 are available as water additives for young chickens. Of note are organic acids added to water, particularly during feed withdrawal (Berge and Wierup 2012). Providing water during feed withdrawal distracts birds from pecking at the litter. Adding organic acids to this water source will increase the acidity of the crop, which can help protect the bird against any *Salmonella* and *Campylobacter* they may ingest when pecking at the litter.

Recommended Best Practices, Water

1. Provide abundant, potable water
2. Clean water distribution systems between flocks
3. Consider feed and water additives listed in Table 3, particularly organic acids during feed withdrawal

Determining Flock Pathogen Status Prior to Harvest

Understanding pathogen status prior to collecting birds for harvest can provide valuable information to inform establishment decision making for slaughter and further processing. Additional information and considerations to maximize use of on-farm sampling results is found in Scheduled Slaughter & Processing, in the section Using Microbiological Sampling and Testing.

Pathogen status of each growout house should be determined. This increases accuracy on farms where only a portion of houses have colonized birds. In addition, this gives establishments the option to schedule negative houses separately from positive houses, provided they can be transported separately.

Several methods are available for collecting and analyzing samples. Some studies suggest that boot swabs may be more sensitive than drag swabs, litter samples, or cloacal swabs. Boot swabs provide establishments with a single sample that represents conditions throughout the poultry house (Mueller-Doblies et al. 2009). Samples should be analyzed for both *Salmonella* and *Campylobacter*. Recent research has shown that at least 30% of broiler flocks are *Salmonella* negative, and that over 48% of broiler flocks are *Campylobacter* negative, based on testing fecal samples collected on the farm prior to slaughter or cecal samples collected at slaughter (Berrang et. al 2015 and Thakur et. al. 2013). Flocks and houses that are negative for both should be considered negative for scheduled slaughter purposes. Flocks and houses that are positive for one or both should be considered positive for scheduled slaughter purposes.

Key Points

Boot Swabs: single-use covers are placed over the wearer's boots. After walking through the growout house, the covers are sent for lab analysis. Provides a measure of the entire house.

Drag Swabs: collection swabs are dragged on strings throughout the growout house and sent for lab analysis. Provides a measure of the entire house.

Litter Samples: a portion of the litter is collected and sent for lab analysis. Can only indicate contamination for the collected sample.

Cloacal Swabs: a swab is used to collect material from the cloaca of a single bird. Multiple swabs can be collected but results will only represent the birds that are tested.

Birds from *Salmonella* and *Campylobacter* negative farms or houses should be transported, slaughtered, and processed separately from positive birds.

Transportation

The presence of *Salmonella* and *Campylobacter* on birds at receiving at slaughter can be linked to dirty transport cages (Cory, et al., 2002, and Slader, et al., 2002). Cross contamination of both birds and cages is frequently made worse when the birds are transported to the establishment. Transport cages are important sources of cross contamination (Berrang, et al., 2003, Slader, et al., 2002).

To prevent such contamination, transport birds in clean containers (Cox and Pavic 2010). Clean, single-use paper liners can be used when transporting chicks but are not recommended for transporting young chickens to slaughter. In all cases, clean and disinfect transportation cages between each load. Minimize the number of individuals involved in removing birds from the growout houses. Figure 6 shows a chicken transport crate that is not washed after every load. There is a significant amount of fecal material built up, which can serve as a source of pathogens for future flocks transported in the crate.

Figure 6

Not recommended: Transport crate that is not washed with sufficient frequency. There is a buildup of fecal material and feathers that can contaminate subsequent flocks during transport.

Using cleaned and disinfected transport cages for each load is especially important after flocks have been sampled prior to harvest. This is because contamination from dirty cages can change the pathogen status of a flock from negative to positive, and reduce the effectiveness of scheduled slaughter and processing decisions.

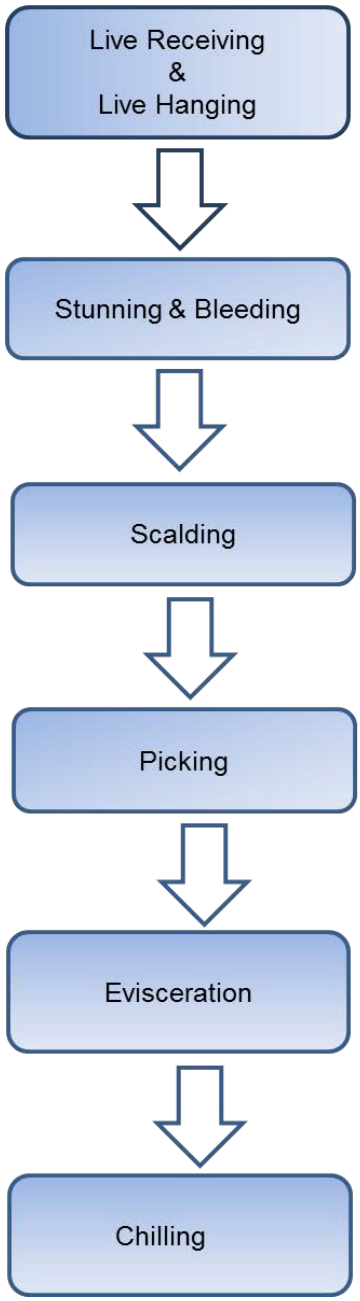
Recommended Best Practices, Transportation

1. Use clean containers and sanitize containers between loads
2. Use new disposable paper liners when transporting chicks to the farm.
3. Minimize number of individuals involved in transport.
4. Clean and disinfect transports crates between each load.

SLAUGHTER AND PROCESSING

IX. Slaughter

This section of the guidance provides information for establishments that slaughter poultry. The diagram below presents the steps in poultry slaughter addressed in this section.



How well an establishment conducts its slaughter dressing procedures has a direct bearing on whether the decontamination and antimicrobial intervention treatments in

place in a poultry operation will have their intended effects. When contamination overwhelms the decontamination efforts and antimicrobial intervention treatments, the establishment may need to take additional steps to reduce pathogens. In order to assess whether an establishment's food safety system is having the effect that the hazard analysis anticipates, each establishment should monitor its overall processes very closely and maintain documentation that supports that its sanitary dressing procedures, coupled with all intervention treatments at slaughter, are effective at addressing *Salmonella* and *Campylobacter* on carcasses under the actual conditions that apply in its operation.

Live Receiving and Live Hanging

This is the point in the slaughter process where poultry arrive at the establishment in transport crates or cages, are unloaded, and are hung on shackles. There is a potential for contamination with enteric pathogens including *Salmonella* and *Campylobacter.* The feathers, skin, crop, and cloaca of birds brought to slaughter are often highly contaminated with *Salmonella* (Kotula and Pandya, 1995) and *Campylobacter* (Berrang et al., 2000).

As described in the previous section, transport cages have been found to be sources of cross contamination of pathogens onto live birds transported to slaughter.

Research indicates that washing the transport cages with water and leaving them to completely dry for 48 hours greatly lowers the levels of *Salmonella* found in the cages. However, this approach adds to the cost of poultry production. Water use, employee time, storage space, and unused equipment are all costs to be considered. One researcher suggested using removable cage floors that could be stored or dried thoroughly.

Key Points

The feathers, skin, crop, colon, ceca, and cloaca of birds brought to slaughter are often highly contaminated with *Salmonella* and *Campylobacter.*

Transport cages are an important source of cross contamination.

Research suggests that a two-step process that first cleans then disinfects the cages is effective at reducing *Salmonella*. Pre-cleaning the cages prior to immersing in hot water for 30 seconds at 60 ºC (140 ºF) or higher or immersing for 30 seconds in a solution of sodium hypochlorite at 750 ppm or higher reduces *Salmonella* on transport cages (Ramesh, et al., 2004). Researchers have also shown a 4 log reduction of *Campylobacter* following crate washing (Allen et al., 2008).

Cleaning followed by sanitation of the unloading and holding area is important. High levels of *Salmonella* and *Campylobacter* found on incoming birds can overwhelm establishment interventions. These levels are carried forward to the next steps of the slaughter process. Studies show links between *Salmonella* and *Campylobacter* at live receiving and later in the process (Fluckey, et al., 2003, Newell, et al., 2001). In addition, one study attributed the conversion of *Campylobacter*-negative birds to *Campylobacter*-positive after exposure to feces in a commercial dump cage (Berrang, et al., 2003). Establishments should consider how the frequency of cleaning transport cages might inform their lotting practices, since research has indicated *Campylobacter* positive birds were linked to dirty transport cages. If

establishments lot product (to achieve microbiological independence) on a flock basis, they should clean and sanitize transport cages between each flock to maintain microbiological independence.

Employee traffic patterns and air flow should be controlled to prevent cross contamination and reduce levels of *Salmonella*. There should be positive airflow moving from inside to outside of the establishment. Standard operating procedures and training, including changing clothes and boots upon arrival, separate facilities for "dirty" versus "clean" employees, and restricting employee movement are measures that can be put in place. One study found employee clothing to be a source of contamination for *Campylobacter* (Herman, et al., 2003).

Most establishments keep detailed records of suppliers and slaughter schedules by lots to monitor output or yields. An establishment could use these records to correlate its own in-house testing programs to determine if there are suppliers that routinely deliver birds carrying a high microbial load.

Addressing these issues with suppliers could lower the microbial level of incoming birds at receiving and thereby reduce microbial loads, particularly pathogens, in chilled carcasses. At the live receiving step establishments should consider the hazards likely to occur (biological, chemical, physical). The establishment is required to have measures in place to ensure that poultry that are dead on arrival are disposed of properly (9 CFR 381.95) and not placed on the slaughter line.

Recommended Best Practices - Live Receiving and Hanging

1. Wash, sanitize, and dry cages thoroughly
2. Provide SOP and employee training
3. Schedule flocks for slaughter based on pathogen loads

Stunning and Bleeding

This is the point in the slaughter process where the bird is stunned, cut, and bled. Stunning methods render birds unconscious. The method of stunning may be electrical, mechanical, or chemical. Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalder (9 CFR 381.65(b)).

Stunning reduces struggling and convulsions. However, wing flapping and quivering that happens because of the electrical stunning can transfer bacterial pathogens from the inside to the outside of the bird and to nearby birds and equipment. Establishments slaughtering turkeys or heavy fowl may find chemical stunning a better method because

of the size of the birds. There is research to suggest Controlled Atmospheric Stunning, a varying mixture of carbon dioxide, argon, and nitrogen, may reduce damage to carcasses. Studies have shown that birds chemically stunned struggle less during the slaughter process, and there are fewer broken bones and less muscle bruising as compared to electrical stunning (Kang and Sams, 1999, and Hoen and Lankhaar, 1999). A study by Musgrove, et al., (1997) showed that *Campylobacter* increased in carcass rinses after stunning. Good feed withdrawal practices can greatly reduce this problem. By decreasing the amount of feces expressed, establishments can reduce fecal cross-contamination on the surface of the carcasses, in the scald tank, and on the feather removal equipment. This decreases the level of *Salmonella* and *Campylobacter* carried forward into the next steps. Figure 7 shows young chickens entering the stunner with minimal external fecal contamination.

Key Points

Stunning methods render birds unconscious

Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalder.

Decreasing the level of *Salmonella* at one step in the slaughter process results in less microbial carry over to subsequent steps.

Figure 7

Best practice: These young chickens show minimal fecal contamination on their feathers as they enter the stunner. These birds are calmly entering the stunner.

Recommended Best Practices – Stunning and Bleeding

1. Electrical stunning and chemical (gas) stunning are very effective stunning methods when implemented correctly.

2. Use well-timed feed withdrawal practices to reduce feces release during stunning.

Scalding

Scalding prepares carcasses for defeathering by breaking down the proteins that hold the feathers in place and opening up the feather follicles. It is the point in the slaughter process where the birds are placed in hot water in order to facilitate feather removal and is the first location during processing where birds are exposed to a common bath, which can allow *Salmonella* cells from positive carcasses to spread *Salmonella* to negative carcasses (Russell, 2012). However, scalding 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.

Scalder water that contains high concentrations of fecal material is a problem. Birds may come in to slaughter facilities with excessive fecal material on the feathers which gets washed off in the scalder water. Figure 8 shows an immersion scald tank with evidence of excessive fecal material contamination. *Salmonella* has been recovered from 100% of the skin and feather samples entering the scald tank (Georgnaras, et al., 1997) and has been shown to survive in the scald tank. Bacteria present in the dirty water may be massaged into the skin and open feather follicles. Also the organic material may be retained on the surface of the bird through evisceration and end up in the chiller, deactivating the chlorine and preventing disinfection. Scalding cannot overcome high numbers of pathogens carried forward from previous steps. To reduce this problem, a bird brush and washer used prior to the scalder can remove some of the incoming dirt and fecal material.

