Improvements for Poultry Slaughter Inspection

Technical Report

May 16, 2008

ACKNOWLEDGEMENTS

This report is the result of efforts and contributions from across the Food Safety and Inspection Service. The Data Analysis and Integration Group of the Office of Food Defense and Emergency Response developed this report in consultation with experts from other program areas including headquarters and field personnel. Key contributions were made by the Office of Policy and Program Development; Office of Field Operations; Office of Program Evaluation, Enforcement and Review; and Office of Public Health Science. In addition, significant contributions to the data analyses and content of the report were made by Science Applications International Corporation (SAIC) and its subcontractors, including Auton Lab of Carnegie Mellon University and RTI International.

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LIST OF ABBREVIATIONS AND ACRONYMS

CDC	Centers for Disease Control and Prevention
CFU	colony-forming unit
CSPI	Center for Science in the Public Interest
FDA	Food and Drug Administration
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
FY	fiscal year
HACCP	Hazard Analysis and Critical Control Points
IVT	intensified verification testing
LOI	level(s) of inspection
MPN	most probable number
NOIE	Notice of Intended Enforcement
NR	noncompliance report
NRTE	not-ready-to-eat
OIG	Office of the Inspector General
PBIS	Performance Based Inspection System
PPIA	Poultry Products Inspection Act
ppm	part(s) per million
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points Final Rule
SPS	Sanitation Performance Standards
Sanitation SOPs	**S**anitation Standard Operating Procedures
TSP	trisodium phosphate
USDA	United States Department of Agriculture

INTRODUCTION

The Food Safety and Inspection Service (FSIS) is considering improvements for poultry slaughter inspection in order to better fulfill the Agency's mission of protecting public health. Some of the improvements under consideration could be implemented under FSIS' existing regulatory framework and other improvements under consideration would involve changes to FSIS' existing regulations for poultry slaughter. The improvements for poultry slaughter inspection being considered are science-based and are being designed with input from stakeholder groups and expert peer review.

The improvements for poultry slaughter inspection under consideration that would not require changes to existing FSIS regulations include the following: 1.) focused inspection activities at points within the poultry slaughter process that are vulnerable to microbial contamination when not controlled and 2.) allocation of flexible inspection resources (e.g. Food Safety Assessments (FSAs)) based upon a public health risk ranking of poultry slaughter establishments. The improvements for poultry slaughter inspection under consideration that would involve regulatory changes include the following: 1.) food safety standards for septicemic/toxemic carcasses and 2.) performance standards for *Salmonella*, *Campylobacter*, and generic *Escherichia (E.) coli*. The food safety regulatory standard for fecal contamination (9 CFR 381.65 (e)) would not be changed. Additionally FSIS is considering changing regulations on chilling carcasses (9 CFR 381.66), reprocessing (9 CFR 381.91), removable animal diseases (9 CFR 381.81 – 381.82; 381.84 – 381.90), and standards of identity (9 CFR 381.76 and 381.1).

FSIS estimates that approximately 60 percent of the foodborne illnesses originating from *Salmonella* in FSIS-regulated products in 2007 are attributable to poultry products. In 2007, FSIS *Salmonella* verification testing found 8.5 percent positive samples, down from 10.5 percent in 2006 and 16.3 percent in 2005. In addition, of the 195 test sets completed in 2007 at broiler establishments, 98 percent met the *Salmonella* performance standard (192 out of 195 establishments), up from 90 percent in calendar year 2006.

To meet the Healthy People 2010 goal of 6.8 *Salmonella* cases per 100,000 persons, the Agency has set an objective of 90 percent of broiler establishments to be in *Salmonella* Category 1 by 2010. In fiscal year (FY) 2006, 45 percent of establishments were in *Salmonella* Category 1. In FY 2007, that percentage had increased to 73 percent.

FSIS' current inspection system focuses on visible animal diseases and was designed before microbial contamination was recognized as a leading cause of foodborne human illness. The proposed system improvements would be better able to protect public health by focusing and integrating its regulatory authority on establishments and process points within slaughter and processing establishments at which control of microbial growth and contamination can have the greatest impact. The regulatory framework of current FSIS inspection activities regarding verification of HACCP, Sanitation SOPs, SPS (FRN Final Rule HACCP and Pathogen Reduction, Vol. 61, p. 38806, July 25, 1996) would continue in the improved system.

The Agency has learned from its experience with HACCP that to better protect public health it must bolster its inspection force's ability to link and respond to instances of noncompliance within establishments. In addition, the Agency also learned that its inspectors must verify not only critical control points of an establishment's overall food system, but also the execution of the decisions made by the establishment in the hazard analysis, particularly prerequisite programs. As described in this report, the Agency is considering data driven and science-based methods for allocating inspection activities, both across and within establishments, to meet those needs. By working within its existing regulatory framework, FSIS would focus inspection resources on those establishments and points within slaughter plants that can have the greatest impact on the microbial growth and contamination of products. This strategic focus is essential because FSIS cannot test all finished product at an establishment and must have a means of ensuring that process control is consistently maintained.

Analysis of FSIS recalls in recent years suggests that, with the current inspection and information infrastructure a critical understanding of hazards and their controls has been lacking, including assessment of the decisions associated with the design of the food safety system, and assessment of the impact of intended use of produced product. The inability to track inspection activities (both positive and negative findings) that would lead to a systematic evaluation of the food safety system has also been lacking, resulting in inspection program personnel not always detecting critical issues at the in-plant level. Additionally, linkage of all findings, including plant data, has not been fully utilized by the inspection force, particularly in detecting problems earlier in the process before product enters commerce.

The system improvements under consideration would be incorporated in FSIS' new information infrastructure. FSIS' new information infrastructure will facilitate better collection of establishment inspection data. The infrastructure is being designed to provide automated monitoring of inspection results and built in alerts for anomalies. The new infrastructure will help inspectors to verify the execution of decisions made in the hazard analysis, including responding to plant data. It will strengthen inspection program personnel's ability to appropriately link and respond to documented noncompliance and to verify corrective actions are fully implemented.

This report outlines the improvements for poultry chicken slaughter under consideration by FSIS and discusses the scientific basis for those improvements. It begins with a discussion of the poultry slaughter inspection improvements FSIS could implement within its existing regulatory authority. The proposed approach for focusing inspection activities within an establishment is discussed followed by the approach for allocating flexible inspection resources across establishments. Each of those approaches has been designed with the goal of identifying and preventing potential public health hazards in establishments before they reach the consumer. Next, improvements for poultry slaughter inspection that would require regulatory changes are discussed. The Agency believes those regulatory changes can help ensure that end products do not pose a public health threat and that requirements for wholesomeness are met. FSIS also believes those standards can also indicate that a food safety system is under control. The report concludes with a discussion of the Agency's enforcement strategy and evaluation plan for the improved poultry slaughter inspection system. Appendices supporting and detailing the sections include attribution and performance measures, data sources, data analyses, risk assessment, inspection prompt tables, and performance standards.

POULTRY SLAUGHTER INSPECTION IMPROVEMENTS

Within-Establishment Focused Inspection

FSIS intends to focus its verification activities on points within the slaughter process that have the greatest potential for microbial contamination if not controlled (vulnerable points). This approach fits within the Agency's existing regulatory framework and is linked to inspectors carrying out their existing inspection procedures related to HACCP, SSOPs, and SPS. As shown in **Figure 1**, inspectors would be prompted by the new information infrastructure to focus their activities on vulnerable points in the slaughter process. Specifically, as part of their routine activities, inspectors would identify noncompliance, verify corrective actions, and record any noncompliance record(s) (NRs) in the new information infrastructure. Other establishment information would also be recorded in the system, including laboratory test results and establishment characteristics. Based on recorded information, the information infrastructure would identify certain public health-related events, or combinations of those events, and would then prompt inspectors to focus their inspection activities on vulnerable points. At those vulnerable points, the inspectors would provide yes/no/insufficient information answers regarding the presence and implementation of control measures. This information could provide stronger support for further regulatory and/or enforcement actions.

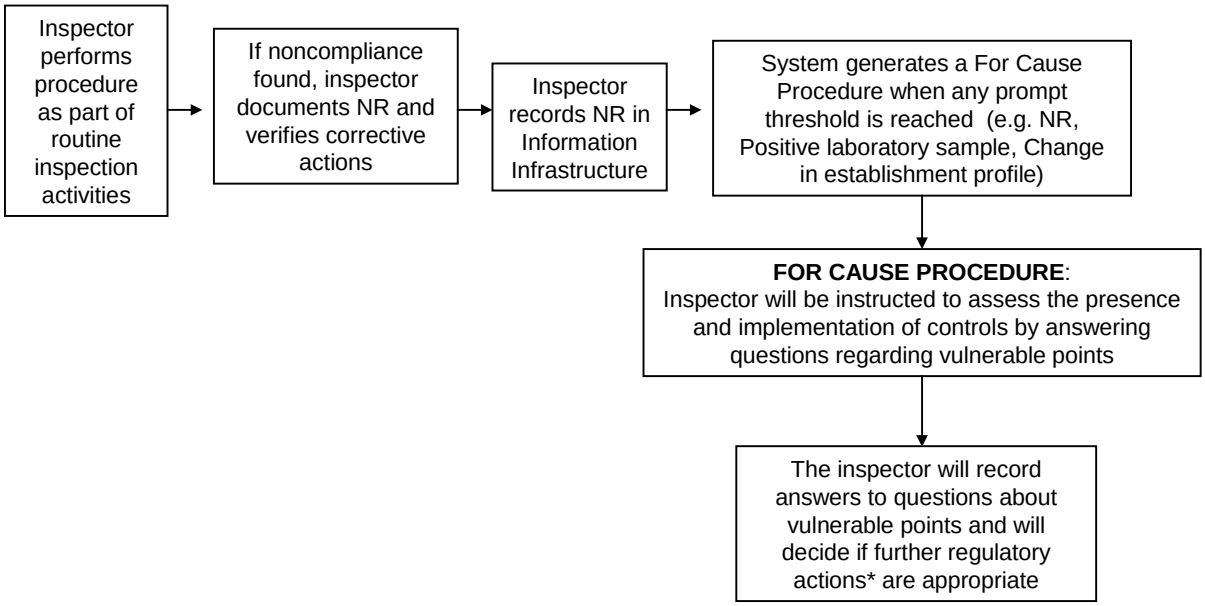

Figure 1. Focused Inspection Activity Information Flow

FSIS' new information infrastructure would continuously monitor inspection findings and laboratory results and would direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached. In response to a prompt, inspectors would be automatically assigned a For Cause procedure by the information infrastructure, which would instruct them to respond to the vulnerable point questions. Inspectors would verify the establishment is in compliance with the FSIS regulations.

The within-establishment focused inspection activity would enable inspectors to more effectively link and take action on instances of noncompliance. It would also assist inspectors to not only verify critical control points in an establishment's overall food safety system, but also to verify the execution and supporting documentation of the decisions made by the establishment in its hazard analysis. On the basis of their hazard analyses, many establishments have decided that a food safety hazard is not reasonably likely to occur because of their prerequisite programs. Therefore, it is important that FSIS verify vulnerable points where commercially available control measures are available regardless of whether they are included in the HACCP plan, SSOP plan, GMPS, SOPs or prerequisite program.