There are two methods for scalding:

- steam-spraying
- immersion

Steam spray systems work by applying a mixture of steam and air at a temperature and pressure designed to scald the surface of carcasses. Immersion scalding is carried out by placing the carcasses into a tank of hot water. Tanks are either single- or multi-stage. Immersion is more common than steam-spraying. However under the right conditions, both methods can reduce *Salmonella* on carcasses (Dickens, 1989).

Figure 8

Not recommended: Excessive fecal material is present in the scalder

The National Chicken Council (NCC) recommends that best management practices include using counter current systems in the scalder with adequate water replacement (NCC, 1992). Water in the tank should move through the system flowing against incoming carcasses. This flow creates a dirty-to-clean gradient. Carcasses moving through the tank are washed by ever-cleaner water. Multiple stage tanks are better than single stage tanks because they create more opportunities to clean the carcasses (Cason, et al., 2000). High flow rates of water and adequate agitation dilute the dry matter and bacterial load in the tank (Cason, et al., 2001).

The water pH should be monitored carefully. A higher, more alkaline pH (9.0 ± .2) is best for reducing *Salmonella* and *Campylobacter* in the water (Humphrey and Lanning, 1987). Making the pH more acidic (3-4) is also effective at decreasing levels of *Salmonella* (Okrend, et al., 1986)). Establishments should monitor the pH in scald tanks as frequently as necessary to determine the pH highs and lows occurring during operation. Once establishments are able to maintain a desirable pH, less monitoring is needed.

Key Points

Scalding is an important step that can reduce levels of *Salmonella* and *Campylobacter* on the carcasses.

Water pH should be monitored carefully

Scalding can be used as an intervention if pH is properly maintained in the scald tank.

Uric acid from poultry feces can reduce the pH from 8.4 to 6.0 in less than 2 hours (Humphrey, 1981). Organic matter in the tank acts as a buffer to maintain a more neutral pH (6-7). *Salmonella* is heat resistant at a neutral pH (Okrend, et al., 1986). *Campylobacter* is most heat resistant at a pH of 7.0 (Humphrey and Lanning, 1987).

Understanding water characteristics is an important aspect in poultry slaughter operations. The source (well or treated surface water or municipal water), hardness, mineral

content, and pH influence the killing action of any antimicrobial chemicals that are added to the water. Poultry establishments using more than one water source should carefully monitor the effect of the water on the chemicals used.

FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products provides a list of approved chemicals that can be used in scalders. Researchers have studied the addition of acetic acid, lactic acid, and a commercial blend of formic and propionic acid to scalders at a concentration of 1% in the presence of material for activity against *Salmonella.* In one study, a blend of formic and propionic acid was found to be more efficacious against *Salmonella* followed by lactic acid and the acetic acid (Cherrington et al., 1992). (Chlorine is not approved for use in the scalder nor is it a practical application. Chlorine is immediately deactivated by the organic load in the scalder and can gas off due to high scalder temperatures.)

Most U.S. poultry processors prefer a hard scald to a soft scald. A hard scald is a shorter scald time at higher temperatures compared to a soft scald. This approach allows better removal of the outer layer of skin (epidermis). The correct water temperature for the appropriate amount of time is important to prepare the carcasses for feather removal. It also reduces dressing defects. When the water temperature is too high, the carcasses become oily. This oiliness makes it easier for *Salmonella* to stick to the surface of the skin. If the carcasses are over-scalded, the meat may start to cook, and the carcasses may be marked unacceptable and rejected by inspectors. If the temperature is too low, the tank becomes a breeding ground for bacteria. *Salmonella* organisms cannot grow at temperature greater than 116.6 ºF (47ºC). Therefore, scalding temperatures higher than 116.6°F (47ºC) should be sufficient to control *Salmonella* growth. Table 4 shows common scalding times and temperatures for various classes of poultry.

Table 4. Common Scalding Times and Temperatures

Class of Poultry	Time /seconds	Temperature /°F	Temperature/°C
Broiler (hard scald)	30-75	138.2-147.2	59-64
Broiler (soft scald)	90-120	123.8-129.2	51-54
Turkey	50-125	138.2-145.4	59-63
Quail	30	127.4	53
Water Fowl	30-60	154.4-179.6	68-82

Reduction of *Salmonella* during scalding generally increases with higher water temperatures (Yang et al., 2001). While scalding above 47 °C controls *Salmonella* growth and initiates inactivation, scalding at 60 °C reduced counts by an additional 0.3–0.5 log units than scalding at 52 or 56 °C (Slavik et al.,1995). Yang et al. (2001) found

that scalding at 60 °C reduced counts by an additional 2 log units than at 50 °C, while reductions were similar when scalding at 55 °C or 60 °C.

Some religious traditions forbid scalding. Under Kosher slaughter, carcasses are soaked in cold water to make feather removal easier. This method, as well as the steam spray method, may produce carcasses with skin more susceptible to *Salmonella* (Clouser, et al., 1995). Establishments should consider this potential effect in deciding what sanitary practices they employ downstream because the high number of pathogens not reduced during scalding can be transferred to future steps in the slaughter process.

Recommended Best Practices – Scalding

1. Have water moving counter current to carcasses.
2. Have high flow rates of water with adequate agitation to dilute dry matter and bacteria.
3. Use multi-staged tanks
4. Maintain water pH at either above or below the optimum pH for *Salmonella* growth (6.5-7.5).
5. Use pre-scald brush systems to clean birds prior to scald tank.
6. Use post-scald rinse.
7. Use inorganic and organic acids in the scalder.

Picking

The feather removal process is designed to remove feathers and the uppermost layer of the skin before evisceration. Carcasses typically pass through rubber picking fingers that mechanically remove feathers from the carcass. Most establishments use a continuous process. However, batch and manual processes are sometimes used in low-volume establishments.

Good process controls at picking are critical. Cross-contamination of the carcasses occurs because of contact with contaminated rubber picking fingers and contaminated reuse water (Georgnaras, et al., 1997, Wempe, et al., 1983). Fecal material is released when picking fingers agitate and rub the carcasses and can lead to cross-contamination between the carcasses (Allen, et al., 2003). Several researchers have determined that

levels of *Salmonella* and *Campylobacter* increase during this step (Acuff, et al., 1986, Izat, et al., 1988, Berrang and Dickens, 2000).

Regular equipment sanitation and maintenance are recommended to minimize cross-contamination when using either batch or continuous picking. The NCC recommends preventing feather buildup during the defeathering process by continuously rinsing the defeathering equipment and carcasses (NCC, 1992). Post-feather removal rinses should be maintained at 160°. Chlorine, acetic acid, and hydrogen peroxide are types of chemical rinses used during defeathering. If birds are plucked manually, the establishment should take care not to cross contaminate by keeping the area as clean as possible and preventing feather buildup.

Key Points

Good process control procedures at picking are critical and can improve an establishment's *Salmonella* performance standard set.

Fecal material is released when picking fingers agitate and rub the carcasses and can lead to cross-contamination between the carcasses.

Establishments can apply washes or antimicrobial interventions post-picking. However, cut surface of hocks should not be washed until FSIS postmortem inspection is complete. Otherwise pathological exudate could be removed or obscured and prevent detection of synovitis by inspectors.

Water reuse is addressed in 9 CFR 416.2(g)(3). This regulation states that water, ice, and solutions 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. An establishment is required to have data to support all decisions regarding reuse, including a decision that reuse will or will not cause adulteration (9 CFR 416.2)(g)(2)).

Recommended Best Practices – Picking

1. Prevent feather buildup on equipment.
2. Regular cleaning and maintenance of rubber picking fingers.
3. Ensure coverage of sanitizer on picking rails and equipment.
4. Use a post picking antimicrobial intervention.
5. Scientifically support any water reuse plan.

Evisceration

Key Points

Evisceration begins at rehang and ends when the carcass enters the chiller.

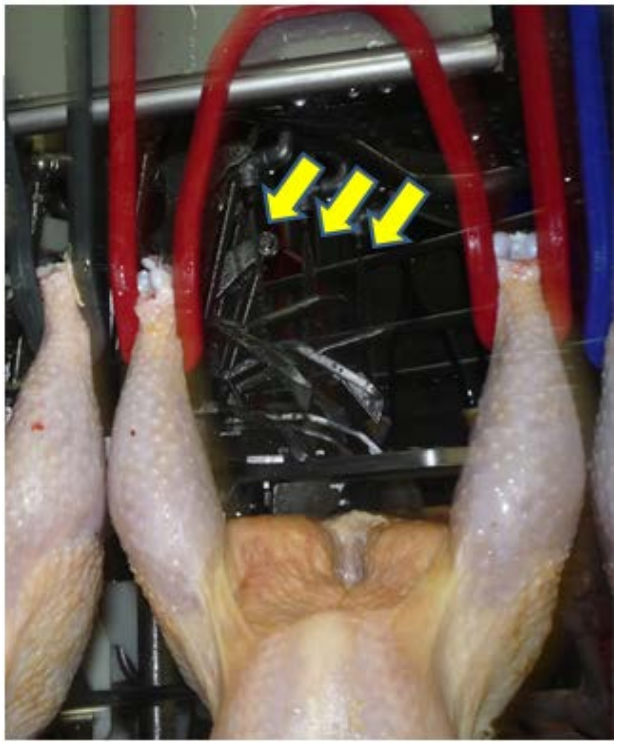
Feed withdrawal practices affect process control throughout the evisceration step.

For the evisceration processes to work efficiently, carcasses need to be placed on the shackles correctly and machinery adjusted to accommodate bird size.

Evisceration 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 (including the gastrointestinal tract and edible offal such as heart, liver, and gizzard) occurs by automated or manual means, along with any trim or processing defects from the poultry carcasses in preparation for chilling. If viscera are not handled properly, or if employee hygiene practices are not followed, an increase in microbial contamination can occur. Feed withdrawal practices affect process control at this step.

For the evisceration process to work well, carcasses need to be placed on the shackles correctly and monitored as they move through the system. Blades should be kept sharpened, and attention given to routine and thorough cleaning. Figure 9 shows an automated opener system that utilizes replaceable blades which are cleaned between each carcass.

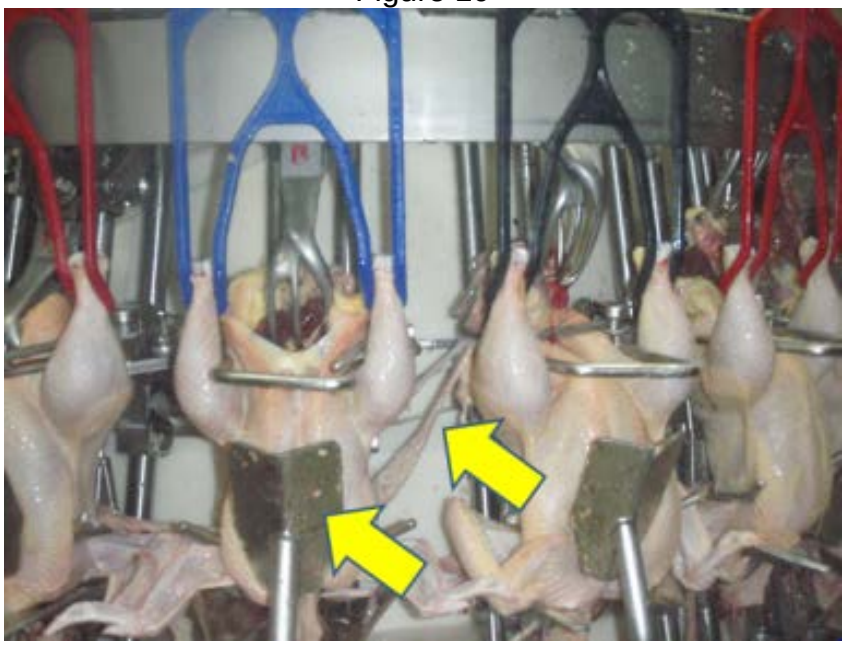
Figure 9



Best practice: Replaceable blades (middle of picture) are washed between each carcass (yellow arrows) to reduce cross contamination. Blades are replaced daily, which minimizes cross contamination as compared to blades that are replaced less often.

Keeping the equipment in good sanitary condition, free from intestinal contents and segments, is important for maintaining good process control. Figure 10 shows viscera that was caught in the machine as well as fat and tissue build up on breast plates and other surfaces that is not being sufficiently rinsed and cleaned between carcasses. These practices can lead to cross contamination.

Figure 10



Not recommended: Viscera are stuck in machine and there is product build up on breast plates and bars around wings and legs (yellow arrows).

Automated transfer (re-hang), rather than manual transfer, of carcasses between the defeathering and evisceration lines can reduce external surface cross-contamination. Equipment used throughout the evisceration process should be installed, adjustments made, and machine performance calibrated effectively to handle the size, shape, gender, feed digestion capability, and live average weights of the birds to be slaughtered. These considerations apply to manual evisceration processes as well. Figure 11 shows a manual venting gun that is rinsed with chlorinated water between each carcass.

Processing flocks with varying weight ranges can result in evisceration machinery performing poorly. Different carcass sizes, for example, because of poor bird size uniformity within a grower house or processing male and female birds together, can result in mis-cuts and resulting fecal contamination. If machines are set for the median weight of the flock, poultry carcasses that are heavier or lighter may not be properly eviscerated. The carcasses are more likely to have their gastrointestinal (GI) tracts split open, resulting in contamination of both carcasses and equipment. The machines need to be maintained in optimum condition and be properly aligned. Failure to maintain eviscerators in optimum condition can result in damaged intestines leading to carcass contamination.

Equipment such as crop removal devices can easily become contaminated with *Salmonella*, causing carcasses to later become cross contaminated (Mead et al., 1994). In some operations, at least half of carcass surfaces are contaminated with crop and upper GI contents immediately before evisceration (Byrd et al., 2002). Retracting the viscera from the body cavity can transfer crop and upper GI contents to the interior body cavity (Byrd et al., 2002). Poultry establishments should be aware of these factors that lead to contamination and implement necessary machinery checks to ensure that evisceration equipment are indeed functioning effectively.

Figure 11

Best practice: This manual venting gun is rinsed with chlorinated water, supplied to the gun by the red hose, between each carcass

Carcass rinses or sprays can be effective interventions for removing incidental contamination from the carcass surface during evisceration. Studies have shown that *Salmonella* prevalence on carcasses can be reduced by 50-90% following rinses (Buncic and Sofos, 2012). However, establishments should aim to consistently implement sanitary dressing procedures rather than rely on carcass rinses or sprays to control pathogens. The NCC recommends whole-carcass water rinses using 20 ppm free available chlorine (NCC, 1992). A 20 ppm free available chlorine rinse post-evisceration can decrease microbial contamination and improve food safety (Waldroup, et al., 1992). The incidence of *Salmonella*-positive carcasses can decrease by one third when carcass rinses are incorporated into the evisceration process (Notermans, et al.,

1980). Rinses can reduce *Campylobacter* as well (Acuff, et al., 1986 and Izat, et al., 1988). When applying water rinses and sprays, establishments should consider the water pressure applied. Some studies have found that elevated spray pressure may force bacteria into muscle or skin rather than washing it off (Buncic and Sofos, 2012).

> ***Key Point***
>
> Antimicrobial interventions are <u>not</u> a substitute for consistently implementing sanitary dressing practices

Rinses or sprays should be designed, installed, and calibrated to remove incidental contamination. When not properly designed or implemented, rinses or sprays may not effectively remove contamination and may even spread contamination from one part of the carcasses to another part or even to adjacent carcasses. Figure 12 shows a rinse that is not calibrated to wash contamination. Figure 13 shows sprays that spread contamination onto other parts of the carcass.

Figure 12

Not recommended: Rinses are not positioned to wash contamination off tail area. On the left, a contaminated carcass moves on the line toward two washes. On the right, the carcass has moved past the washes, and the contamination remains. In this situation, should the nozzles be moved up, it is likely that due to the high pressure and angle of the spray, contamination may not be washed off but instead may spread to surrounding areas of the carcass.

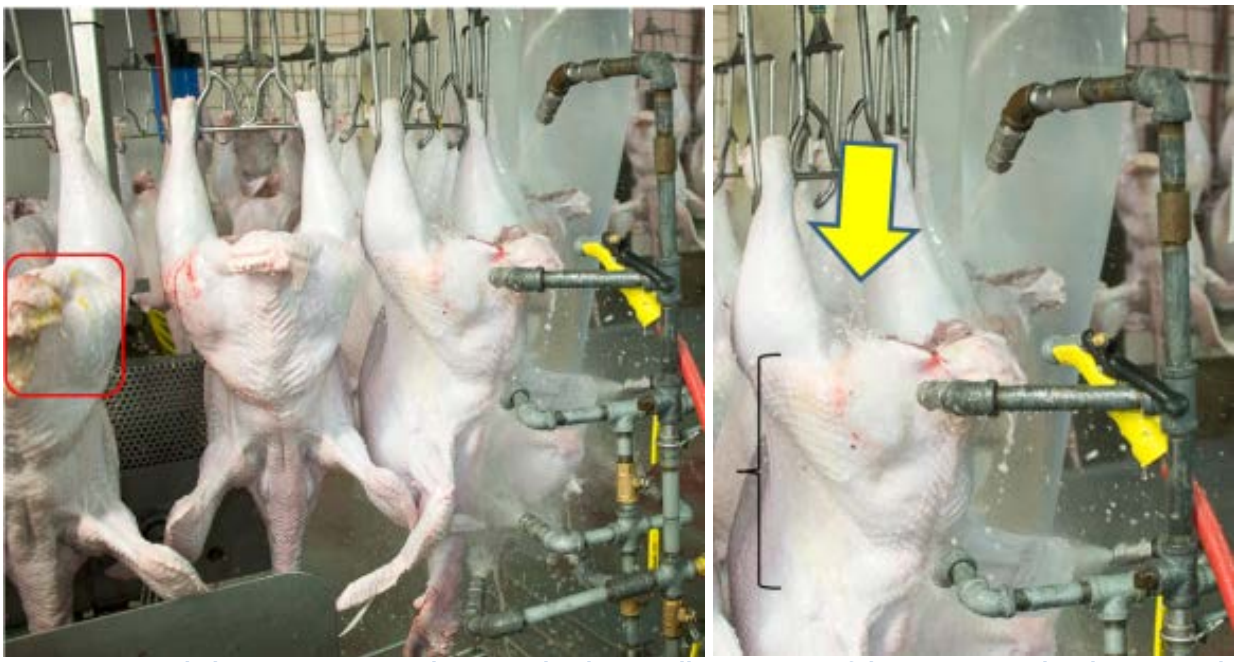
Multiple *Salmonella* and *Campylobacter* controls throughout the evisceration process are recommended. Pathogens are not effectively removed by using one carcass rinse, and a multiple hurdle approach works best against pathogens.

Some poultry processors consistently produce *Salmonella* or *Campylobacter* positive carcasses, while others produce carcasses that upon testing typically do not have detectable levels of *Salmonella* or *Campylobacter*. These variable test results may be the result of differences in sanitary dressing practices. Sanitary dressing practices

should be implemented throughout the slaughter process, in a manner that produces a clean, safe, wholesome poultry product in a sanitary manner. For example, rates of visible contamination on the carcasses after crop removal vary greatly depending on crop removal practices. In some establishments, fewer crops rupture because the crops are extracted toward the head (and downward) rather than toward the thoracic inlet (and upward) (Buhr et al., 2000). This is an important consideration for *Salmonella* control, because crop tissue often contains *Salmonella.*

Note that some carcasses may become incidentally contaminated with feces and ingesta even with strict sanitary dressing practices. However, fecal contamination should be minimized.

Figure 13



Not recommended: Overspray spreads contamination to adjacent areas of the carcass. In the closeup on the right, the middle spray bar results in splashing of water from the thigh up over the back of the thigh and onto the abdomen area (under yellow arrow), where it will run down the breast area. The contaminated vent area visible on the left (inside the red box) will not be washed off when it goes through the middle spray bar. Instead it will spread contamination to adjacent areas. This is also true of the faint yellow contamination on the outside of the thigh and bird's side (black bar of the right image).

Recommended Best Practices – Evisceration

1. Adjust and maintain equipment regularly as needed to accommodate bird size.

2. Enforce employee hygiene standards.

3. Ensure that feed withdrawal practices that affect process control at this step have been implemented effectively.

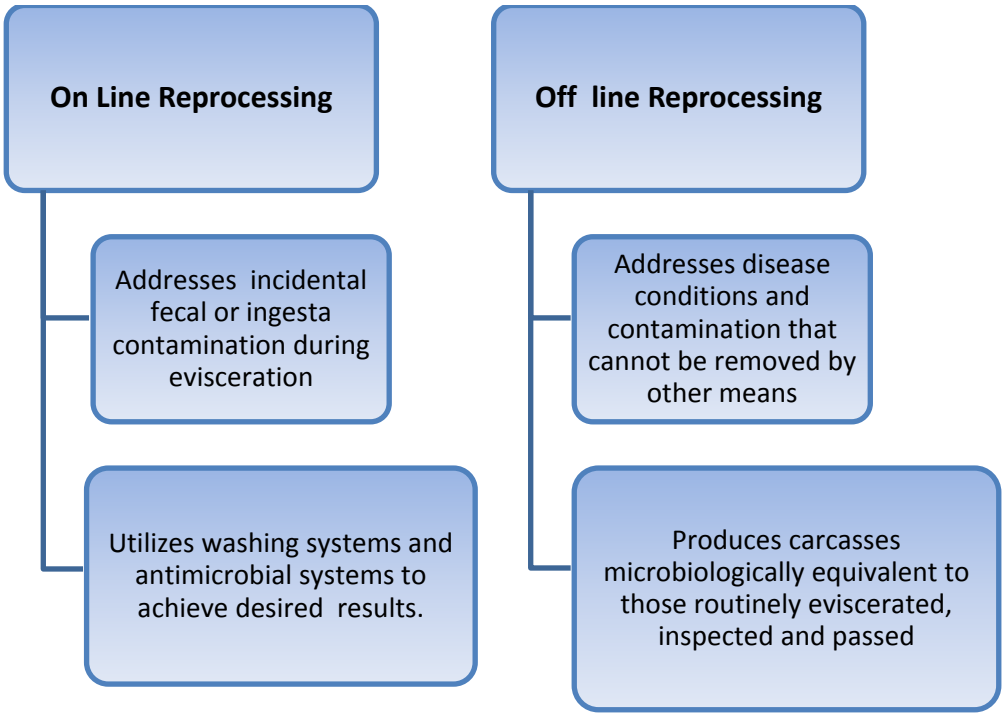
Chilling

This is the point where eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 CFR 381.66(b)(3). Additional information on chilling requirements can be found in the FSIS compliance guide Modernization of Poultry Slaughter Inspection: Chilling Requirements.

Antimicrobial Intervention Use for On-line and Offline Reprocessing and for Chilling Procedures

Reprocessing systems are used to control *Salmonella* on visibly contaminated carcasses. Both on-line (OLR) and off-line (OFLR) reprocessing systems can be used to remove incidental contamination during the evisceration. On-line reprocessing is not a "remedy" or a substitute for poor sanitary dressing practices during evisceration. The on-line reprocessing system may be able to remove visible contamination, but the invisible contamination can remain if the intervention is overwhelmed.

NOTE: Carcasses must be free of visible fecal contamination prior to entering the chilling system as required by 9 CFR 381.65(f).



FSIS has posted lists of the approved OLR and OFLR systems. The lists will be regularly updated and will be attached to FSIS Directive 7120.1, Safe and Suitable Ingredients Used in The Production of Meat, Poultry, and Egg Products, in a future revision of the document.

If an establishment desires to use an OLR or OFLR system that has not been approved by the Risk Innovations and Management Staff (RIMS) or wishes to modify an approved OLR or OFLR system, the establishment is responsible for submitting a protocol requesting permission to conduct an in-plant trial. Per the Memorandum of Understanding (MOU) between FDA and FSIS, FSIS would consult with FDA regarding safety of the proposed chemical. FSIS would review the protocol for any prohibitions that can potentially affect product safety, safety of inspection personnel, interfere with inspection procedures, or require a change to the Agency's regulations. If the in-plant trial is granted, FSIS would issue a letter granting permission to conduct an in-plant trial. More information regarding in-plant trials can be found in the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols.

An establishment that uses chlorine or other antimicrobials as a part of its sanitary dressing and process control procedures or employs a pre-chill carcass wash that may affect the pH of the chiller water should address the effect of the pH of the chiller water on the efficacy of any antimicrobials used in the chiller.