The within-establishment inspection method is based on the scientific literature and Agency experience with HACCP and contamination events. Using a generic process diagram, common steps in poultry slaughter establishments were identified. A literature review was carried out to identify which steps in the slaughter process are most vulnerable, based on the reduction of microbial load at each step and the commonly available control measures that would reduce pathogen levels to the lowest levels possible under commercial conditions. Next, using the literature review as a guide, a group of FSIS experts determined a set of questions that inspectors should answer at each step of the slaughter process to help determine whether the food safety system is in control; this is the set of questions inspectors will be prompted to answer by the new information infrastructure at the vulnerable points (see Figure 1).

The prompts in FSIS' new information infrastructure would direct inspectors to examine vulnerable points in the process and to answer questions about process control at those points. Inspection program personnel would write NRs for observations at vulnerable points in accordance with FSIS regulations for poultry products. Observations at vulnerable points may reveal the establishment is failing to maintain sanitary conditions (9 *Code of Federal Regulations* [CFR] 416.1) or failing to implement Sanitation SOPs (9 CFR 416.13) and, consequently, yielding product that may be injurious to health. They could also demonstrate that an establishment is not executing a prerequisite program identified within the hazard analysis which would mean the establishment is failing to properly validate that the HACCP plan is functioning as intended (9 CFR 417.4 [a]). Such a finding could possibly bring into question whether supporting documentation for decisions in the hazard analysis is adequate (9 CFR 417.5 [a] [1] & [2]), and whether the hazard analysis itself is adequate (9 CFR 417.2) and would also bring into question whether the HACCP plan is adequate (9 CFR 417.6 [a]). Details of the product-specific prompts and questions are provided in Appendix B of this report. The process diagram and literature review are described below.

FSIS would develop training and guidance materials for focused inspection activities to ensure inspectors understand how to carry out their focused inspection activities by responding to questions regarding vulnerable points and making decisions about noncompliance based upon responses to those questions. The within establishment inspection method has been designed to reinforce the food safety regulatory training inspection program personnel currently receive.

An example of a focused inspection prompt and related For Cause procedure is provided in **Figure 2**. In the diagram, the prompt depicted is a poultry slaughter establishment exceeding the food safety standard critical limit for visible fecal contamination. If an inspector finds that an establishment is exceeding the critical limit while conducting a 03J procedure, the FSIS inspector

would document an NR and verify corrective actions. The information infrastructure would continuously monitor inspection results and when the threshold for HACCP noncompliance is reached, a For Cause procedure would be generated for the inspector. The inspector would carry out a For Cause procedure and would respond to questions regarding the implementation of control measures at vulnerable points. The inspector would record his or her responses to the questions regarding vulnerable points in the information infrastructure, and, when appropriate, may use the responses to those questions to document an NR and/or enforcement action. Conducting For Cause procedures as a result of previous findings of noncompliance in an establishment would not preclude an inspector from taking enforcement actions at the time of the initial noncompliance finding.

Prior to implementation of the focused inspection activities, FSIS would conduct a historical data analysis of inspection findings in order to determine prompt thresholds. In addition, FSIS would conduct a methods evaluation that would include a field evaluation and workshop. During the field evaluation FSIS would evaluate the proposed prompts carrying out focus groups with FSIS field employees and walking through prompt scenarios for different product categories in FSIS regulated establishments. After that initial evaluation, the prompts would be further refined based upon a workshop at which stakeholders (FSIS field employees, academics, industry, and consumer representatives) would play out different prompt scenarios.

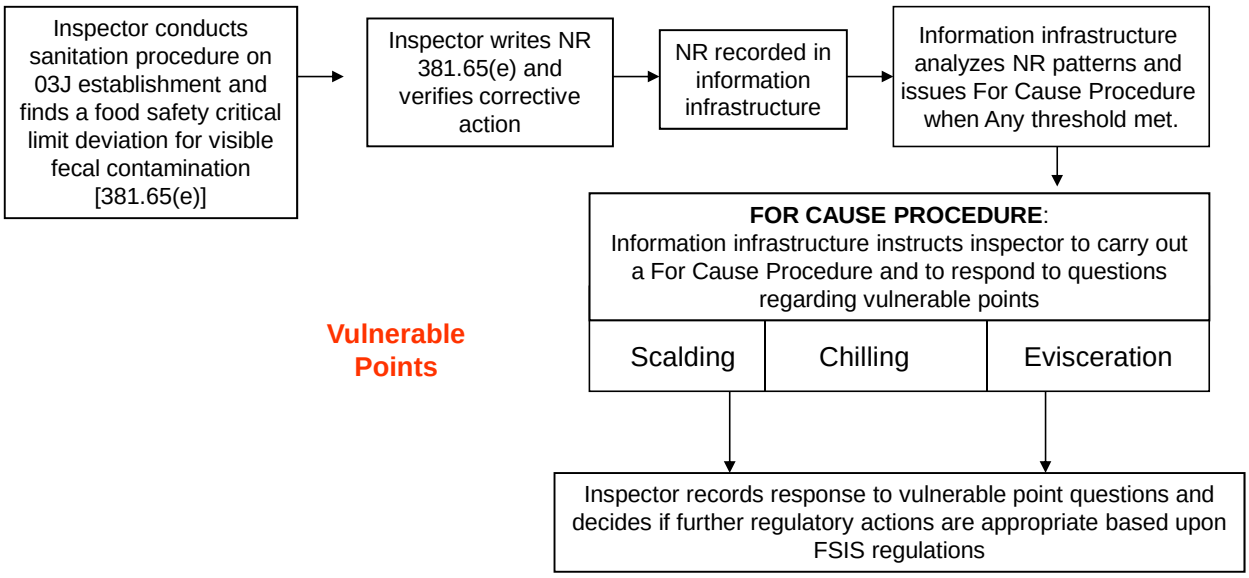

Figure 2. 03J HACCP Noncompliance Prompt Example

Poultry Slaughter Process Diagram

A generic process diagram was used to identify the common steps in poultry slaughter establishments. The key steps in poultry slaughter, shown in **Figure 3**, are live receiving, scalding, picking, evisceration (including on-line reprocessing), and chilling. The diagram reflects the improvements for poultry slaughter inspection currently under consideration by FSIS.

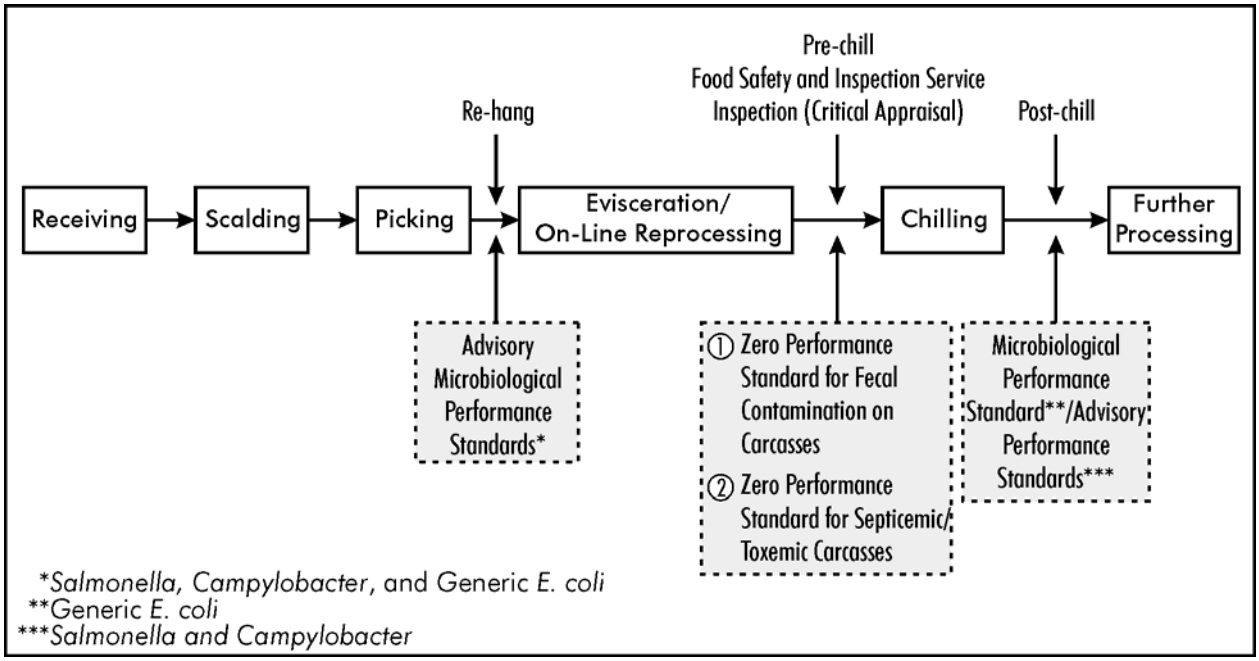

Figure 3. Poultry Slaughter Process Diagram Under Improved Inspection System

Live receiving is the initial step in the slaughter process, and begins when live poultry are received on the establishment's official premises. Once poultry are removed from transport cages, they are suspended in shackles, immobilized in accordance with humane Good Commercial Practices, and rendered unconscious in preparation for exsanguination (bleeding).

Scalding begins when the poultry carcass enters the scald system and ends when feather removal commences. Scalding prepares the carcass for feather removal by breaking down the proteins holding feathers in place and opening up feather follicles. Immersion scalding is the most common scald technology in use and is best described as dragging carcasses through a tank of hot water.

Picking eliminates the feathers and stratum corneum in preparation for evisceration. Feather removal begins when carcasses enter the feather removal equipment and continues until the exterior surface of the poultry carcass is free of feathers and cuticle. Feather removal technology is fairly uniform across the poultry industry. Carcasses pass through one or more pieces of equipment that remove feathers by the mechanical action of rubber picking fingers beating against the carcass. Most establishments utilize a continuous process; however, batch processes are common in small, low-volume establishments. Some very small establishments rely on manual methods to remove feathers.

Evisceration removes the internal organs and any trim/processing defects from the carcass in preparation for chilling. The technology varies widely across the poultry industry, but always includes the following basic process steps: remove head and oil gland; sever attachments to vent;

open body cavity; extract viscera; harvest giblets; and remove and discard intestinal tract and air sacs, trachea and crop, and lungs.

As part of evisceration, some plants use on-line reprocessing, generally an inside-outside carcass washer that uses FDA approved antimicrobial agents to remove contamination from inside carcasses. Temperature and pressure, nozzle type and arrangement, flow rate, and line speed are all aspects of the reprocessing system.

Chilling removes the natural heat from the carcass and is complete when regulatory temperature requirements are met. The primary chilling technologies in use are immersion and air chilling; immersion chilling is more common.