X. Further processing

This section of the guidance provides information for establishments that further process raw poultry to produce products such as:

- Poultry parts
- Injected, mechanically tenderized, or vacuum tumbled poultry products
- Comminuted (including ground) poultry products, include products such as patties and sausages that are made using comminuted poultry
- Stuffed chicken products

> ***Key Point***
>
> Comminuted products are those that are ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced or otherwise processed to reduce particle size

The factors discussed in sections III through VII of this compliance guideline also apply to further processing. Establishments that slaughter as well as further process poultry should also consider the guidance provided in the Slaughter section.

Raw source material considerations and the HACCP system

There are two different sources for raw materials used in further processing: 1) in-house source materials (e.g., source materials from an establishment's own slaughter operation) and 2) incoming source materials from one or more supplying establishments. An establishment's knowledge of the production of source materials from its own slaughter operation is different than the knowledge of the production of purchased or otherwise incoming product.

Whether the source of raw materials used in further processing is another establishment, an establishment's own slaughter operations, or both, an establishment should consider how the source materials it uses in its processes can affect food safety decisions. A prudent establishment would incorporate this knowledge into its hazard analysis decisions to inform development of its HACCP system, including developing SSOPs, prerequisite programs, and CCPs.

Along these lines, if an establishment produces a raw or otherwise NRTE chicken product from parts received from other establishments, it can consider using only parts that are at or below a specific *Salmonella* (or *Campylobacter*) percent positive as the source material for making this product. In this scenario, considering the carcass category of the supplying establishment (e.g. only accepting parts from carcass category 1 establishments) would not be as useful because parts and not carcasses are the immediate source materials. FSIS sampling of the industry indicates that pathogen prevalence increases as products are further processed from carcasses, to parts, to comminuted product. It is unclear what benefit requirements for carcasses would provide when the incoming source materials used to produce the finished products are not carcasses. Category 1 carcasses may go on to further processing within an

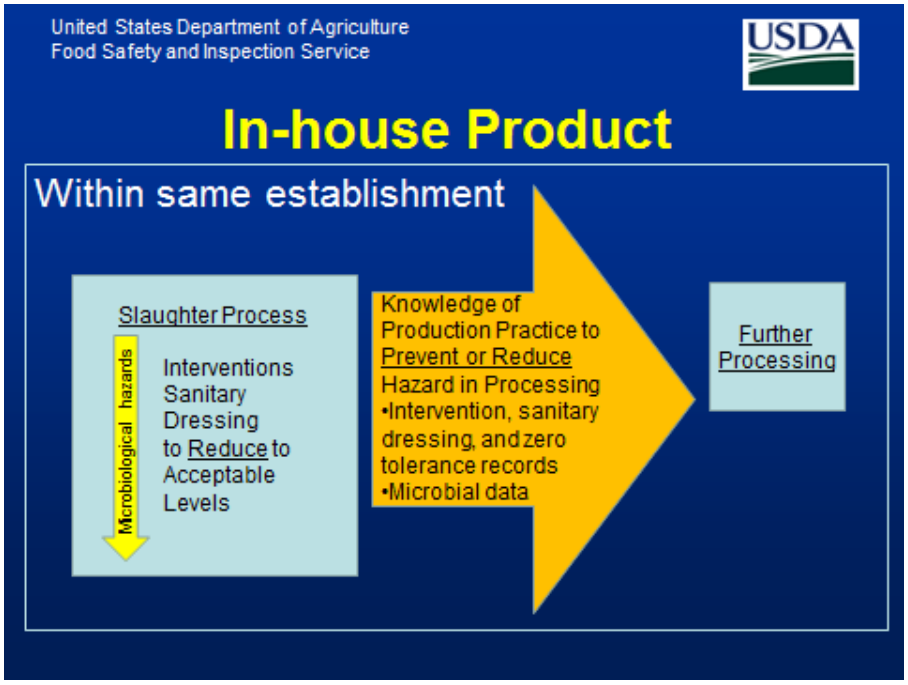
establishment and be cross-contaminated or otherwise processed to result in a higher level of pathogens on chicken parts (or comminuted) than the carcass results would suggest.

In-House Source materials

Slaughter establishments that further process carcasses they produce are self-suppliers (they produce in-house source materials). For in-house source materials, the establishment has direct knowledge regarding the source materials' production, including pre-harvest information, sanitary dressing procedures, zero tolerance findings, antimicrobial treatments and records of critical operating parameters, and any microbial testing data. The establishment also has direct control of its processes and can monitor, verify, and correct its own processes more quickly than for product received from outside suppliers. It can verify that sanitary dressing and any interventions are being applied consistently as designed; it can implement corrective actions when it identifies that sanitary dressing procedures and any interventions have not been applied as designed; and it can identify and correct underlying problems that result in any repeated sanitary dressing or intervention failures.

Figure 14 below shows the direct knowledge the slaughter establishment has concerning the production of in-house source materials during the slaughter process.

Figure 14



If an establishment identifies problems in its own slaughter operations, for example that sanitary dressing was not consistently implemented, it should consider how this problem may impact food safety decisionmaking during further processing. Similarly, if an establishment identifies problems during further processing, for example that ground

poultry sampling identified that a lot exceeded acceptable pathogen levels, the establishment should identify whether factors at slaughter may have contributed to the problem.

Incoming Source Materials from Supplying Establishments

Establishments have less knowledge available about and control over source materials that are produced at other supplying establishments. However, there are a number of actions that establishments receiving raw poultry for further processing can take to limit *Salmonella* and *Campylobacter* in their incoming source materials. All establishments receiving raw poultry from supplying slaughter establishments should require the supplier to follow good sanitary dressing procedures to prevent contamination of poultry during slaughter. In addition, establishments should consider requiring that incoming raw materials be treated with interventions shown to reduce *Salmonella* and *Campylobacter*. Establishments could also require that suppliers test source materials for pathogens of concern and have a plan for how to use test results in their decision-making.

> ***Key Point***
>
> As part of the entire food safety system, food safety decisions made at slaughter impact further processing, regardless of which establishment slaughters poultry and produces source materials.

Establishments receiving source materials from outside suppliers should consider implementing the above actions as purchase specifications and incorporating such specifications in their HACCP plans, Sanitation SOPs, or other prerequisite programs. If establishments producing raw poultry products require their suppliers (both within and outside their corporate structure) to meet purchase specifications, they should also ensure that their suppliers actually meet these purchase specifications. They may accomplish this in several ways, by requiring, for example:

- a document (e.g., letter of guarantee) from each supplier that provides assurance that the supplier employs CCPs or other control points that address *Salmonella* and *Campylobacter* and that describes the CCP, the monitoring of the CCP, and the use of any interventions; and
- certificates of analysis (COAs) (i.e., actual test results) and the sampling method used by the supplier of the source material.

A further processing establishment receiving source materials should also maintain records (e.g., its own testing results, ongoing communication with suppliers, or third party audits) that verify on an on-going basis that it is executing its program to achieve the two conditions above in a consistent and effective manner. Ongoing verification ensures that such an establishment consistently receives product in which *Salmonella* and *Campylobacter* are prevented or controlled to acceptable levels.

Establishments that receive source materials from outside suppliers should still consider applying validated interventions during further processing. Such establishments should also consider carrying out their own testing of incoming source materials. As described in the Sampling and Testing section, testing should preferably measure the pathogen

load of incoming source material so that establishments can ensure that their processes are not overwhelmed by incoming pathogen load. In addition, they should consider testing finished products to verify their systems reduce pathogens to acceptable levels.

An establishment may be able to obtain detailed information concerning the purchased/incoming source material on a lot-by-lot basis (preferably, lots are defined as being microbiologically independent) from its supplier. In this situation, the receiving establishment may be able to support that pathogens are not reasonably likely to occur (NRLTO) at receiving based on the implementation of a prerequisite program (e.g., purchase specifications) that prevents the potential hazard from becoming reasonably likely to occur (RLTO). Such establishments that address pathogens in this manner should do the following:

- have a written program that describes the purchase specifications that it will implement to show that pathogens are NRLTO at receiving;

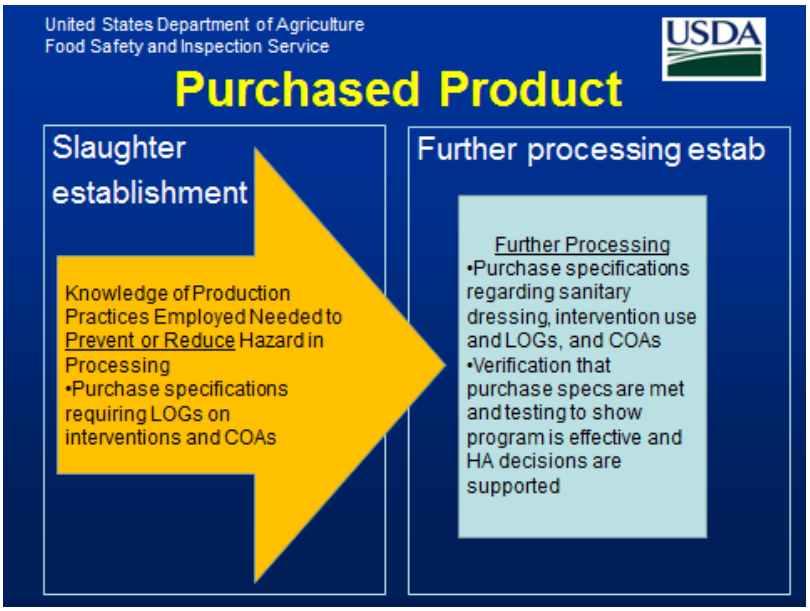
- require information (for example, through letters of guarantee) on the supplying establishment's interventions that provide assurance that the supplier uses interventions that address pathogens such as *Salmonella* and *Campylobacter*;

- obtain certificates of analysis (COA) affirming that source materials have been tested. If a receiving establishment is unable to obtain COAs, the establishment should obtain other evidence that each shipment or lot of purchased/incoming source materials was tested. In these situations, establishments should:

    - be aware of the sampling and testing method the supplier uses, and
    - be aware of the supplying company's information concerning the specific product codes that were sampled and tested.

Figure 15 below shows the knowledge of the source materials' production that receiving establishment should be able to obtain by having a relationship with its suppliers.

Figure 15



It is possible that a receiving establishment is not able to obtain detailed information concerning the purchased product's production on a lot-by-lot basis from its supplier. When a receiving establishment is only able to obtain general information concerning the production of purchased/incoming source materials, the establishment must take other measures to support its hazard analysis decision-making (9 CFR 417.5(a)(1)) at receiving. These measures may include, but are not limited to, the following options:

1. The receiving establishment may determine that pathogens such as *Salmonella* and *Campylobacter* are RLTO on incoming source materials and apply an antimicrobial treatment as a CCP.
2. The receiving establishment may be able to support that *Salmonella* and *Campylobacter* are NRLTO in incoming source materials at receiving based on the implementation of a prerequisite program (e.g., antimicrobial treatment preventive measures on incoming raw materials) that prevents the potential hazard from becoming RLTO during its process including rigorous recordkeeping documentation. For this situation, establishments should do the following:
    - o have a written program that describes the antimicrobial treatment preventive measures that it will implement to show that *Salmonella* and *Campylobacter* are NRLTO at receiving;
    - o maintain supporting documentation for the program;

- maintain records that demonstrate that the program is being implemented as written (i.e., verification records of the critical operating parameters);
- maintain records that provide on-going evidence that the program effectively reduces pathogens to acceptable levels (e.g., its own verification testing) to support its decision that pathogens such as *Salmonella* and *Campylobacter* are NRLTO at receiving; and
- describe actions that the establishment will take when it fails to implement the program, or when it otherwise finds that the program has failed to prevent the hazard.

Note that for option 2, if establishments determine that *Salmonella* and *Campylobacter* are hazards not reasonably likely to occur because of prerequisite programs, they are required to have records associated with their Sanitation SOP or other prerequisite programs that show these programs are preventing a food safety hazard from being reasonably likely to occur as part of their HACCP decision making documents. When prerequisite programs are not effectively designed or consistently implemented, the hazard analysis is not supported, and FSIS would consider the hazard to be reasonably likely to occur. In this case, establishments must then take corrective actions (including reassessment) as set forth in 9 CFR 417.3(b).

3. The receiving establishment may be able to support that pathogens are NRLTO in the purchased source materials at receiving based on the implementation of its own verification testing measures in conjunction with purchase specifications that require information on the supplying establishment's interventions that provide assurance that the supplier employs CCPs that address pathogens such as *Salmonella* and *Campylobacter*.

Sanitation and Reducing Cross-Contamination

Poultry carcasses processed as parts or used to make ground products may have a higher incidence of pathogens because of possible cross contamination between positive and negative parts and carcasses during further processing. The sanitation considerations discussed in the Sanitation section also apply to further processing operations. This section discusses factors that establishments producing parts or comminuted poultry should consider to maintain sanitation and minimize cross-contamination during further processing.

> ***Key Point***
>
> *Salmonella* and *Campylobacter* can be found inside feather follicles in the skin. When skin is cut, these pathogens can be exposed and spread during processing to previously uncontaminated product.

Opportunities for cross-contamination during further processing exist in various situations. One situation is when products are commingled (for example, parts are collected in combo bins for further processing). Another situation when pathogen spread and cross-contamination may occur is during parts cut-up or during the grinding (or other comminuting) process, specifically when skin is cut, ground, or otherwise broken.

Salmonella and *Campylobacter* can be found in feather follicles in the skin (Kim et al 1996; Wu et al., 2014). These areas may not be accessible until they are disturbed, for example during cut-up or grinding, when they can result in exposure of and spread of pathogens. National prevalence data from FSIS Chicken Parts Baseline sampling indicate that skin-on parts were more likely to be positive for *Campylobacter* than parts without skin (FSIS, 2013).

Opportunities for cross-contamination occur following the heat treatment step during production of raw but heat treated poultry (for example, NRTE breaded, stuffed poultry products). For these products, it is essential that the finished product be processed in a manner to reduce the frequency and level of contamination before packaging at the establishment (e.g., by controlling cross-contamination between the time when products emerge from the hot oil or other batter-setting process until they are in final packaging). Handling of these types of products by the consumer may contribute to cross contamination in the home.

Cross contamination can also occur when products are produced in one part of an establishment and further processed in another part. How product containers are handled within an establishment can increase cross contamination. Figure 16 shows tub containers used to hold poultry parts for further processing. The tubs were stored on dirty pallets, and employees touched the bottoms of the tubs when they emptied their contents into a hopper before using their hands to push the contents into the hopper. Not only does this practice result in cross contamination, it is also an example of an insanitary practice.

Figure 16

Not recommended: Plastic tubs used to hold raw poultry parts are stacked on wooden pallets, which are moved to another area in the establishment for further processing. Establishment employees picked up the tubs and frequently touched the bottoms of the tubs when emptying them into the hopper. Then, without first sanitizing their gloves, employees pushed the parts into the hopper. This is an example of both cross contamination and not maintaining operational sanitation.

Product contact surfaces such as belts, augers, paddles, knives, hooks, and other implements should be regularly cleaned and sanitized to reduce cross contamination during operations. Figures 17a and 17b show that sanitary conditions during further processing are not being maintained due to buildup of organic material.

Figure 17a

Not recommended: Sanitary operation is not being maintained. There is significant buildup of fat and other organic material on the belts. This presents an increased risk of cross contamination.

Figure 17b

Not recommended: Sanitary operation is not being maintained. There is a significant buildup of fat and other organic material on the conveyors, blades, and associated product contact surfaces. This presents an increased risk of cross contamination.

Establishments should keep in mind that finished poultry products they produce that go for further processing at other establishments may be used to produce non-intact products such as those that are injected, tenderized, or vacuum tumbled. Finished

poultry products may also be used as source materials for comminuted products, such as ground, mechanically separated, or similarly processed products including patties and sausages. Because processes used to manufacture such products may increase the risk of cross-contamination and pathogen spread, establishments producing poultry parts for further processing should minimize opportunities for cross-contamination and consider whether the use of additional interventions for such products may prevent or reduce pathogens to acceptable levels.

Establishments should also consider how their lotting practices can be designed to minimize cross-contamination. Achieving microbiological independence between lots can also limit product that may be implicated in a recall. The Lotting Practices section and microbiological sampling section provide information on lotting practices.

Recommended Best Practices, Sanitation and Reducing Cross Contamination

1. Clean product contact surfaces, including knives, as often as required to maintain sanitation during operations
2. Knives and other tools should be sanitized between each carcass
3. Consider using an antimicrobial intervention on parts

Additional considerations for Non-intact parts and products (mechanically tenderized, injected, or vacuum tumbled)

Mechanical tenderization, such as needle and blade tenderization, injection with solutions, and vacuum tumbling are methods that some establishments use to tenderize products, add flavor, or add similar ingredients to raw poultry parts and to carcasses. However, these processes can contribute to cross-contamination with pathogens. Any contamination on the outside of carcasses or parts may be carried to the inside through penetration by needles and other devices. Reusing injection solutions such as brines or marinades also presents risk for contamination of the solution by pathogens.

Parts or carcasses can become contaminated by the physical action of the needles or blades pushing surface contamination into muscle interior. Contamination can also occur through introduction of contaminated liquid that is injected or forced into the muscle by injecting or vacuum tumbling. Contamination may be increased the longer solutions are reused and the greater the volume of product treated.

Key Points

Blades and needles can push outside contamination into the interior of muscle.

Injection solution picks up bacteria from contaminated product

Reused injection solution can push high levels of bacteria into the interior of muscle

The longer injection solution is reused, the greater the contamination

Establishments should consider the effects of injected solutions in its hazard analysis (9 CFR 417.2(a)) and support all decisions made in the hazard analysis, 9 CFR 417.5(a)(1). Establishments that choose to tenderize, inject, or vacuum tumble raw poultry should consider the following factors:

Operational sanitation should be maintained during the process, including evaluating the frequency that needles need to be replaced to minimize product residue buildup on the inside of the needle, which can be very difficult to remove.

Establishments should consider the microbiological impact of introducing pathogens mechanically (through needles and blades) and by reusing a solution. Any solution reuse should be addressed in the HACCP plan or in the SSOP or another prerequisite program. Risk from microbial pathogens introduced during non-intact processes may be reduced in several ways:

- by limiting this process to products that will undergo a lethality treatment at another federally inspected establishment
- applying antimicrobial interventions to product just prior to treatment with needles or blades
- limiting the time that solution is reused and maintaining a solution temperature of less than or equal to 40 °F (4.4 °C) to prevent pathogen outgrowth
- treating reused solution with interventions to minimize or eliminate pathogens. Ultraviolet (UV) light treatment (Beers et al., 2010) can reduce pathogens in recirculated brine. Figure 18 shows a UV intervention in place on a recirculated brine system.

Figure 18

Best practice: Antimicrobial UV light system in place to reduce pathogens in recirculated brine injection system

Establishments should also consider how any solution reuse affects the establishment's lot designation.

Recommended Best Practices, Sanitation During Production of Non-Intact Products

1. Consider applying antimicrobial interventions to products prior to tenderizing or injecting
2. Do not reuse injection needles if product residue cannot be removed
3. Limit reusing injection solution to poultry that will receive a lethality treatment.
4. Establishments that choose to reuse injection solution should consider using antimicrobial interventions to the solution and should limit the time it is reused prior to sanitizing the injection system.

Additional considerations for comminuted products

Producers of comminuted poultry products should also consider that because of the often fine texture of these products, meat and protein residues of these products may extend into very small or unexpected food contact surfaces in grinding and other equipment. In addition to the factors already discussed, establishments that make comminuted poultry products should consider the information in this section with regard to minimizing microbial pathogens and creating and maintaining sanitary conditions.

Additional surfaces of processing equipment, including grinders, blenders, pipes, and other components and surfaces in contact with the product require focused attention to ensure adequacy of sanitation procedures. These surfaces may include hoppers, augers, blades, grates, product blenders, and patty makers. Establishments should also be aware of parts of equipment that can harbor bacteria, such as rubber gaskets and similar pieces that may be difficult to reach and sanitize, and ensure that they are sanitized when other surfaces are.

Key Point

Contaminated source materials going into a grinder, mechanical separator, or other comminuted poultry equipment can result in contamination of all product until the next cleaning and sanitizing is performed

The fine texture of comminuted product and the processes used to make them create a situation where one contaminated component can spread contamination into multiple batches of product. Systematic sanitizing of belts and other implements can break the chain of any contamination that slips through. Rather than the contaminant being spread across lots, it will be stopped or at least diminished.

Different source materials used to produce comminuted products can present different risks of pathogen contamination. Establishments should consider the following when making processing decisions for comminuted products.

Source Materials Can Affect Pathogen Status of Comminuted Product

Certain poultry parts may be more likely to be contaminated with pathogens and therefore more risky to use as source materials to produce comminuted poultry products. The FSIS Chicken Parts Baseline study (FSIS, 2013) found that chicken necks were significantly more likely to be contaminated with *Salmonella* and *Campylobacter* (55% for both) than other parts including breasts, legs, and wings (between 20-44% for *Salmonella* and between 16-43% for *Campylobacter*). Establishments should consider not using chicken necks in comminuted poultry products or only using them in comminuted products that are intended for a lethality treatment.

Similarly, skin-on and bone-in source materials used in comminuted chicken products present increased risk of contamination with *Salmonella* and *Campylobacter*. As previously discussed, skin can contain *Salmonella* and *Campylobacter* in feather follicles that can be exposed during the grinding or other comminuting process and spread throughout a lot. Chicken neck skin has typically been found to be more contaminated than other parts of the carcass. Research by Wu et al. (2014) concluded that neck skin included in ground chicken presents a significant risk for the introduction of pathogens. Table 6 shows that ground and other raw comminuted chicken products (such as sausages and patties) sampled by FSIS that were produced using skin-on source materials were more likely to be contaminated with *Salmonella* and *Campylobacter*[7]. FSIS found that source materials for ground and other raw comminuted turkey products that were skin-on as compared to skin-off were less likely to be contaminated with *Salmonella* (and not different for *Campylobacter*). It is not known why this is the case. Table 7 shows the risk for use of bone-in source materials for comminuted turkey products.

[7] FSIS Not Ready-to-Eat Comminuted Poultry Exploratory Sampling Project results from samples collected June 1, 2013 through January 31, 2014.

Table 6. FSIS exploratory sampling testing results, raw comminuted chicken by source material composition

Comminuted Chicken Products	*Salmonella* prevalence in this source material	*Salmonella* presence risk relative to the lowest prevalence source material (Deboned & skinless)[8]	*Campylobacter* prevalence in this source material	*Campylobacter* presence risk relative to the lowest prevalence source material (Deboned & skinless)[4]
Mechanically separated	83.5%	2.3-fold increase	20.4%	20.4-fold increase
Ground and Other Comminuted Products				
Bone-in & Skin-on	63.1%	1.7	10.8%	10.8
Bone-in & Skinless	57.1%	1.6	21.4%	21.4
Deboned & Skin-on	60.4%	1.6	2.2%	2.2
Deboned & Skinless	36.7%	N/A	1.0%	N/A

The interior of poultry bones can contain pathogens as well. In a recent study, 0.8% of chicken bones sampled were positive for *Salmonella* (Wu et al., 2014). In a different study, 5.2% of turkey bones sampled were positive for *Salmonella* (Cui et al., 2014). Although these may appear to be low percentages, again because of the nature of comminuted processes, contamination can spread throughout an entire batch or lot from a few contaminated bones. FSIS sampling data indicates that both chicken and turkey raw comminuted products produced using bone-in source materials are more likely to be contaminated with *Salmonella* and *Campylobacter* than those produced using deboned source materials. Table 6 shows this for comminuted chicken products, and Table 7 shows this for comminuted turkey products.

Tables 6 and 7 indicate pathogen prevalence for comminuted products based on whether source material contained bone (chicken and turkey) or skin (chicken only). Analysis of FSIS comminuted poultry exploratory sampling results shows that it is more likely that comminuted chicken will be positive for *Salmonella* when its source materials contain both bone and skin (63.1%). However, for *Campylobacter*, comminuted chicken products made from bone-in and skinless source materials were highest, with 21.4% prevalence. Comminuted chicken made from deboned and skinless source materials had the lowest prevalence for both pathogens (36.7% for *Salmonella*, and 1% for *Campylobacter*).