Literature Review

Based on the existing scientific literature on poultry slaughter, carcasses can be contaminated or cross-contaminated during live receiving, picking, and evisceration. However, the greatest opportunities for decreasing or limiting microbial contamination using available control measures occur at scalding, evisceration, and chilling. A detailed description of the literature regarding microbial contamination and control measures is presented in Appendix C. Below, the literature on microbial contamination and control measures at each step of the slaughter process and why certain points were determined to be vulnerable is summarized.

Live Receiving: During live receiving, microbial contamination may occur from pathogens on the feathers and skin and in the crop, cecum, and colon of poultry. Microorganisms present on or in live poultry at live receiving can lead to cross-contamination of carcasses throughout the slaughter process (Clouser et al. 1995, Berrang et al. 2000, Campbell et al. 1982, Newel et al. 2001, Fluckey et al. 2003). In addition, the exterior of the carcass may become contaminated due to immobilization, which causes live poultry to void feces (Papa and Dickens 1989, Musgrove et al. 1997).

Although a number of control measures may reduce incoming microbial load, including washing and sanitizing crates and feed withdrawal, pre-harvest controls are the most effective for reducing the incoming microbial load. Because pre-harvest controls are outside of FSIS' regulatory purview, FSIS has not focused its inspection activities on live receiving in this report. However, establishments can and do apply controls at this point in the operation and may incorporate decision-making criteria in their food safety systems (e.g., prerequisite programs).

Scalding: Scalding washes dirt and feces from the exterior of the carcass, offering the greatest opportunity to remove microorganisms compared with any other processing step. Reductions reported at scalding have ranged from a 38 percent decrease in *Salmonella*-positive carcasses (Geornaras et al. 1997), a 312 most probable number (MPN)/100 cm^3 decrease in *Campylobacter jejuni* on turkey skin (Acuff et al. 1986), and up to a 4.1 $\log_{10}$ reduction in *Campylobacter*/ml in carcass rinses (Berrang and Dickens 2000). Lillard (1990) found a 1.1 $\log_{10}$ decrease in aerobic bacteria and a 1.5 $\log_{10}$ colony-forming unit (CFU)/ml decrease in *Enterobacteriaceae*, respectively, in carcass rinses.

Microbial cross-contamination can also occur during scalding from microorganisms present on the external and internal surfaces of the carcass and in the scalding water. This has been shown

for *Salmonella*, *Campylobacter, Staphylococcus aureus, Listeria (L.)* spp., and aerobic bacteria (Berrang et al. 2000, Berrang et al. 2003, Kaufman et al. 1972, Geornaras et al. 1997, Cason et al. 2000, Wempe et al. 1983, Mulder et al. 1978, Cason et al. 1999).

A great deal of research has been conducted investigating which scalding techniques are most effective for limiting cross-contamination. Effective controls include counter-current scalding (Waldroup et al. 1992), multistage scalding (Cason et al. 2000), proper time-temperature combination, and maintaining pH.

Because scalding can lead to major reductions in microbes and has the potential to be a major site of cross-contamination between flocks, if not properly controlled, it has been identified as one of the vulnerable points at which to focus FSIS inspection activities.

Picking: Microbial contamination may occur during picking from microorganisms present on the external and internal surfaces of the carcass, as well as on the feather removal equipment (Izat et al. 1988, Berrang and Dickens 2000, Berrang et al. 2001, Clouser et al. 1995, Geornaras et al. 1997).

Within the feather removal equipment, the rubber picking fingers and recycled water have been demonstrated to be sources of cross-contamination (Geornaras et al. 1997, Wempe et al. 1983, Whittemore and Lyon 1994, Mead et al. 1975, Allen et al. 2003, Mulder et al. 1978, Geornaras et al. 1997).

Interventions applied during feather removal have yielded mixed results. Some interventions have lead to reductions (Mead et al. 1994, Allen et al. 2003, Berrang et al. 2001). Other interventions have not shown an effect (Berrang et al. 2000, Mead et al. 1975). Given the inconsistent results and the lack of well-established, effective control measures to overcome the high levels of cross-contamination at picking, this step was not identified as one of the vulnerable points at which to focus FSIS inspection activities.

Evisceration: Contamination from microbes present on carcasses and equipment surfaces may occur during evisceration. The incidence of potential biological risk factors on carcasses and equipment, as well as the change in absolute numbers, varies widely between poultry processing operations due to differences in processing and sanitation practices. For example, *Salmonella*-positive carcasses have been seen to increase 2.4 percent during evisceration (Lillard 1990), 7.0 $\log_{10}$ *Campylobacter jejuni*/g from intestinal content during evisceration (Oosterom et al. 1983), 278 MPN/100 cm^3 *Campylobacter jejuni* (Acuff et al., 1986), and 0.41 $\log_{10}$/1000 cm^3 *Campylobacter jejuni* on skin samples (Izat et al.,1988). Carcass handling during evisceration cross-contaminates products prior to opening the body cavity and after extracting the viscera, as demonstrated by marker studies (Mead et al. 1994, Mead et al. 1975, Byrd et al. 2002). However, reductions can also be seen at evisceration, indicating that control measures can have an important effect. Reductions ranging from 0.18 $\log_{10}$ to 0.61 $\log_{10}$ have been seen at evisceration (Berrang and Dickens 2000, Berrang et al. 2003, Lillard 1990).

One of the main control measures for evisceration is on-line reprocessing. On-line reprocessing is generally an inside-outside carcass washer that uses FDA approved antimicrobial agents to remove fecal and/or ingesta contamination from inside carcasses that occurred during evisceration. Temperature and pressure, nozzle type and arrangement, flow rate, and line speed

all influence the effectiveness of the on-line reprocessing system. Other interventions include carcass washes which may or may not use chlorine as an antimicrobial. Multiple washers in series are generally more effective than a single large washer. Bashor et al. (2004) and Kemp et al. (2001) found that a three-stage system decreased *Campylobacter* by 0.45 $\log_{10}$ CFU/ml compared to 0.31 $\log_{10}$ CFU/ml in a single-stage system. Acuff et al. (1986) and Izat et al. (1988) found that an on-line carcass wash reduced *Campylobacter jejuni* 344 MPN/100 cm^3 and 0.7 $\log_{10}$ CFU/1000 cm^3, respectively.

Carcass rinses are effective interventions for removing loose material from the carcass surface during evisceration (Byrd et al. 2002). Waldroup et al. (1992) recommended a 20 part per million (ppm) chlorine carcass rinse post-evisceration as part of a strategy shown to decrease microbial contamination and improve food safety. Mead et al. (1975) found that a 10–20 ppm free available chlorine rinse did not eliminate a marker organism; but 18–30 ppm free available chlorine reduced recovery of the marker organism from the 50^{th} to the 20^{th} revolution at the transfer point. Jimenez et al. (2003) found that carcass rinses reduce visible feces and bile on post-evisceration broiler carcasses by 3.4 percent and 2.9 percent, respectively. Carcass rinses can also reduce visible biological hazards. Notermans et al. (1980) found that the incidence of *Salmonella*-positive carcasses decreased 36.5 percent when carcass rinses were incorporated into the evisceration process, compared with a 20.5 percent increase without carcass rinses.

The addition of antimicrobial agents generally increases the effectiveness of carcass washers. Fletcher and Craig (1997) found that 23 ppm free available chlorine reduced the incidence of *Campylobacter*-positive carcasses from 77 percent to 72 percent and *Salmonella*-positive carcasses from 5 percent to 2 percent. Bashor et al. (2004) found that trisodium phosphate (TSP) decreased *Campylobacter* by 1.3 $\log_{10}$ CFU/ml, and acidified sodium chlorite decreased 1.52 $\log_{10}$ CFU/ml. Yang and Slavik (1998) reduced *Salmonella* on carcasses 1.36 $\log_{10}$ CFU with 10 percent TSP, 1.62 $\log_{10}$ CFU with 5 percent cetylpyridinium chloride, 1.21 $\log_{10}$ CFU with 2 percent lactic acid, and 1.47 $\log_{10}$ CFU with 5 percent sodium bisulfate. Whyte et al. (2001) found that 10 percent TSP combined with 25 ppm free available chlorine decreased *Salmonella* by 1.44 $\log_{10}$ CFU/g and *Campylobacter* by 1.71 $\log_{10}$ CFU/g.

Because of the potential cross-contamination at evisceration and the effective controls developed at this point (including on-line reprocessing, carcass rinses, and antimicrobial agents), evisceration has been identified as one of the vulnerable points for focusing inspection activities to determine whether controls are present and properly implemented.

Chilling: Microbial cross-contamination during chilling may occur from microorganisms on the carcass and in the chiller environment. Chilling involves submerging carcasses sequentially in a tank filled with chilled water, often with an antimicrobial, causing the temperature of the carcasses to drop. The free-flowing water provides an opportunity for unattached microorganisms to redistribute on the carcass and across carcasses. *Salmonella* and *Campylobacter* are the most common pathogenic microorganisms present on carcasses and in the immersion chiller environment (Clouser et al. 1995, Wempe et al. 1983, Loncarevic et al. 1994).

A number of studies have shown that immersion chilling is effective at reducing microbial contamination such as:

- Enterobacteriaceae, *E. coli*, and coliforms (Jimenez et al. 2003)

- Aerobic Plate Count, coliform, and *E. coli* (Berrang and Dickens 2000)
- Aerobic Plate Count and Enterobacteriaceae (Lillard 1990)
- *Salmonella (*Mulder et al. 1976, Bilgili et al. 2002)
- *Campylobacter* species (Berrang and Dickens 2000, Izat et al. 1988, Bilgili et al. 2002)

However, immersion chilling can be a site of increased microbes due to cross-contamination, as demonstrated for *Salmonella* by Lillard (1990) and Sarlin et al. (1988).

Because chilling can lead to major reductions in microbes, but has the potential to be a major site of cross-contamination between flocks, it has been identified as one of the vulnerable points at which to focus FSIS inspection activities.

Across Establishment Public Health Risk Ranking Algorithm

The overall goal for improving poultry slaughter inspection is to achieve measurable improvements in the control of foodborne pathogens and, thereby, to reduce the potential public health impact of poultry slaughter establishments on foodborne illness. The National Academy of Sciences and the Government Accountability Office have recommended that FSIS reduce its reliance on organoleptic (sensory) inspection, and redeploy its resources by using inspection methods that are based on the risks inherent in processing and slaughter operations. The purpose of this section is to present an algorithm for categorizing poultry slaughter establishments with respect to their potential impact on public health. FSIS recognizes that development of a public health risk ranking algorithm will be an ongoing process, and that the proposed algorithm may continue to evolve as more information about the risks associated with particular products and about the predictive indicators of food safety process controls at slaughter establishments becomes available.

Background

In 2004, FSIS began the process of developing a risk-based inspection program that would focus more inspection resources on processing establishments that posed a greater food safety risk. The outcome of this process was a risk-based inspection algorithm to rank the potential risks at processing establishments for the purpose of allocating more inspection resources to riskier plants. This algorithm combined an estimate of the potential risk that was considered inherent to the product (inherent risk measure) and an estimate of how well the establishment controlled those potential risks (risk control measure). The algorithm employed nine parameters to characterize the risk present in an establishment.