[8] For bone-in and skin-on source materials, *Salmonella* prevalence in comminuted chicken was 63.1%. The lowest prevalence product, made from deboned and skinless source materials, was 36.7%. To calculate the relative risk, each source material type was divided by the lowest risk product: 63.1/36.7 = 1.7. This same method was used to determine the relative risk for *Campylobacter*

The tables also indicate how much more likely products made from different source materials are to contain pathogens, as compared to the product with lowest prevalence (products made from deboned and skinless source materials). Raw comminuted chicken products made from bone-in and skin-on source materials were 1.7 times more likely to be positive for *Salmonella* and 10.8 times more likely to be positive for *Campylobacter* compared to those made from deboned and skinless source materials.[4]

Mechanically separated poultry nearly always contains skin and bones in their source materials, because of the nature of the processing of this product. FSIS sampling results indicate for both chicken and turkey, both *Salmonella* and *Campylobacter* prevalence was highest for mechanically separated poultry. For this reason, establishments should consider not using mechanically separated poultry as a component in NRTE comminuted products, or only using it in comminuted products that are intended for a lethality treatment.

Table 7. FSIS exploratory sampling testing results, raw comminuted turkey by source material composition

Comminuted Turkey Products	*Salmonella* prevalence in this source material	*Salmonella* presence risk relative to the lowest prevalence source material (Deboned)	*Campylobacter* prevalence	*Campylobacter* presence risk relative to the lowest prevalence source material (Deboned)
Mechanically separated	47%	2.8-fold increase	5%	11.3-fold increase
Ground and Other Comminuted Products				
Bone-in	31%	1.9	2%	4.1
Deboned	17%	N/A	0.5%	N/A

It is important to keep in mind that the data in Tables 6 and 7 represents FSIS data from all establishments sampled in the exploratory program and without consideration of the amount of skin or bone going into comminuted processes. Each individual establishment should determine the extent that skin-on and bone-in source materials may contribute to pathogens in finished product. This determination can be made by sampling and testing comminuted products made from different source materials. For example, although FSIS data indicates that, in general, skin-on source materials may not play a significant role in the pathogen status of comminuted turkey, establishments producing comminuted turkey should sample and test their comminuted turkey products to assess the extent that skin-on source materials influence pathogen status in their own finished products.

Establishments that do not test products by source material should consider the information provided in the tables during decisionmaking in their processes. Using the information in the prevalence column of the tables, establishments can compare the relative risk of using different types of source materials. For example, in the absence of its own sampling results, an establishment can compare using bone-in and skin-on source materials (10.8% *Campylobacter* prevalence) with using deboned and skin-on source materials (2.2%) to determine that the relative risk is 4.9 (10.8/2.2). This means there is almost a 5 times greater chance that the bone-in source material will result in *Campylobacter* being present in the finished product. Therefore, there is likely a benefit to using the deboned source materials instead of the bone-in source materials.

Interventions

Guidance provided in the general Intervention Use section applies to interventions used during further processing. This section provides information on antimicrobial interventions that may be used to prevent or control pathogens during further processing of poultry products.

Unless otherwise stated, interventions described in this section have been reviewed for safety and suitability and are listed in FSIS Directive 7120.1. Interventions that have not been reviewed for safety and suitability are identified as such. Establishments, intervention manufacturers, and other users that would like to implement interventions not listed in FSIS Directive 7120.1 would need to submit for review a protocol to FSIS describing the proposed function of the substance in the specific poultry or meat product and conditions of use, as described in the Intervention Use section.

Establishments may consider using interventions during further processing to decrease pathogens. Antimicrobial interventions may be applied to source materials prior to further processing, to parts, during grinding or other comminuting process, and during blending of ground or comminuted products. High pressure pasteurization (HPP) is another intervention that may be applied to raw comminuted product. Although applying interventions to source materials used in comminuted products can reduce pathogens in finished product, contamination may still occur during the process itself when skin or bones are broken, as discussed in the previous section. Establishments should consider these factors when evaluating their use of interventions.

Establishments should evaluate the adequacy of any *Salmonella* and *Campylobacter* interventions they apply to parts or sections during further processing, including those source materials that are specifically intended for non-intact use (such as grinding or other comminuted processes). Part of the evaluation should include consideration of variability of *Salmonella* and *Campylobacter* levels on source materials. The same considerations discussed in the general Interventions section apply to selecting and applying interventions during further processing. It also applies to parts or sections that are sent to other establishments for any kind of further processing because they may be used as source materials in comminuted or otherwise non-intact raw product.

Interventions to control *Salmonella* or *Campylobacter* can be applied by spraying or dipping (immersion). Generally, immersion is more effective than spraying because it ensures better coverage and longer contact time (Buncic and Sofos, 2012; McKee, 2014). Loretz et al. (2010) reported that acetic acid (20 ppm at 4°C) resulted in a *Salmonella* log reduction (log CFU) of 1.4 when applied as a dip (immersion), compared to a log reduction of 0.8 when applied as a spray. A potential challenge with immersion is maintaining the proper level of active chemical as it becomes absorbed and neutralized by organic material such as fat and protein, or the natural decomposition of a compound as a result of chemical reactions, heat, or light. It is important to verify with sufficient frequency that the critical operational parameters of an antimicrobial dip are maintained. It may be necessary to either add more chemical or even to completely change the solution to maintain effectiveness. Figure 19 shows an antimicrobial dip being applied to boneless, skinless poultry parts prior to grinding.

Figure 19

Best practice: Boneless, skinless poultry parts receive an antimicrobial dip prior to being ground

The following pages presents information on some antimicrobial interventions that may be used during further processing and which have been studied to control pathogens during further processing. This information is summarized in Attachment 2.

Establishments need to adhere to the limits in the conditions of use for chemicals as described in FSIS Directive 7120.1 and 9 CFR 424.21. In addition, the establishment needs to determine the optimum concentration for its process based on the critical operational parameters in its scientific support. Any ranges for pH, concentration, or

other parameters included in this section are provided to give a general indication of these values, but they do not on their own represent critical limits.

Inorganic and Organic Chlorine-based Treatments

Chlorine is the most commonly used disinfectant in the poultry industry (Buncic and Sofos, 2012; Oh, 2014). It is relatively inexpensive, has a broad spectrum of activity, and is quick acting. Its drawbacks include corrosiveness to processing equipment at low pH, loss of effectiveness at higher pH values, loss of effectiveness with increasing organic matter load, and longer contact time required as compared to some other antimicrobial interventions. Commonly used chlorine compounds include liquid chlorine, hypochlorites, inorganic chloramines, and organic chloramines. It is typically used at pH 6.0 – 7.5.

Chlorine added to water produces free available chlorine in the forms of hypochlorous acid and hypochlorite ions. Hypochlorous acid is the form most lethal to microorganisms.

Acidified sodium chlorite

Acidified sodium chlorite (ASC) is a type of chlorine compound that is a strong oxidizer.It enters bacterial cells and weakens or kills them by lowering the pH inside. ASC is safe and suitable for use on poultry carcasses and parts at concentrations of 500-1200 ppm, as indicated in FSIS Directive 7120.1. It is used at pH 2.3 - 2.7 and acidified with an organic acid, such as lactic acid, citric acid, or acetic acid. A benefit of ASC is that it is not as highly affected by the presence of organic material as chlorine.

Trisodium Phosphate

Trisodium phosphate (TSP) is an inorganic, non-chlorine-containing compound with a high pH. Its pH is between 11 – 13 and is used at concentrations of 8 – 12%. A benefit of high pH is that it gives TSP detergent-like activity, which can improve effectiveness against microorganisms. The main disadvantage of using TSP is the high discharge of phosphate into the sewer, which may be a violation of local, state, or federal Environmental Protection Agency sewer discharge regulations.

Quaternary Ammonium Compounds

Quaternary ammonium compounds (QAC) are a group of positively charged organic compounds that may have detergent-like properties (Schmidt, 2012). Most have a high pH (pH 6-10), are used at concentrations ≤1%, and are effective in killing a wide variety of microbes. Cetylpyridinium chloride (CPC) is an example of QAC. CPC is an odorless, colorless, stable compound that does not self-decompose and is not affected by organic material. QACs persist in solution for a relatively long time. QACs are not compatible with soaps, anionic detergents, or low pH solutions. CPC must be rinsed off poultry after use with water containing no more than 50 ppm chlorine. The major disadvantage of QAC is that some may be less effective in hard water that contains >500 mg/L hardness (Miller, 2012).

Organic Acids and Organic Oxidizers

Organic acids and organic oxidizers used at the proper pH are effective in being able to enter bacteria to inhibit or kill them from the inside. Peroxyacetic acid (PAA) is an organic oxidizer. It has been studied on poultry parts to control pathogens. PAA is a mixture of the peroxy compound, hydrogen peroxide, and acetic acid. It is a versatile compound as different formulations are available that may be used over a wide temperature range (0 to 40°C) and wide pH range (3 to 7.5). PAA is affected by protein or other organic materials to a lesser degree than chlorine is (Bauermeister et al., 2008). There is ongoing research about the effectiveness of using PAA on chicken parts to control *Salmonella* and *Campylobacter*.

Studies comparing chemical interventions

In one study, Del Rio (2007) evaluated acidified sodium chlorite (ASC), trisodium phosphate (TSP), citric acid, and peroxyacids against *Salmonella* on chicken legs. The concentrations used were: ASC 1200 ppm with citric acid added until pH 2.7 was reached (final pH 2.70); TSP 12% (final pH 13.03); and peroxyacids 200 ppm (Inspexx 100, Ecolab, St. Paul, MN; final pH 3.75). The temperature of the disinfection solution at use was 18°C. Chicken legs containing approximately 9 log CFU/ml *Salmonella* were dipped in the disinfection solutions for 15 minutes and drained at 20°C for 15 minutes. The number of bacteria killed was then measured. All treatments resulted in *Salmonella* reduction, with ASC and TSP having greater effectiveness than PAA (log reduction of 2.05, 1.86, and 0.93, respectively).

In another study (Chen et al., 2014), researchers treated *Salmonella* and *Campylobacter* inoculated chicken parts (bone-in and skin-on) with chlorine, PAA, and cetylpyridinium chloride (CPC) at various concentrations in a chilled immersion system for 25 sec. PAA and CPC significantly reduced *Salmonella* and *Campylobacter* in a dose-dependent manner. Water and chlorine had little effect in reducing *Salmonella* and *Campylobacter*.

A study by McKee et al. (2013) compared the pathogen reduction of antimicrobial interventions applied to chicken parts, including those used to produce ground product. Chicken parts were treated with different concentrations (0.35% and 0.60%) of cetylpyridinium chloride (CPC), (0.07% and 0.10%) peracetic acid (PAA), and (0.003%) chlorine in a parts decontamination tank. Preliminary research shows that parts immersed/dipped into PAA had the greatest reductions of *Salmonella* and *Campylobacter* followed by CPC. Chlorine was the least effective. However, this lack of effect may be related to short contact times (<20 sec) for chlorine. Findings from this preliminary study suggest that dips/immersions are more effective than single spray systems when treating parts because of their longer contact times and complete coverage.

Complete critical operational parameters have not yet been published based on these studies, and research is on-going.

Bacteriophages

Bacteriophages (also called phages) are naturally occurring organisms (viruses) that infect only bacteria (Hagens and Loessner, 2010). Phages cannot infect humans (Lu and Breidt, 2015). Phages are ubiquitous in the environment – in the water, in soil, and on food consumed (Guenther, 2009). Once phages infect bacteria they can produce progeny phage (multiply). This phage multiplication results in the death of the infected bacteria. After multiplication, the phages produced infect other susceptible bacteria present.

Anti-*Salmonella* Phage listed in Directive 7120.1 This anti-*Salmonella* phage treatment that may be used on raw poultry carcasses, raw poultry parts, poultry products, and ready-to-eat poultry (prior to slicing). The intervention is approved to be applied by spray at a concentration of 10^6-10^7 plaque forming units per gram (PFU/g) of food product.

During the time this compliance guide was being updated, a scientific journal article was published using this anti-*Salmonella* phage at 10^8-10^9 PFU/g in combination with different organic antimicrobial agents (Sukumaran et al., 2015). It is important to note that even though the research is summarized below, this intervention technique (using this phage at this dose and in combination with other agents) has not been granted a NOL and may not be used without FSIS review. A NOL must be obtained through the FSIS New Technology process before using this intervention technique.

The phage application researched by Sukumaran, et al. (2015) was on chicken skin and skinless chicken breast filets. The study combined a 20 second dip at 4°C in organic antimicrobial compounds followed by a spray application of anti-*Salmonella* phage (10^8-10^9 PFU/g). The organic antimicrobial compounds tested were: cetylpyridinium chloride (CPC) at 0.6%; lauric arginate (also known as lauramide arginine ethyl ester; LAE) at 200 ppm; and peroxyacetic acid (PAA) at 50 and 400 ppm.