- Volume
- Inherent risk (attribution)
- *Salmonella* verification category (three categories)
- FSIS regulatory test results (*E. coli* O157:H7, *Salmonella,* and *L. monocytogenes* in ready-to-eat products; *E. coli* O157:H7 in ground beef)
- *L. monocytogenes* reduction interventions used by ready-to-eat product establishments (four categories)

- Regulatory health-related instances of noncompliance (NRs)
- Food recalls
- Enforcement actions
- Consumer complaints

The algorithm was reviewed by the United States Department of Agriculture (USDA) Office of the Inspector General (OIG) and suggestions for improvement were made (OIG 2007). Suggestions from OIG, industry sources, and consumer groups have been incorporated, to the extent possible, in the current algorithm.

Conceptual Approach

Risk is defined as the combination of the consequence (hazard) of an event and the probability of occurrence of that event. Any health-based ranking algorithm should account for both factors. With respect to poultry slaughter establishments, the consequence (hazard) of a contamination event is the magnitude of negative human health impacts that could occur following a contamination event, while the probability of a contamination event is related to the adequacy of the food safety systems in the establishment (see **Figure 4**).

FSIS acknowledges that quantification of public health impacts resulting from a chicken slaughter establishment is not exact. Rather, the goal is to segregate establishments into categories of high, medium, and low probability of contributing to negative public health outcomes.

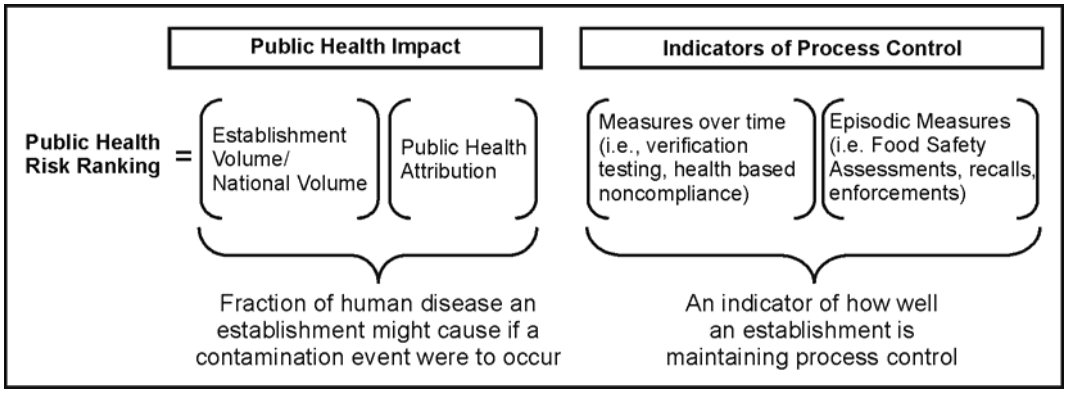

Figure 4. Factors Contributing to a Public Health Risk-Based Ranking Algorithm

Data Sources

Various data sets have been identified that could be used to categorize meat and poultry establishments with respect to relative potential impact on public health. Those data sets are described in detail in Appendix D.

Production Volume

FSIS inspection personnel estimate production volume using a range of pounds produced in a typical day over a period of days in a 30-day period. FSIS believes that higher production

volumes are of greater concern because establishments that produce larger volumes of product have a greater potential to impact public health. Stakeholders have questioned whether inspection program personnel can accurately estimate an establishment's production volume. FSIS acknowledges that its inspection personnel are not currently able to precisely and accurately collect production volume information.

FSIS believes that collecting production volume data, including pounds of product produced by product type, is important, and that the Agency needs to account for this information in the design of its verification activities. Consequently, through the new information infrastructure FSIS expects to work to develop a mechanism for inspection program personnel to identify specific production records on which such information is based, and to provide the establishment management an opportunity to review the collected information. Collection of production volume data in this manner would provide FSIS a means to verify the source and accuracy of the information. The OIG (OIG 2007) has concurred with this approach to obtaining industry-verified estimates of process volume.

Attribution

The ability to identify which foods are vehicles for specific cases of illnesses is a basic element of prioritizing and allocating resources to reduce the level of foodborne illness. The National Academy of Sciences (IOM/NRC 2003) and consumer groups (Waldrop 2007) have endorsed, in principle, the application of attribution data in prioritization efforts. Appendix A gives an overview of an approach for performing microbial foodborne disease attribution, and for relating FSIS inspection activities to public health impacts and public health goals. No single source of information can currently provide a comprehensive picture of the food attribution issue. Thus, it is necessary to combine a number of different methods and studies to arrive at more defensible estimates. The best estimates come from combined consideration of illness outbreak data, illness case-control studies, risk assessments, pathogen serotype data, and expert elicitation (Batz et al. 2005). FSIS has adopted this approach and considered the best information currently available.

- Outbreak data – The public health risk ranking algorithm employs the Centers for Disease Control and Prevention (CDC) outbreak data in developing estimates for food attribution. Reported data on foodborne disease outbreaks can be valuable in establishing a link between foodborne illness and the food sources that cause them. A strength of disease outbreak data is that the specific food sources causing the outbreak have generally been identified. However, only a small fraction of total foodborne disease is caused by outbreaks (usually in the range of 5 to 15 percent) and the food sources that cause outbreaks may be different than those that cause sporadic foodborne diseases. Nevertheless, outbreak data represent the largest epidemiological dataset available for attribution studies and are a valuable source of information linking foodborne human illness with specific food sources. As demonstrated in Appendix A, attribution estimates for the major FSIS-inspected food categories of beef, poultry, pork, and deli meats derived from CDC outbreak data agree closely with estimates from two expert elicitations. This increases confidence in using the outbreak data.
- CDC case-control studies – CDC has conducted 18 twelve month population-based case control studies over the period 1996 to 2007 (Patrick 2007). The purpose of these studies

was to identify risk factors (food sources) associated with sporadic illnesses. FSIS has reviewed CDC case-control studies relevant to identification of food types contributing to human cases of *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* illnesses. Unfortunately, the utility of the published studies is limited in that: (1) there are very few studies; and (2) they are only able to identify one or two major sources of human exposure. For example, for *Salmonella*, CDC identified chicken and undercooked ground beef prepared outside the home, undercooked eggs, international travel, and exposure to birds and lizards as risk factors. For *Listeria monocytogenes*, CDC identified melons and hummus eaten at a commercial establishment, and living on a cattle farm as risk factors. Because of the limitations of these data, CDC case-control studies were not used for the attribution approach presented in Appendix A.

- Risk assessments - The value of current risk assessments for developing food attribution studies is limited since they are generally focused on a single food product or process and, therefore, do not provide attribution estimation across a range of food types, including both USDA- and Food and Drug Administration (FDA)-inspected foods. For example, FSIS has conducted risk assessments on *Salmonella enteritidis* in Shell Eggs and *Salmonella* spp. in Egg Products (FSIS 2005), *E. coli* O157:H7 in ground beef (FSIS 2001), *E. coli* O157:H7 in intact (non-tenderized) and non-intact (tenderized) beef (FSIS 2002), and *Listeria monocytogenes* in deli meat (FSIS 2003). Because these studies focused on a single food product, they are not used for the attribution approach presented in Appendix A. Various efforts are underway to use risk assessments in attribution studies, including using meta-analysis of multiple studies and developing new exposure models that consider multiple pathways to human exposure. As these efforts develop they will be incorporated into the attribution methodology.

- Pathogen serotype - A CDC/FDA/FSIS effort is underway to use *Salmonella* serotype data to estimate attribution for meat and poultry products (Guo 2007). This effort is characterizing the relative contribution of specific broad categories of meat and poultry products to total human *Salmonella* illness for these meat and poultry products. Currently, because of a lack of data, it does not include FDA-inspected products, except eggs. FSIS has initiated a program of collecting *Salmonella* serotype data on broilers; these data will be available in the future to improve attribution estimates.

- Expert elicitation - The use of expert elicitation in determining food attribution has been endorsed by the National Academy of Sciences (IOM/NRC 2003). FSIS is employing two different expert elicitations on food attribution: (1) an expert elicitation sponsored by FSIS (Karns et al. 2007) using a panel of 12 food safety experts to attribute foodborne illnesses of *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* to handling and consuming foods in 25 processed meat and poultry product categories; and (2) an expert elicitation performed by Resources for the Future and Carnegie Mellon University (Hoffmann et al. 2007), which used a panel of 42 food safety experts to estimate food attribution for each of 11 pathogens. Appendix A gives more detail on these two studies. A valuable contribution of the Hoffmann et al. (2007) study is that it includes both FSIS- and FDA-regulated food categories. Thus, it provides a more complete picture of disease attribution than the FSIS expert elicitation. However, the FSIS expert elicitation provides more detail on specific FSIS-inspected meat and poultry food categories. Both elicitation studies provide different, yet valuable perspectives on the food attribution problem. It is acknowledged that expert

elicitation studies have limitations, but the analysis in Appendix A indicates that at least for *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes*, the two expert elicitations agree remarkably well with each other, giving increased confidence in their attribution estimates. In addition, the CDC outbreak data also produces attribution estimates that agree with the expert elicitations. Again, this increases confidence in the results of these two expert elicitations for the three pathogens considered.

- Combined approach – As described previously, the FSIS attribution methodology relies on two expert elicitations (Karns et al. 2007 and Hoffmann et al. 2007) and the CDC outbreak data. After review of all currently available approaches, FSIS has determined that these three data sources are the most comprehensive currently available datasets for use in estimating foodborne disease attribution. As additional datasets and other approaches (such as serotype data for *Salmonella* sporadic disease) are developed, they will be incorporated into the attribution methodology.

Public Health Significant NRs

FSIS inspection personnel document a regulatory noncompliance at an establishment by recording a noncompliance record (NR) in the Agency's Performance Based Inspection System. When inspectors issue an NR, they cite one or more applicable regulatory requirements from a list of over 500 potential citations. The rate at which an establishment fails to meet these requirements and receives an NR is considered by FSIS to be an indication of the establishment's ability to control risk. An FSIS panel ranked each regulatory requirement based on its public health significance, as measured by a loss of process control. Specifically, each regulatory requirement was categorized into one of four categories according to how strongly each indicated a loss of an establishment's food safety system process control. The regulatory requirements that were considered most strongly related to public health, 66 out of 564 possible regulatory citations, are referred to in this report as "W3NRs." Only about 12 percent of all possible NRs have been identified as indicative of a definite loss of process control.

In poultry slaughter establishments, fecal contamination on carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal going to slaughter. FSIS enforces a "zero tolerance" standard for visible fecal material on poultry carcasses just prior to carcasses entering the chiller. The presence of fecal material on broiler carcasses as they enter the chiller [NR 381.65(e)] is the second most frequent cause of the issuance of a W3NR at poultry slaughter establishments. FSIS considers this NR and other public health-related NRs an indication of loss of process control.

An establishment is required to share records of its food safety programs with FSIS, even if those records are not part of the establishment's HACCP plan. FSIS Directive 5000.2 states that FSIS inspection personnel, on at least a weekly basis, are to review the results of any testing or monitoring activities that the establishment performed that may have an impact on the establishment's hazard analysis. Every poultry slaughter establishment must have a hazard analysis and a HACCP plan(s) to list food safety hazards, critical control points, the critical limits at each critical control point, procedures and frequency of monitoring of the critical control points, all corrective actions for deviations of critical limits, recordkeeping system to

document monitoring verification procedures and frequency performed. Establishments are required to record written hazard analysis including all supporting documentation, written HACCP plan(s) including decision making documents related to selection of critical control points, monitoring of critical control points and their critical limits, including recording of actual times, temperatures or other quantifiable values. Every poultry slaughter establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The records associated with the Sanitation SOPs are to be completed by the beginning of the same shift the next operating day. When an unforeseen hazard occurs, 9 CFR 417.3(b)(4) requires the establishment to perform a reassessment to determine if the unforeseen hazard should be incorporated into the HACCP plan. Slaughter establishments are required to immediately correct any non-compliance documented in an NR. When there has been direct product contamination or a deviation from a critical limit, all corrective actions taken must be recorded and available to FSIS upon request.

An analysis by Carnegie Mellon University (CMU) considered the predictive ability of subsets of NRs as indicators of *Salmonella* contamination. They considered three classes of NRs: all NRs, all public health-related NRs as defined by an industry coalition, and all W3NRs. This analysis provides insight as to whether NRs or subsets of NRs are indicators of the likelihood that an establishment would have a loss of food safety control and, therefore, measures their importance as a possible component of the public health risk ranking algorithm. Carnegie Mellon found that an establishment with a W3NR in a given 7 day period is three times more likely to have a positive *Salmonella* verification testing result in the next 14 days than an establishment without a W3NR. An establishment with an industry coalition-defined NR is about 2.3 times more likely to have a positive *Salmonella* verification testing, and an establishment with any type of NR is about 1.8 times more likely. All of these results are statistically significant and statistically different from each other. Thus: (1) the occurrence of an NR from any of the three sets of NRs is a statistically significant predictor of an increased probability of a positive *Salmonella* test in the following 14 days; and (2) W3NRs are better predictors than the industry coalition NRs, which are better predictors than all types of NRs. In other words, the risk of failing a test for *Salmonella* is substantially elevated at establishments that recently were found to be noncompliant as documented with a W3NR. Additional details about the CMU analysis are provided in Appendix E. In addition, FSIS has conducted a risk assessment that supports a relationship between public health-related procedures and the control of *Salmonella*. Details of that risk assessment are provided in Appendix F.

Adulterated Product

Establishments that ship adulterated meat or poultry product demonstrate a loss of food safety system process control. Adulterated product is defined in the statutes and is characterized by numerous conditions that can occur in production and handling of food. Generally, during the slaughter operation, the following circumstances are the most likely reasons why poultry is determined to be adulterated: it consists in whole or in part of any filthy, putrid, or decomposed substance; it is unsound, unhealthful, unwholesome or other otherwise unfit for human food; it has been prepared, packed or held under insanitary conditions; it may have become contaminated with filth; and it may have been rendered injurious to health. Food recalls are one indication of the shipment of adulterated product. For not-ready-to-eat poultry, epidemiologically-associated illnesses involving *Salmonella* have resulted in product recalls.

Enforcement Actions

Enforcement actions result from an establishment's ongoing failure to comply with FSIS regulations and lack of ability to implement and maintain corrective action. Depending on the noncompliance(s) the establishment may be subject to different enforcement actions (e.g. regulatory control action, withholding or suspension without prior notification; withholding with prior notification; CFR 9 Part 500).

Food Safety Recalls

A recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or otherwise are non-complying. FSIS monitors recalls of meat and poultry products produced by federally-inspected establishments and publishes summary data on the FSIS Web site.

FSIS classifies recalls based on relative health risk, as follows:

- Class I: Reasonable probability of serious, adverse health problem or death
- Class II: Remote probability of adverse health problem
- Class III: No adverse health consequences

Class I and Class II affect public health. More details on the three classes of recalls are given below.

> *Class I*. This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For example, the presence of pathogens in a ready-to-eat product, the presence of *E. coli* O157:H7 in ground beef, or a reasonable probability of a health hazard situation due to an allergenic substance.
>
> *Class II*. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. For example, the presence of small, blunt-edged foreign materials (e.g., plastic).
>
> *Class III*. This is a not a health hazard situation because the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe nonallergenic substances, such as excess water.

FSIS is considering using Class I recalls as an indicator of loss of process control.

Link to an Outbreak

Any establishment that is linked to a disease outbreak will receive a higher ranking.

Food Safety Assessment

Food Safety Assessments (FSAs) are conducted to analyze an establishment's control of its food safety systems, in accordance with FSIS Directive 5100.1. While performing an FSA,

Enforcement, Investigations, and Analysis Officers (EIAOs) assess whether meat and poultry establishments have designed their food safety systems to control, and thereby minimize, the presence of hazards such as *Salmonella, E. coli* O157:H7, and *L. monocytogenes.*

FSIS recognizes that an FSA yields the Agency's best evidence about the design of an establishment's food safety system, in that it provides a top-to-bottom examination of a facility with a focus on interventions and practices used to control the presence of pathogens. The OIG audit (OIG 2007) suggested that FSIS implement an action plan with specific milestone dates for capturing the results of FSAs in an appropriate configuration that allows for effective analysis. In September 2007, FSIS awarded a contract to build the Agency's new information infrastructure. FSIS plans to have a functional domestic inspection module, including a new electronic FSA module, ready for deployment in mid-2009. The new information infrastructure will facilitate effective analyses by capturing similar types of information for all establishments in quantifiable terms, and storing detailed FSA findings in an electronic format.

To ensure consistency and uniformity in the FSA process, FSIS is creating a new FSA instrument, consisting of sections containing a series of data gathering and data analysis questions tailored to the specific food safety hazards and regulatory requirements associated with each HACCP process category (e.g., raw ground product). The new FSA reporting instrument will be web based and interactive with the new domestic inspection model to obtain needed profile data. It will also consist of questions to help structure an EIAO's investigation reporting, as well as prompt the officer to explain his or her findings; provide consistent information for analysis purposes to inform policy and inspection resource allocation, and contain a tracking system to ensure FSAs for cause are getting performed, and that all relevant establishments are assessed at least every 4 years.

Guidance for conducting FSAs related to the control of *Salmonella* in poultry slaughter establishments is given in FSIS Notice 49-07. EIAOs are to assess whether poultry slaughter establishments have designed their food safety systems to control, and thereby minimize, the presence of *Salmonella.* Particular attention is to be paid to determining how an establishment that is either in *Salmonella* verification Category 2 or Category 3 is attempting to ensure the control of *Salmonella* (See discussion of categories in *Salmonella Performance Standards and Verification Testing* below.) Establishments can address *Salmonella* in their HACCP plans, SSOPs, or other prerequisite programs.

In the new information infrastructure, FSAs will have a quantitative score associated with them. The quantitative score is obtained by the addition of points for positive controls and zero points for no control or negative controls (noncompliance). Only yes/no and multiple choice questions in the FSA are scored. The range of FSA scores will be normalized so that all scores lie in a fixed range to facilitate the use of FSA results in a ranking algorithm.

Salmonella Performance Standards and Verification Testing

The PR/HACCP rule sets *Salmonella* performance standards for establishments slaughtering selected classes of food animals or producing selected classes of raw ground products to verify that industry systems are effective in controlling the contamination of raw meat and poultry products with disease-causing bacteria. Raw products with established performance standards include carcasses of cows/bulls, steers/heifers, market hogs, and broilers. Processed products

measured by performance standards include ground beef, ground chicken, and ground turkey. The performance standards for these product classes are based on the prevalence of *Salmonella* as determined from the Agency's nationwide microbiological baseline studies conducted before PR/HACCP was implemented. In addition, turkey carcass sampling for *Salmonella* was initiated June, 2006. Guidance using young turkey carcass baseline levels can be found in the *Federal Register*, Vol. 70, No. 32, pp. 8058-8060.

FSIS performs *Salmonella* verification testing at establishments that produce nine categories of raw meat and poultry products. The appropriate number of samples within a test set for a given product are collected from an establishment over successive days, with the plan (or goal) of one sample being collected each day of operation. For example, for a facility processing young chicken carcasses, 51 samples would be collected on 51 successive days when the establishment is slaughtering poultry. FSIS inspection personnel verify that establishments are meeting the standards by collecting randomly selected product samples and submitting them to one of three FSIS laboratories for *Salmonella* analysis, according to procedures described in Appendix E of the PR/HACCP Final Rule: *Federal Register*, Vol. 61, No. 144, pp. 38917-38928.

Depending on frequency of production, product type, and availability of resources, the time to complete a set ranges from two months to over a year. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time. FSIS considers *Salmonella* verification testing a direct indicator of the effectiveness of process control in a poultry slaughter establishment. Percent positive in the most recent *Salmonella* sample set is used as an indicator of process control. Annual reports summarizing results for calendar years are available on the FSIS Web site.

In response to increasing *Salmonella* levels in young chicken plants from 2002 to 2004, FSIS began a program in July 2006 to categorize establishments based on *Salmonella* set performance. FSIS found that establishments with samples at or less than 50% of the standard do so with remarkable consistency and predictability. Conversely, FSIS found that establishments with higher percent positive results show much greater variability and inconsistency in their sample results (71 FR 9773). Accordingly, establishments are placed in one of three categories to reflect their level of process control. Category 1 establishments are those with two consecutive sets at less than or equal to 50 percent of the performance standard or guidance for its product class and represent consistent process control. An establishment that has completed only one set (that is greater than 50 percent without exceeding the performance standard or guidance) or that has one most recent or two consecutive *Salmonella* sets at greater than 50 percent of the performance standard or guidance for its product class without exceeding it, is considered to have variable process control and is placed in Category 2. (At present an establishment that has completed only one set at or below 50 percent of the performance standard or guidance will not be categorized until a second set is completed; FSIS is developing a new category for such establishments.) An establishment that fails a set demonstrates highly variable process control and is placed automatically in Category 3.

Salmonella Serotypes

Isolates of *Salmonella*-positive samples are serotyped at the USDA Animal and Plant Health Inspection Service's National Veterinary Services Laboratories in Ames, Iowa. *Salmonella*

testing and serotype data, along with complementary data from molecular and phenotypic analyses, provide an opportunity to examine the association among serotypes isolated on-farm, from meat and poultry products, and from human cases of salmonellosis.

Some of the more common serotypes isolated from meat and poultry products are rarely isolated from human patients. Conversely, some of the serotypes frequently found in human cases of salmonellosis are not commonly found in meat and poultry products. Serotypes identified from human cases of salmonellosis can also be found in other food and non-food sources.

CDC identifies Typhimurium, Enteritidis, Newport, Javiana, Montevideo, Heidelberg and I 4,[5],12:i:- as the seven most commonly identified *Salmonella* serotypes causing human infection in the United States. Combined, these serotypes accounted for a majority (64 percent) of human infections in the Foodborne Diseases Active Surveillance Network (FoodNet) sites in 2006.