Chicken skin treated in this manner achieved the following *Salmonella* reductions: CPC, 2.1 log reduction; LAE, 2.4 log reduction; PAA (50 ppm), 1.7 log reduction; and PAA (400 ppm), 0.9 log reduction.

Skinless chicken breast treated in this manner achieved the following *Salmonella* reductions: CPC, 2.2 log reduction and LAE, 2.6 log reduction. (The PAA dip was not studied on skinless chicken breast.)

Physical Interventions

Electrolyzed Oxidizing Water Treatment

Electrolyzed oxidizing (EO) water is inexpensive, must be generated on-site with specialized equipment, has strong bacterial killing effect, and has little residual (long-lasting) effect. EO water is acidic and is an effective antimicrobial immersion/dip solution. However, it usually requires much longer contact time than other interventions, so spraying may not be an appropriate application method.

Research has shown that EO can reduce pathogens on poultry parts. Park (2002) reported reductions of 3 log CFU/g on chicken wings inoculated with *Campylobacter jejuni* by soaking them in EO water (pH of 2.57, ORP of 1082 mV and free chlorine of 50 mg/L) with 100 rpm agitation for 30 min.

At this time, the use of EO systems is permitted on poultry carcasses (as per FSIS Directive 7120.1 Rev 20). EO systems are not currently permitted for use on poultry parts. However, New Technology submissions for inclusion of EO systems on poultry parts are encouraged.

EO water is produced by passing direct current voltage through a dilute sodium chloride (salt) solution. The result of the reaction is the production of two types of water (Hsu, 2005). It is the EO water that has low pH (2.3-2.7), high oxidation-reduction potential (>1000 mV), and high dissolved oxygen. A high oxidation-reduction potential means that more oxidation will occur. That translates to a greater capacity to form free radicals that kill bacteria (Venkitanarayanan, 1999). Huang (2008) and Hsu (2005) provide detailed descriptions on the concepts. The production of EO water containing sodium chloride (1-12% w/v) results in the formation of sodium hypochlorite (NaOCl) and hypochlorous acid (HOCl). HOCl functions as if chlorine gas was added into the poultry parts disinfection solution without the need to store a dangerous gas.

It is important to point out that although EO water is strongly acidic, it is different from strong acids such as hydrochloric acid or sulfuric acid in that it is not corrosive to skin, to mucous membranes in the nose and lungs, or to poultry carcasses or parts (Huang, 2008). However, the HOCL (sodium hypochlorite) generated by the EO process may cause breathing irritation that can be reduced with proper ventilation (Huang, 2008).

Crust freezing

Crust freezing is a process in which the surface of the carcasses is rapidly frozen with a stream of cold air such as carbon dioxide (CO_2) or nitrogen (N_2). (This intervention technique has not been reviewed by FSIS, and therefore, has not been granted a NOL. A NOL must be obtained through the FSIS New Technology process before using this intervention.)

This technique is based on rapid ice crystallization on the meat surface resulting in a thin frozen crust followed by temperature equalization. During crust freezing, only the superficial (outer) layers of tissue are frozen with the underlying meat near freezing. It is important to note that a superficial freeze on the exterior of meat or freezing meat solidly through in a spiral freezer is not the same as crust freezing. Crust freezing is rapid freezing and is done to achieve 3-7 mm frozen layer depending on the thickness of the meat itself.

There are also immersion spiral freezers that have a nitrogen bath on the front of the freezing process for foods that need an instant crust freeze. Crust freezing requires a very short time. Immersion of meat for a longer time will result in complete freezing and would be considered to be cryogenic freezing (discussed below).

The time required for crust freezing depends on the temperature of the freezer, the thickness of the poultry part, and the thickness of the ice crust desired. Freezing can kill bacteria or weaken them such that other pathogen interventions have greater effectiveness.

Freezing has been shown to decrease the viability of *Campylobacter* (Georgsson et al., 2006). Boysen and Rosenquist (2009) treated skinless chicken breast fillets in a continuous CO_2 belt freezer into a low temperature freezer (-55°C). The fillets were crust frozen and reached an outer surface temperature of approximately -1°C. Crust freezing resulted in a 0.42 log CFU/g (statistically significant) reduction of *Campylobacter*.

Note that spiral freezing is not synonymous with crust freezing. Spiral freezing is designed to freeze poultry and poultry parts, such as individually quick frozen product. It is a method for storage and long-term preservation. The process of spiral freezing may not be relied on to control pathogens without additional support.

<u>High Pressure Inactivation</u>

A typical high pressure processing (HPP) system consists of a pressure vessel, pressure transmission fluid (usually water), and pressure generating pumps. HPP is a technology by which a product is treated at a very high pressure. HPP requires specialized equipment and is usually applied off-site where that equipment is located. HPP treatment kills or inhibits microorganisms, and researchers have studied its effectiveness in reducing pathogens in comminuted chicken and chicken parts. An advantage of using HPP is that surviving microorganisms can be more sensitive to other types of antimicrobial interventions as compared to bacteria that have not been exposed to HPP (Alpas, 2000).

Liu (2012) investigated high pressure inactivation of *Campylobacter* in comminuted chicken breast meat (individual meat particle size of ≤1 mm^3) inoculated with *Campylobacter jejuni* at 6 log CFU/g. Polyethylene glycol was used as the pressure

transmission fluid. Compression and decompression rates were 300 MPa/min. The temperature of the system was maintained by a water-jacketed unit. The temperature during compression and decompression did not exceed 2°C. Pressure at 400 MPa at 40°C for 30 min reduced *Campylobacter* counts from 6 log to below the detection limit of 1.48 log CFU/g (reduction of approximately 4.5 log).

Escriu (2009) treated finely minced chicken inoculated with 6 log CFU/g *Salmonella* with HPP at 400 MPa at 20°C for 2 min with a water-oil mixture used as the pressure transmission fluid. *Salmonella* was reduced between 3.26 to 4.35 log CFU/g.

Tananuwong (2012) applied HPP to chicken breast inoculated with *Salmonella* (7 log CFU/g) at 300 MPa at 35°C for 1 min and achieved approximately 2 log reduction.

Cryogenic Freezing

Cryogenic freezing is defined as freezing at -74.2°F (-59°C) or below (Balasubramanian, 2012) using liquefied gases called cryogens. Two popular cryogens used are liquid carbon dioxide (CO2) and liquid nitrogen (N2). Cryogens are completely inert (non-reactive or flammable), colorless, odorless, tasteless, and have minimal environmental effects. Tunnel and spiral belt are the two common commercial designs (Shaikh and Prabhu, 2007). Cryogenic freezers are insulated enclosures or chambers surrounding a product conveyor with a method to introduce and regulate the amount of cryogen into the chamber. It is important to note that during cryogenic freezing, meat is not immersed into the cryogen, e.g, liquid carbon dioxide or liquid nitrogen. The meat is sent on a conveyor a short distance above the cryogen. It is the vapor of the cryogen that causes the meat to freeze. (This intervention technique has not been reviewed by FSIS and, therefore, has not been granted a NOL. A NOL must be obtained through the FSIS New Technology process before using this intervention.)

Gunther (2015) studied the effect of cryogenic freezing (using liquid nitrogen vapor) on *Campylobacter*-inoculated ground turkey patties containing polyphosphates. It is important to note that polyphosphates are not part of the cryogenic freezing process. Rather, some establishments add polyphosphates during routine poultry processing to enhance the moisture absorbance, color, and flavor and to reduce product shrinkage of poultry. Gunther analyzed the patties for surviving *Campylobacter* after the patties were cryogenically frozen at -80°F (-62.2°C) for 4 minutes (using liquid nitrogen vapor) and stored at -20°F for 7 and 33 days.

This treatment achieved log reductions of *Campylobacter* in the frozen patties after 7 and 33 days at -20°C of 2.5 logs and 3.2 logs, respectively.

Cryogenic freezing is similar to individual quick freezing (IQF) in that the outcome results in poultry that is completely frozen solid. The way cryogenic freezing differs from IQF is the technology used to achieve the frozen state including how it is applied to product and associated operational parameters. Establishments performing IQF typically use conventional compressor-type refrigeration units, e.g. blast freezing such

as in spiral freezers. It would not be sufficient to indicate that IQF or other processing freezing procedure reduces pathogens without scientific support that such a procedure results in a pathogen reduction and identifies the associated critical operational parameters.

Irradiation using Ionizing Radiation

Food irradiation is the process of exposing food to high levels of radiant energy and is applied by directing ionizating radiation to food products. Food can be irradiated commercially for several purposes: to extend shelf-life, eliminate insect pests, or reduce numbers of pathogenic microorganisms. Ionizing radiation can penetrate deeply into food, killing insect pests and microorganisms without raising the temperature of the food significantly (Jaczynski, 2003). Ionizing radiation kills bacterial cells by damaging its DNA (Tahergorabi, 2012; Verma, 2001).

Ionizing radiation results from cobalt-60, cesium-137, x-rays, and electron beams. Cobalt-60 (^{60}Co) is a common source of a form of ionizing radiation called gamma irradiation. It has high penetrating power (Ahn, 2013), which allows the treatment of poultry of variable sizes, shapes, and densities (including frozen and unfrozen). X-rays are also used to produce ionizing radiation. X-rays have high penetrating power but are typically not used for treatment of food because it is not an efficient process (Tahergorabi, 2012). Another way of producing ionizing radiation is by applying an electron beam (e-beam). In this approach, a stream of high-energy electrons is applied to products. Because the radiation penetrates only a few centimeters, it is useful to treat thin layers of food (Jaczynski, 2003; Ahn, 2013). The electron beam may be applied over moving food on a conveyor, unlike some other sources of ionizing radiation. Electron beam systems require regular maintenance, high electric power, and cooling as the equipment produces high heat (Ahn, 2013).

The maximum dosage of ionizing radiation is 3 kGy applied to raw poultry (fresh and frozen). The maximum dosage limit allowed for poultry is based on the safety determination that was made by FDA (21 CFR 179.26(b)(6)). A requirement that FDA placed on the use of irradiation is that the packaging of irradiated poultry must be air permeable and does exclude moisture and microorganisms from penetrating the package barrier.

To promote processing flexibility and innovation that will lead to improvements in food safety, FSIS does not specify at which point irradiation may or may not be applied. Under HACCP, an establishment must control the conditions under which product is held from initial processing through irradiation and packaging to ensure and preserve the intended antimicrobial effects of irradiation (64 FR 72150)[9].

Thayer (1991) used gamma irradiation at 0 to 3.6 kGy on sterile, mechanically deboned chicken meat inoculated with approximately log 9.9 cfu/g *Salmonella* Typhimurium. In this study, the higher the dose of gamma radiation used, the higher the kill rates of

[9] Irradiation of Meat Food Products; Final rule. Dec 21, 1999. Federal Register. 64: 72150-72166.

Salmonella (log reductions). Gamma irradiation was also more lethal for *S*. typhimurium at higher temperatures and in the presence of air (as opposed to in a vacuum). The researchers found that using gamma irradiation resulted in a log reduction between 5.5-7 log. More details of the conditions used to achieve these log reductions are available in the research article.

In a different study, Thayer (1992) inoculated fresh, nonfrozen chicken wings with *Salmonella* Typhimurium and used five gamma irradiation doses: (0, 0.90, 1.80, 2.70, and 3.60 kGy) in air at 5°C. All *Salmonella* were killed on samples inoculated with 10 or 100 CFU/wing. Surviving *Salmonella* were detected on chicken wings inoculated with either 1,000 or 10,000 CFU/wing after irradiation with 1.8 kGy, but the numbers were very low (below detection). No *Salmonella* were detected following gamma radiation doses of 2.7 or 3.6 kGy. This study demonstrated that irradiating poultry could result in significant reductions in *Salmonella* on raw chicken wings.

Another study found that applying electron beam irradiation to boneless, skinless chicken breasts containing naturally occurring bacteria resulted in an approximately 5-log reduction in *Salmonella* and *Campylobacter*. The doses applied were 1.0 and 1.8 kGy at ambient temperature and both doses resulted in comparable reduction of *Salmonella* and *Campylobacter* (Lewis 2002).

Recommended Best Practices, Interventions during Further Processing

1. Applying antimicrobial interventions during further processing can be part of an effective multiple hurdle approach to reducing pathogens.
2. Dipping is generally a better application method than spraying as it ensures full coverage of an intervention for a longer period of time.