Overview of the Public Health Risk Ranking Algorithm

The purpose of the proposed public health risk ranking algorithm is to separate poultry slaughter establishments into three levels of inspection (LOI) based on indicators of how well an establishment's food safety process control systems are performing (e.g., HACCP activities, in-plant SSOPs, SPS activities, and prerequisite programs). The process has two steps. First poultry slaughter establishments would be separated into three categories based on indicators of the effectiveness of their process control systems. Those levels would be as follows:

- routine inspection (LOI 1)
- focused inspection (LOI 2)
- in-depth inspection (LOI 3)

Then, those establishments in LOI 2 would be further ranked based on their potential public health impact (see page 24 for additional details). For some applications, it would also be necessary to rank establishments in LOI 1. It would not be necessary to rank order establishments in LOI 3 since all establishments in LOI 3 would receive in-depth inspection.

A diagram of the process is presented in **Figure 5**.

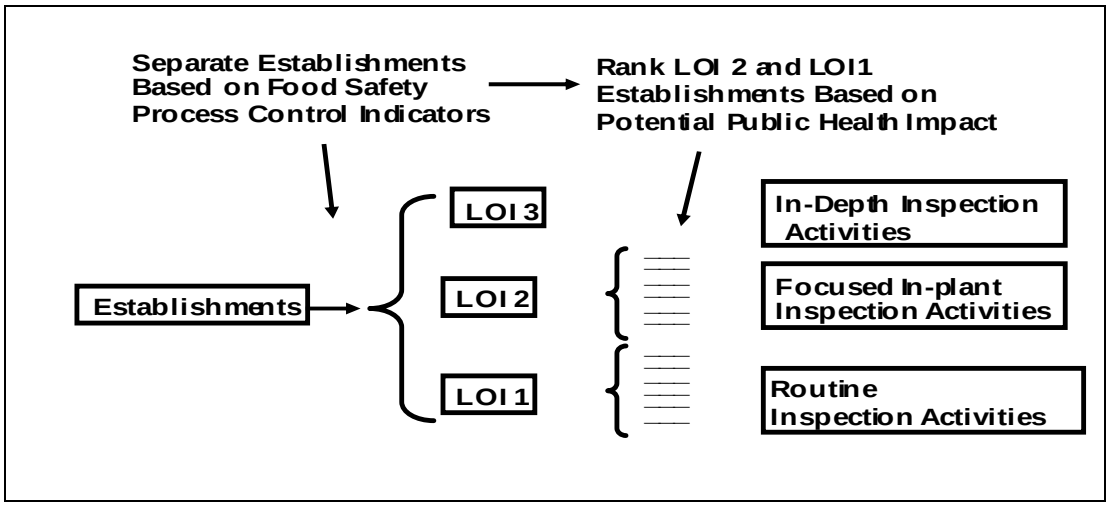

Figure 5. Overview of the Public Health Risk Ranking Algorithm

Levels of Inspection

FSIS' Pathogen Reduction and HACCP Systems final rule mandates measures to target and reduce the presence of pathogenic organisms in meat and poultry products. Those measures include FSIS testing to verify pathogen reduction performance standards are being met, plant microbial testing to verify process control for fecal contamination, written SSOPs, and mandatory HACCP systems in all meat and poultry plants. HACCP provides the framework for industry to maintain science-based process controls to achieve pathogen control.

The algorithm under consideration uses measures of process control to categorize establishments into three LOI, defined as:

- LOI 1—Establishments that have demonstrated they consistently maintain an effective level of food safety process controls. Those establishments would receive a routine or baseline LOI consisting of:
  - routine in-plant inspection, and
  - focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system).
- LOI 2—Establishments with some indication that they may not be maintaining food safety process controls at a level compatible with industry norms. Those establishments would receive an increased LOI consisting of:
  - routine in-plant inspection;
  - focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system); and
  - focused verification activities at vulnerable points on a routine frequency to verify the food safety system is under control

  These LOI 2 establishments would receive a higher priority, relative to LOI 1, for an in-depth FSA.
- LOI 3—Establishments with strong indications that they are not maintaining food safety process controls. Those establishments would receive the highest LOI consisting of:

- routine in-plant inspection;
- focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system);
- focused activities at vulnerable points on a routine frequency to verify the food safety system is under control; and
- performance of an FSA on the establishment and, if justified, intensified verification testing (IVT).

Establishments in LOI 3 would be scheduled for an FSA and would remain in LOI 3 until their FSA results demonstrate they are in compliance or an enforcement action is taken.

Criteria for Poultry Slaughter Establishment to Receive In-depth Inspection (LOI 3)

Slaughter establishments in LOI 3 would be scheduled for an FSA and possibly an IVT to assess the status of the establishment's food safety systems. Any food safety process control issue would be corrected or an enforcement action could be taken. Once a satisfactory FSA is completed and any process control issues are corrected, the establishment would move to LOI 2 if an IVT is ongoing. Once both the FSA and IVT are completed and all other food safety system issues are satisfactory, the establishment would move to LOI 1 or LOI 2 depending on other factors. It would not be intended that establishments remain in LOI 3 for significant periods of time.

LOI 3 poultry slaughter establishments would be those that satisfy ANY of the following criteria.

- Establishment is in *Salmonella* or *Campylobacter** verification testing Category 3.
- Establishment has an enforcement action (i.e., NOIE) or adulterated or misbranded products shipped (captures recalls including those related to human illness).
- Establishment is linked to a foodborne disease outbreak.
- Establishment has sustained structural damage due to a natural disaster or other cause.
- Establishment has a high health-related NR rate (e.g., insanitary dressing, zero tolerance, and residues) relative to other plants producing the same products. The use of public health-related NRs as a criterion is justified through predictive analysis. The window of time over which NRs are looked at is to be determined. The example provided in Box 1 uses 30 days as the window of time and the 97th percentile or above.
- Establishment has a repetitive *Salmonella* serotype of human health concern or PFGE match.**

*This criterion could not currently be applied. FSIS is considering proposing an advisory *Campylobacter* performance standard for poultry slaughter. FSIS may consider a category system for *Campylobacter* as exists currently for *Salmonella*.

**This criterion could not currently be applied. FSIS will begin collecting this data in its new information infrastructure.

Criteria for Poultry Slaughter Establishment to Receive Routine Inspection (LOI 1)

Poultry slaughter establishments in LOI 1 would be those that demonstrate they consistently maintain an effective level of food safety process controls. Those establishments would receive a routine or baseline LOI.

LOI 1 establishments would be those that satisfy ALL of the following criteria.

- Establishment did not have an enforcement action (i.e., NOIE) in the past 4 months or adulterated or misbranded products in commerce in the past 4 months (captures recalls including those related to human illness).
- Establishment is in lower percentile of percent positives on most recent *Salmonella* or *Campylobacter* verification testing sample set, unannounced sampling or other *Salmonella* or *Campylobacter* testing program. State or local or other *Salmonella* or *Campylobacter* testing results will be considered if they are available in new information infrastructure.
- Establishment is in lower percentile of public health-related NR rates (e.g., Insanitary Dressing, Zero Tolerance, Residue) relative to other plants producing the same products. The use of public health-related NRs as a criterion is justified through predictive analysis.
- Establishment has not been confirmed to be linked to a foodborne disease outbreak in the past 6 months.
- Based on history of health-related NR rates (past month), establishment is above the percentile cut-point for LOI 1 percent positives and below the cut-point for LOI 3.
- Establishment is above the lower percentile (LOI 1 cut-point) on most recent FSA score.*
- Establishment is above the lower percentile (cut-point for LOI 1) of scores on focused in-plant verification questions regarding food safety vulnerable points.*
- Establishment is above lower percentile (cut-point for LOI 1) of *Salmonella* serotypes of human health concern or PFGE matches. FSIS will collect this data as part of the *Salmonella Initiative Program.**

* This criterion could not currently be applied. FSIS is considering proposing an advisory *Campylobacter* performance standard for poultry slaughter. FSIS may consider a category system for *Campylobacter* as exists currently for *Salmonella*.

** This criterion could not currently be applied. FSIS will begin collecting this data in its new information infrastructure.

Criteria for Poultry Slaughter Establishment to Receive Focused Inspection (LOI 2)

LOI 2 establishments would be those that are not in the routine (LOI 1) or in-depth (LOI 3) LOI categories. An establishment would belong in LOI 2 if any of the following statements are applicable:

- Based on its history of *Salmonella* testing, the establishment is above the lower percentile cut-off point for LOI 1 for percent positives on most recent sample set, unannounced sampling or other *Salmonella* testing programs.

- The establishment has an enforcement action (e.g., NOIE) or adulterated or misbranded products shipped (captures recalls including those related to human illness) in the past 120 days, for which an FSA has been completed and corrective actions have been verified, but other criteria for LOI 1 are not satisfied.
- The establishment is confirmed to be linked to a foodborne illness outbreak in the past 6 months, for which an FSA has been completed.
- Based on its history of health-related NR rates, the establishment is above the percentile cut-off point for LOI 1 percent positives and below the percentile cut-off point for LOI 3. The use of public health-related NRs as a criterion is justified through predictive analysis. The window of time over which public health-related NRs are looked at is to be determined. The example provided in Box 1 uses 30 days as the window of time, the 97^{th} percentile or above for LOI 3, and the 86^{th} percentile or below for LOI 1.
- The establishment is above the lower percentile (cut-off point for LOI 1) on most recent FSA score.*
- The establishment is above the lower percentile (cut-off point for LOI 1) of scores on focused in-plant verification questions regarding food safety vulnerable points.*
- The establishment is above lower percentile (cut-off point for LOI 1) of *Salmonella* serotypes of human health concern or PFGE matches. FSIS will collect this data as part of the *Salmonella* Initiative Program.**

* This criterion could not currently be applied. FSIS is considering proposing an advisory *Campylobacter* performance standard in the poultry slaughter rule. FSIS may consider a category system for *Campylobacter* as exists currently for *Salmonella*.

** This criterion could not currently be applied. FSIS will begin collecting this data in its new information infrastructure.

Ranking of Poultry Slaughter Establishments by Public Health Impact

After establishments are separated into one of three categories of inspection, the next step would be to rank order establishments in category LOI 2 by potential public health impact. It would not be necessary to rank order establishments in LOI 3 since all establishments in LOI 3 would receive in-depth inspection. For applications other than inspection, it may be necessary to also rank establishments in LOI 1. Establishments in LOI 1 and 2 would be ranked according to pathogens and product type. Specifically, a separate list of rankings would be developed for *Salmonella*, *E. coli* O157:H7, *L. monocytogenes*, *Campylobacter*, and a fifth category of establishments that are not susceptible to any of those specific pathogens. Those five lists could be combined into an overall ranking of the LOI 2 establishments based on public health impact. The ranking process is described below.

First, all LOI 1 and 2 establishments would be ranked by public health impact. The process would be as follows:

- For a specific product (e.g., ground beef, broilers), compute the product fractional volume = Vi / ∑Vi for an establishment i, where Vi is the volume of the product produced by establishment i, and ∑Vi is the total volume of the product produced by all establishments.
- Obtain the foodborne disease attribution for pathogen-product class (e.g., intact chicken consumption causes about 10 percent of all *Salmonella* illnesses – see Appendix A).
- The potential public impact from an establishment producing the pathogen-product pair is then estimated as the product of the fractional volume times the pathogen-product pair attribution.
- If the establishment produces more than one product with the same pathogen of concern, select the maximum potential public impact.