Cooking instructions

FSIS identified a lack of validated cooking instructions provided for ground turkey burger patties associated with a *Salmonella* outbreak. Guidance on validation is available in the FSIS Compliance Guideline HACCP Systems Validation. In addition, the guidance includes an example of the types of scientific support and in-plant data an establishment should gather to support that its cooking instructions for consumers are validated.

Establishments should provide cooking instructions that will result in a safe internal temperature being reached using the cook time and cooking methods provided in the instructions for a given poultry product. For the preparation of safe poultry products, establishments should provide cooking instructions so that the endpoint temperature and, if applicable, rest time will ensure a 7 log reduction of *Salmonella* or other reduction consistent with requirements for producing ready-to-eat poultry products (9 CFR 381.150). Available information indicates that a temperature of 165°F (74°C) with no rest time (instantaneous) is sufficient to destroy *Salmonella* by at least 7 log units (NACMCF, 2006). Because *Campylobacter* is more susceptible to heat, a temperature of 165°F (74°C) should also destroy this pathogen to acceptable levels. For this reason, establishments are not required to demonstrate reductions in *Campylobacter* if the scientific support shows sufficient reductions in *Salmonella*. Establishments that design cooking instructions to achieve an endpoint temperature of 165°F (instantaneous) can cite this guidance as scientific support for the endpoint temperature. Establishments can also design cooking instructions to achieve other endpoint temperatures and rest times provided there is scientific support demonstrating at least a 7-log reduction in *Salmonella* is achieved.

Cooking instructions for raw poultry should include, at a minimum:

(1) The method of cooking;

(2) A validated minimum internal temperature that would destroy any pathogens throughout the product;

(3) Whether the product needs to be held for a specified time at that temperature or higher before consumption; and

(4) Instruction that the internal temperature should be measured by the use of a thermometer.

Key Point

Cooking instructions should be practical. If instructions direct consumers to use a cooking method that is not practical or not likely to achieve the necessary level of food safety (e.g., microwaving or cooking frozen product in a toaster oven), the cooking instructions may not result in destroying *Salmonella* and *Campylobacter*.

When providing instructions to use a thermometer to measure temperature of the product, the instructions should specify a location within the product that represents the lowest temperature in the product. Establishments may need to perform temperature

mapping studies to identify this location (for example, if a product has multiple layers such as a NRTE breaded, stuffed poultry product or has multiple components).

Validation of the cooking instructions should be based on a "worst case" scenario. This includes cooking the product using the lowest time that instructions may specify and validating instructions for products of the largest weight and size within product specifications. As part of ongoing verification, establishments should verify that products are still within the specifications of the products the cooking instructions were validated for in terms of composition, thickness, size, and any filling (for stuffed products).

Specific variables that establishments should consider in developing and providing cooking instructions for poultry products include:

Thickness of the product: The thickness of the product is a critical factor for heat transfer. The thicker a product, the longer it will take for the core of the product to reach the desired endpoint temperature. An example of considering product thickness with regard to product cooking instructions is an establishment that produces consumer packaged bags of frozen chicken breasts. Such an establishment should provide cooking instructions for the largest size piece that is typically found in a consumer package.

Product composition: Related to the thickness of the product, the type of product (intact parts, injected or tenderized parts, or comminuted) and what it contains can also affect heat transfer due to differences in:

- Size and shape. Additional information on how shape and size can affect heat transfer is available in the FSIS Compliance Guideline HACCP Systems Validation.
- presence or absence of bones
- fat content. Additional information on how fat content can affect heat transfer is available in the FSIS Compliance Guideline HACCP Systems Validation.
- whether product is comminuted, sectioned-and-formed, mechanically tenderized, injected with solution, vacuum tumbled, or intact whole muscle. Heat transfer in whole muscle is decreased compared to comminuted muscle (Tuntivanich et al 2008).
- whether the product is stuffed or breaded
- whether there are any air pockets in the products, such as might be found in some stuffed products with fillings such as butter
- the composition of any added marinades (with oil, sugar and salt, acid, seasonings, or phosphates). Such added ingredients can increase thermal resistance (Tuntivanich et al 2008).

Establishments should consider how the above variables may influence the effectiveness of cooking instructions they provide for different products they produce.

Product appearance. If a raw poultry product is not-ready-to eat but has a cooked appearance, or it is not obvious that the product is raw, the product should bear conspicuous labeling alerting the user that the product is not-ready-to-eat and must be cooked for safety. The labeling should bear safe handling instructions if the poultry component is not ready to eat and a prominent statement on the principal display panel indicating product is not-ready-to-eat, e.g., “Cook thoroughly” or “Raw.” Establishments should also consider clarifying on the label that product should be handled carefully to avoid cross-contamination and instruct consumers to wash their hands after handling products. Also, if nutrition facts are present, the serving size should be based on the ready to cook reference amount customarily consumed (9 CFR 381.412). FSIS provides additional guidance regarding cooking instructions for uncooked, breaded, boneless poultry products that also may be stuffed or filled, charmarked, or artificially colored in its guidance document Information on Validation of Labeled Cooking Instructions for Products Containing Raw or Partially Cooked Poultry.

Labels for uncooked breaded, boneless poultry products should include a statement that clearly conveys that the product is not-ready-to-eat and needs to be cooked before it can be safely consumed. Three key elements for an effective statement are (1) terms that reflect that the product is not ready to eat, for example, “Uncooked,” “Raw,” “Raw - Cook Thoroughly,” “Raw, See Cooking Instructions;” (2) a specific endpoint internal temperature, i.e., 165 degrees F or higher; and (3) a direction to measure the endpoint safe minimum temperature by a food thermometer. Statements that include these three key elements should appear on the principal display panel of consumer packaged products in order to give consumers consistent and prominent information about the nature of the product. Additional information is available in the FSIS document Labeling Policy Guidance for Uncooked, Breaded, Boneless Poultry Products.

State of the product at the start of cooking, e.g., frozen versus refrigerated. The initial temperature of the tested product should be the lowest expected temperature at the start of cooking. As recommended in Grocery Manufacturer’s Association’s (GMA’s) 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products, even if the instructions require thawing before cooking, it may be worthwhile to consider additional tests to assess the impact on cooking adequacy if the consumer does not fully thaw the product prior to cooking. Alternatively, two sets of cooking instructions could be provided: one for preparation of thawed product and one for preparation of frozen product.

If cooking instructions have not already been developed, the establishment can collect data during its own cooking trials to determine the length of time it takes to reach the desired endpoint temperature. Such a study should at least consider conditions likely to result in the lowest endpoint temperature or worst-case scenario (NACMCF, 2006). Establishments developing cooking instructions for raw poultry products may find additional useful information in the GMA’s 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products.

FSIS does not recommend that cooking instructions be developed for microwave ovens due to difficulty in applying heat uniformly. Inconsistencies in microwave cooking make it more challenging to develop adequate cooking instructions applicable to microwave ovens than for most other methods of cooking. In addition to the variables discussed previously, factors specific to microwave ovens can impact cooking ability, such as microwave oven wattage, position of the product within the microwave oven, and rotation of the product during microwave cooking.

It is important for establishments to ensure that the actual product being labeled is similar to the product studied because differences in the product formulation and cooking method have an impact on heat transfer and as a result, the amount of time it takes to reach the desired endpoint temperature. Otherwise, establishments cannot be sure that the desired endpoint temperature will be met if different critical operational parameters are used. An example: an establishment develops cooking instructions for ground turkey patties that are 99% lean (1% fat) and 1/3 inch thick. If an establishment applies these cooking instructions to patties that are 90% lean (10% fat) and ½ inch thick, consumers may not achieve the desired endpoint temperature because the increased fat and patty thickness decrease heat transfer.

Recommended Best Practices, Validating Cooking Instructions

1. Cooking instructions should be validated to show that the cook time and cook method will result in a safe internal temperature for a given product
2. Provide validated, clear cooking instructions on the label for consumer-packaged products
3. Consider whether qualities of different raw products (such as thickness or fat content) may mean that validated cooking instructions for one product may not be validated for a different product

XI. References

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Attachment 1

Analysis of askFSIS Questions Received on the HACCP Plan, Hazard Analysis, Prerequisite Programs, and process control related to Campylobacter

Analysis Objectives

- To determine the number of askFSIS questions received from industry related to the HACCP Plan, Hazard Analysis, Prerequisite programs, and process control related to *Campylobacter*.
- To identify trends in question types in order to identify areas in the guidance that needed clarification.

Methodology

AskFSIS questions meeting the following criteria were identified for this analysis:

- Submitted between March 16, 2013 through May 9, 2014;
- Submitted by FSIS inspection program personnel or establishments on controlling *Campylobacter*

Each question was then assigned a question topic based on the primary content of the question.

Results

98 questions were identified in the askFSIS system related to the HACCP Plan, Hazard Analysis, Prerequisite programs, and process control related to *Campylobacter*. The breakdown of the questions by topic is as follows:

Question Topic	Number of questions received
HACCP plan/hazard analysis	35
Process control	25
Sampling/Testing	21
Scientific documentation	6
Use of interventions	6
Seeking guidance documents	3
Performance standards	2
Total	**98**

Attachment 2

Antimicrobial interventions for further processed poultry. Parameters are provided to guide establishments in choosing antimicrobial interventions that are appropriate to their processes. Values indicated are not critical operational parameters. Establishments need to identify the critical operational parameters used and provide scientific support for the values they select.

Intervention	Pros	Cons	Typical parameters	Reference
Chlorine-based treatments	- Inexpensive - Broad spectrum - Quick acting	- Corrosive at low pH - Ineffective at high pH - Neutralized by high organic load - Formation of trihalomethanes	pH: 6.0 – 6.5 concentration: 20 – 50 ppm free chlorine temperature: 4°C Application: dip or spray	Buncic and Sofos, 2012 Oh, 2014
Organic acids	- Low toxicity compared to some other chemicals - Broad spectrum - Not affected by hard water - relatively stable in the presence of organic matter	- Can be expensive - Can be corrosive at high temperatures	pH range: 2.5 – 5.4 concentration: 1.5 – 5% temperature: 4°C application: dip or spray	Zhao, 2006
Acidified Sodium Chlorite (ASC)	-inexpensive	- Can form halogenated organic compounds - Neutralized by organic matter	pH range: 2.3 – 2.9 concentration: 500 – 1200 ppm temperature: 4°C Application: dip or spray	Wang, 2014 Alonso-Hernando, 2013
Peroxyacetic acid	- Broad pH range - Broad temperature range - Affected by organic matter to a lesser degree than chlorine - No rinse required	- expensive	pH: 3.0-7.5 concentration: 100-1000 ppm temperature: 4°C Application: dip or spray	McKee, 2014 Chen, 2014
Trisodium Phosphate (TSP)	- Inexpensive	- High pH may affect poultry after prolonged contact	pH: 11 – 13 concentration: 8 – 12% temperature: 20 – 30°C Application: dip or	Capita, 2002 Del Rio, 2007

Intervention	Pros	Cons	Typical parameters	Reference
			spray	
Electrolyzed Oxidizing (EO) water treatment	- Noncorrosive to equipment and personnel - Inexpensive to operate	- Solution rapidly loses antimicrobial activity if electrolysis is stopped - neutralized by organic matter - may be expensive to set up system	EO water has the following characteristics[3]: pH: 2.1 – 2.7 ORP: >1000 mV free chlorine: 8 – >70 mg/L Application: dip	Huang, 2008 Park, 2002
Crust freezing	- No chemicals on food; no rinse required	- Expensive to install - Requires source of CO_2 or N_2	Operates at approximately -30° to -55°C Application: N/A	Georgsson, 2006 Boysen and Rosenquist, 2009
Cryogenic Freezing	- No chemicals on food; no rinse required - Odorless, colorless, tastless	- Expensive to install and operate - CO_2 or N_2 are dangerous to handle	Operates at approximately -59°C Application: N/A	Shaikh and Prabhu, 2007
High Pressure Processing (HPP)	- No chemicals on food; no rinse required	- Expensive to install - Typically done at a separate establishment	Operates at pressures >100 MPa Application: N/A	Liu, 2012 Simonin, 2012
Gamma irradiation	- No chemicals on food; no rinse required	- Expensive to install - Typically done at a separate establishment - Socially unpopular	≤3.0 kGy packaging must be air permeable(21 CFR 179.26(b)(6))	Thayer 1991 and 1992