Second, the ranked establishments would be sorted into one of four pathogen categories—*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and *Campylobacter*—or placed in a fifth category of establishments not susceptible to any of those pathogens. For each pathogen category, the upper and lower 50th percentile would be placed into two separate groups, called LOI 2a and LOI 2b, respectively. Depending on FSIS priorities (e.g., performance standards, seasonality), the cut-off point for establishing LOI 2a and LOI 2b may be amended for specific pathogens.

Algorithm Verification

Using young chicken slaughter as an example, values for the parameters of the ranking algorithm, under consideration were assembled, and the algorithm was applied to separate young chicken slaughter establishments into three LOI. The parameters are discussed below.

Young Chicken Slaughter Establishments

A dataset of the 195 young chicken slaughter establishments receiving FSIS inspection and *Salmonella* verification testing in 2007was assembled for purposes of this analysis.

Salmonella Verification Testing

In July 2006, FSIS began a program to categorize establishments based on *Salmonella* set performance, as described on page 17. Establishments are placed in one of three categories to reflect their level of process control. In order to be placed in Category 1, an establishment must show consistent process control by having two consecutive sets at less than or equal to 50 percent of the performance standard or guidance for its product class. An establishment that has completed only one set (that is greater than 50 percent but without exceeding the performance standard or guidance) or that has one most recent or two consecutive *Salmonella* sets at greater than 50 percent of the performance standard or guidance for its product class without exceeding it, is considered to have variable process control and is placed in Category 2. (At present an establishment that has completed only one set at or below 50 percent of the performance standard or guidance will not be categorized until a second set is completed; FSIS is developing a new category for such establishments.) An establishment that fails a set

demonstrates highly variable process control and is placed automatically in Category 3. As of December 2007, 74 percent of broiler establishments are in Category 1, 24 percent in Category 2, and only 2 percent (three establishments in total) are in Category 3. The three young chicken slaughter establishments in *Salmonella* verification Category 3 would be placed in LOI 3.

In addition to the *Salmonella* category, the distribution of scores (percentages) on the most recent *Salmonella* verification sample set across 195 young chicken slaughter establishments was used as an indicator to separate establishments in LOI 1 from LOI 2. The *Salmonella* verification testing on the 2007 sample set range from 0.0 percent to 52.9 percent, with a mean of 7.6 percent (see **Table 1**). As can be seen in Table 1, the mean (7.6 percent) of the distribution lies in the 3rd quintile. More than twelve percent (12.4 percent) of the establishments had 0.0 percent positives.

Table 1. Distribution of *Salmonella* Percent Positives in the 2007 Sample Set for Young Chicken Slaughter Establishments

	1st Quintile	2nd Quintile	3rd Quintile	4th Quintile	5th Quintile
Salmonella Rate (Percent)	0.0–1.96%	1.96–3.9 %	3.9–7.8%	7.8–11.8%	11.8–529%

W3NR Rate

The distribution of scores (percentiles) on the public health-related regulatory noncompliance rates (W3NRs) over the most recent month across 195 young chicken slaughter establishments was used as an indicator to separate establishments into LOI 1, LOI 2, and LOI 3. The distribution of W3NR rates for establishments from November 21–December 21, 2007, ranged from 0.0 percent to 11.84 percent, with a mean of 2.54 percent (See **Table 2**). As can be seen in Table 2, the mean (2.54 percent) of the distribution lies in the 4th quintile. Twenty-two percent of establishments (43 establishments) had a 0.0 percent W3NR rates. The cut-point separating LOI 1 from LOI 2 establishments was the 86th percentile; the cut-point separating LOI 2 from LOI 3 was the 97th percentile.

Table 2. Distribution of W3NR Rates in Most Recent Month Available (Nov. 21–Dec. 21, 2007) For Young Chicken Slaughter Establishments

	1st Quintile	2nd Quintile	3rd Quintile	4th Quintile	5th Quintile
W3NR Rate	0.0–0.0%	0.0–0.95%	0.95–2.1%	2.1–3.57%	3.57–11.84%

The two most frequent causes for the issuance of a W3NR at young chicken slaughter establishments are: (1) lack of protection of product during processing, handling, storage, loading, unloading, or transporting [416.4(d)] (3.6 percent of all NRs); and (2) the presence of visible fecal material on carcasses entering the chiller [381.65(e)] (3.3 percent of all W3NRs).

Levels of Inspection

Applying the ranking algorithm and the cut-points discussed above to the 2007 dataset resulted in 9 young chicken slaughter establishments in LOI 3 (4.6 percent), 44 establishments in LOI 2 (22.6 percent), and 142 establishments in LOI 1 (72.8 percent). For those parameters for which distribution information is used, the cut-points used to determine the LOIs were as follows:

LOI 3: The top 3 percent of public health-related NRs (W3NR rates).

LOI 1: The lower 86th percentile of *Salmonella* verification sample sets and the lower 86th percentile on public health-related NRs (W3NR rates).

Those levels could be adjusted to account for resource availability by using different cut-off points for *Salmonella* and W3NR rates.

FSIS would further refine the proposed across establishment algorithm by continuing to analyze the results of the algorithm for different HACCP product categories. FSIS would utilize these findings to refine the criteria in the algorithm.

Box 1. Sample Distribution of Poultry Slaughter Establishments by Level of Inspection (LOI), Calculated Using 2007 Food Safety and Inspection Service Data

Population of Establishments Used in Example

A dataset of the 195 young chicken slaughter establishments receiving FSIS inspection and *Salmonella* verification testing in 2007 was assembled for purposes of this analysis.

Criteria Used

Salmonella Verification Testing

Broiler Establishment Distribution by *Salmonella* Category as of December, 2007:
Category 1: 74%
Category 2: 24%
Category 3: 2% (All of these would be placed in LOI 3.)

Distribution of Salmonella Results

- The distribution of percentages on the most recent *Salmonella* verification test data across 195 young chicken slaughter establishments is used as an indicator to separate establishments into LOI 1 or LOI 2.
- For this example, being in the bottom 96th percentile for *Salmonella* positives on most recent *Salmonella* verification set would place a plant in LOI 1. (Therefore, out of the 195 establishments, 187 would be eligible to be in LOI 1 based on *Salmonella* data.) NOTE – the 96th percentile is used for this example. A different *Salmonella* cut-point may be used for other food categories.

W3NR Rate

- The distribution of scores (percentiles) on the health-related regulatory noncompliance rates (W3NRs) over the most recent month across 195 young chicken slaughter establishments is used as an indicator to separate establishments in LOI 1, LOI 2, and LOI 3.
- For this example, using data from November 21, 2007 through December 21, 2007:

– Being in the top 3rd percentile or above of the W3NR rates would place a plant in LOI 3. (Therefore, out of the 195 establishments, 6 establishments would be in LOI 3 based on W3NR rates.)
– Being in the lowest 96th percentile on W3NR rates would make a plant eligible to be in LOI 1. (Therefore, out of the 195 establishments, 187 would be eligible to be in LOI 1 based on W3NR Rate.)

Other Criteria

- Enforcement actions: For the time period considered, one poultry establishment had an applicable enforcement action.
- Recalls: For the time period considered, no poultry establishment had an applicable recall.
- Linked to an outbreak: For the time period considered, no poultry establishments were linked to an outbreak.
- Natural disasters/structural damage: For the time period considered, no poultry establishments had structural damage due to a natural disaster or other cause.

Resulting Levels of Inspection

- Applying the ranking algorithm and the cut-points discussed above resulted in the following distribution of establishments.

– 9 young chicken slaughter establishments in LOI 3 (4.6 percent)
– 44 in LOI 2 (22.6 percent)
– 142 in LOI 1 (72.8 percent)

Public Health-Related Performance Standards

In order to improve its poultry slaughter inspection, FSIS is considering proposing a number of performance standards directly or indirectly related to public health which would require a change to existing FSIS regulations. Those performance standards would be for *Salmonella, Campylobacter*, septicemic and toxemic animal diseases, and generic *E. coli*. The current food safety standard for fecal contamination would not be changed. Scientific information relevant to those standards is summarized in this section. In addition, FSIS is considering Other Consumer Protections, including standards for non-septicemic and non-toxemic animal diseases and standards of identity for dressing defects. They are discussed in Appendix G. Additionally FSIS is considering amending regulations on chilling and reprocessing.

The Agency has also published a Federal Register Notice (73 FR 4767-4774) announcing new policies for Salmonella Verification Sampling, including establishing the *Salmonella* Initiative Program (SIP). The SIP is a voluntary incentive-based program offering waivers of certain regulatory requirements to meat and poultry establishments. In the program, the participating establishments will sample daily for *Salmonella* and weekly testing for *Campylobacter*, *Salmonella,* and generic *E. coli* at 2 locations (post-chill and rehang). Additionally, monthly enumeration will be required. Also, serotyping and subtyping of positives will be shared collaboratively to compare with CDC. FSIS expects to collect data from this establishment testing to help determine the appropriateness of microbial performance standards under consideration.

Septicemic and Toxemic Animal Diseases

Septicemic and toxemic poultry carcasses are a public health concern because carcasses or parts that exhibit those conditions are likely to contain infectious agents (bacteria, virus, richettsia, fungus, protozoa, or helminth organisms) that could be transmitted to humans. Under current regulations, FSIS inspection program personnel are responsible for condemning all septicemic/toxemic poultry carcasses (§ 381.83). Consistent with current regulations, FSIS is considering proposing that establishments operating under the new system meet a performance standard for zero septicemic or toxemic poultry carcasses before the chilling tank, and that establishments address the hazard of septicemic or toxemic conditions in their HACCP plans.

Generic E. coli

Under current regulations, each official establishment that slaughters poultry must sample whole carcasses and test for generic *E. coli* at the end of the chilling process or, if that is impractical, at the end of the slaughter line. Generic *E. coli* are enteric bacteria found in the intestines of animals, associated with fecal material. The presence of generic *E. coli* at high levels indicates the presence of intestinal material or filth, and, thus could be used as a measure of sanitation. The presence of *E. coli* above some specific level at the end of the chilling process or the end of the slaughter line could be a means to verify sanitary conditions. FSIS, therefore, is considering having poultry slaughter establishments meet new performance standards for generic *E. coli*, reflecting sanitary conditions.

More specifically, FSIS is considering requiring establishments to measure generic *E. coli* at two points in the process: at re-hang and at post-chill. The frequency of this testing by establishments

would be the same as in FSIS current regulations (CFR 9 381.94 (a)). The number of samples would be divided between the two sampling points. Performance standards would be specified for measured levels of generic *E. coli* at post-chill. Advisory levels would be specified at the reduction of levels (on the logarithmic scale) between the rehang and post-chill locations. Although a performance standard for generic *E. coli* is not a direct indicator of pathogen levels, it does reflect sanitation; consequently, public health benefits are expected because achieving compliance with generic *E. coli* performance standards is expected to cause changes in process controls in some establishments, which in turn could reduce pathogens.

To define the performance standards and to estimate the relationships of changes of generic *E. coli* levels with changes in pathogens levels or incidence, FSIS, with the Agricultural Research Service, conducted a study of 20 establishments to determine: (1) generic *E. coli* distributions, for the purpose of developing the *E. coli* performance standard (sanitation); and (2) the relationship of levels and reductions in the levels of generic *E. coli* with corresponding levels or incidences and reductions of these in *Salmonella* and *Campylobacter*. A summary of analyses of the data and further explanation of the performance standards are presented in Appendix H.

FSIS is currently conducting a baseline study in young chickens in which the incidence and levels of generic *E. coli*, *Salmonella* and *Campylobacter* are being measured both at rehang and post-chill. As those and other data become available, further analyses, including a risk assessment, will be conducted to ensure that the distributions and correlations seen in the Agricultural Research Service study are consistent. The information collected from this survey might aid in estimating potential benefits from setting and enforcing generic *E. coli* performance standards.

Salmonella and Campylobacter

Under the improved inspection system, FSIS is considering advisory performance standards for pathogens, specifically *Salmonella* and *Campylobacter*, and making testing by establishments mandatory. As outlined in FSIS' *Progress Report on Salmonella Testing of Raw Meat and Poultry Products, 1998–2006* (FSIS 2006), as part of the *Salmonella* verification testing program, performance standards were set for the prevalence of *Salmonella* on certain raw meat and poultry products, including poultry. The standards were established relative to national estimates of the prevalence of *Salmonella* contamination by product class. Prevalence estimates were derived from nationwide baseline studies of *Salmonella* conducted during the 1990s, prior to the implementation of PR/HACCP. Compliance procedures were established such that, based on a set of samples collected and analyzed by FSIS, when an establishment operates at the baseline prevalence, it has an 80 percent probability of passing the criterion. The performance standards and guidance materials that FSIS published are, thus, expressed in terms of the maximum number of *Salmonella*-positive samples per set rather than target prevalence. For poultry with a target *Salmonella* prevalence of 20 percent, the number of samples in a sample set and the maximum number of positive samples to satisfy the criterion are 51 and 12 respectively. In an effort to drive continuous improvement in *Salmonella* levels, FSIS plans to reevaluate that performance standard when data are available from the young chicken baseline study currently underway.

The young chicken baseline study currently underway is also measuring the incidence and levels of *Campylobacter*. Once available, FSIS plans to use the data to propose an advisory performance standard for *Campylobacter*. The data will also be used in future FSIS risk assessments.

ENFORCEMENT STRATEGY FOR POULTRY SLAUGHTER INSPECTION IMRPOVEMENTS

Enforcement for zero septicemia, zero toxemia performance standard:

Inspection program personnel issue a noncompliance record (NR) for each carcass they find with fecal matter or with septicemia or toxemia at or after the carcass inspection station, as described in Table 3. If FSIS found that the establishment failed to meet any of those performance standards and also failed to take corrective actions or took inadequate corrective actions, FSIS would initiate enforcement under the rules of practice (9 CFR Part 500). If the establishment did not comply with those performance standards and failed to take corrective actions or took inadequate corrective actions, FSIS could take a withholding action or suspension with prior notification because the HACCP system may be inadequate.

Enforcement for the Sanitation Control Performance Standard for Generic E. coli

The Poultry Products Inspection Act (PPIA) has recognized that sanitary conditions in establishments are critical to the safety and wholesomeness of the products yielded. Any product found to have been "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health" is adulterated. No product will be granted inspection or marked "inspected and passed" unless sanitary conditions and practices required by the Secretary are maintained. Only products found not to be adulterated may be marked "inspected and passed;" products may not be distributed for food use without the affirmative determination that they are not adulterated.

Generic *E. coli* are enteric bacteria, found in the intestines of animals. Therefore, the presence of *E. coli* at high levels indicates a substantial presence of intestinal material, which is filth. Because it is associated with intestinal materials, FSIS is proposing that *E. coli* levels be a measure of sanitation. Under 21 USC 453(g) (4) of the PPIA, the term "adulterated" is defined to include poultry products that have been "prepared, packed or held under insanitary conditions whereby (they) may have become contaminated with filth, or whereby (they) may have been injurious to health"

If establishments fail to meet the sanitation control performance standard for generic *E. coli*, they would be required to take corrective actions as they would do under the HACCP plan or SSOPs. If, through FSIS testing, the post-chill standard is exceeded, FSIS would write an NR. FSIS would initiate enforcement under the Rules of Practice (9 CFR 500). The statutory basis is Section 7(a) and Section 4(g)(4) of the PPIA. If establishments fail to meet this performance standard, this noncompliance will indicate that establishments have not maintained adequate sanitary practices to prevent the entry into, flow, or movement in commerce of poultry products that are adulterated. Table 3 summarizes the enforcement strategy for generic *E. coli*.

Testing for Salmonella by the Establishment

FSIS is considering revising the regulations [381.94 (b)] to require establishment testing for *Salmonella* in the improved inspection system. FSIS is also considering that the *Salmonella* standards would be published in *Federal Register* notices to be updated as new information and data become available (e.g., new national baseline). Table 3 summarizes the enforcement strategy for *Salmonella* that FSIS is considering.

Table 3. Enforcement Strategy for Poultry Slaughter Inspection Improvements

HACCP Septicemic /Toxemic Carcasses	• 9 CFR 417 • Rules of Practice (9 CFR 500) • Enforcement on individual carcass defect (NR for individual defect) • Statutory basis: Adulteration [Section 4(g)(1) of the PPIA]
Generic *E. coli* Testing by Establishment	• Revised 9 CFR 381.94(b) • Rules of Practice (9 CFR 500) • Enforcement of requirement to test and meet standard • Failure of establishment to test and meet standard will result in NR • Statutory basis: Adulteration [Section 7(a), Section 4(g)(4) of the PPIA] • Unannounced sampling by FSIS
***Salmonella* and *Campylobacter* Testing by Establishment**	• Revised CFR 381.94 • If not meeting standard increase frequency of testing and corrective actions; share pathogen isolates or molecular patterns with FSIS Unannounced sampling by FSIS
Sanitation SOPs/SPS (may include vulnerable points)	• 9 CFR 416 • Rules of Practice (9 CFR 500) • Enforcement on sanitation process control (NR if process out of control) • Statutory basis: Adulteration [Section 7(a), Section 4(g)(4) of the PPIA]

Key: CFR=*Code of Federal Regulations*; FSIS= Food Safety and Inspection Service; HACCP= Hazard Analysis and Critical Control Points; NR=noncompliance record/report; PPIA=Poultry Products Inspection Act; SPS=Sanitation Performance Standards; SSOPs= sanitation standard operating procedures.

If the establishment fails to meet the advisory standards, it would be required to take corrective actions, including intensifying their testing and sharing pathogen isolates or their molecular patterns with FSIS until control is regained.

Testing for Campylobacter by the Establishment

FSIS is considering revising the regulations [381.94 (b)] to require establishment testing and meeting standards for *Campylobacter* in the improved poultry slaughter system. The *Campylobacter* standards to be met would be published in *Federal Register* notices to be updated as new information and data become available (e.g., new national baseline).

If the establishment does not meet the advisory standard, it would be required to take corrective actions, including intensifying their testing and sharing pathogen isolates or their molecular patterns with FSIS until control is regained, as shown in Table 3.

Sanitation SOPs and SPS, may include vulnerable points

The PPIA has recognized that sanitary conditions in establishments are critical to the safety and wholesomeness of the products yielded. Any product found to have been "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health" is adulterated. No product will be marked "inspected and passed" unless sanitary conditions and practices required by the Secretary are maintained. Only products found not to be adulterated may be marked "inspected and passed;" products may not be distributed for food use without the affirmative determination that they are not adulterated.

FSIS does not intend that an inspector write an NR based on a single observation or a non-regulatory condition at a vulnerable point. Rather, the Agency intends that sufficient evidence is needed to show that an establishment is not employing adequate controls, as evidenced by vulnerable point and other inspection findings. If such evidence is found, then the establishment might be failing to maintain sanitary conditions (9 *Code of Federal Regulations* [CFR] 416.1) or failing to implement Sanitation SOPs (9 CFR 416.13) and might be producing product that is injurious to health as a result. If there is sufficient evidence to demonstrate that an establishment is not executing a prerequisite program identified within the hazard analysis that encompasses one or more of the vulnerable points, then the establishment may be ~~is~~ failing to properly validate that the HACCP plan is functioning as intended (9 CFR 417.4 [a]). This, in turn, may bring into question whether supporting documentation for decisions in the hazard analysis is adequate (9 CFR 417.5 [a] [1] & [2]), and whether the hazard analysis itself is adequate (9 CFR 417.2). If evidence is sufficient, the findings may possibly bring into question whether the HACCP plan is adequate (9 CFR 417.6 [a]).

EVALUATION AND REFINEMENT OF THE IMPROVED POULTRY SLAUGHTER INSPECTION SYSTEM

Prior to implementation, FSIS would further refine the focused inspection activities and public health risk ranking algorithm under consideration.

To further refine the focused inspection activities FSIS would undertake a methods evaluation that would include a field evaluation and workshop. During the field evaluation FSIS would evaluate the proposed prompts by carrying out focus groups with FSIS field employees and walking through prompt scenarios for different product categories in FSIS regulated establishments. After that initial evaluation, the prompts would be further refined based upon a workshop at which stakeholders (FSIS field employees, academics, industry, and consumer representatives) would play out different prompt scenarios. FSIS would also undertake a historical data analysis to determine the thresholds for the proposed prompts. FSIS would analyze the frequency of prompts for different product types in order to identify anomalies. This analysis would be used as the basis for prompt thresholds.

FSIS would further refine the proposed public health risk ranking algorithm by continuing to analyze the results of the algorithm for different HACCP product categories. FSIS would utilize those findings to refine the criteria in the algorithm. FSIS would also evaluate the ranking of FSIS establishments by the proposed algorithm in relationship to significant public health events

to improve the algorithm's ability to predict and prevent significant public health events, such as recalls. In addition, FSIS would continue to develop methods to refine its attribution estimates by working with CDC and FDA to incorporate sporadic illness and serotype information.

Prior to implementation of poultry slaughter inspection improvements, FSIS would develop its evaluation plan. The plan would include the types of outcome analyses to be conducted. The results of those analyses would be used to refine the inspection system. Outcome analysis has a role in program evaluation work, and seeks to measure how well a program achieves its designed objectives. The stated goals of most (though not all) FSIS programs are expressed in terms of improvements in public health, such as reductions in foodborne illness. Given the difficulty of measuring changes in foodborne illness—especially attributable to a given type of food, Agency program, or establishment(s)—intermediate outcomes, such as changes in pathogen prevalence or changes in product recalls, are typically articulated and measured in lieu of direct public health outcomes. FSIS would evaluate the slaughter inspection improvements in terms of the Healthy People 2010 goals using the performance measures discussed in Appendix A.

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