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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 381 and 500

[Docket No. FSIS-2011-0012]

RIN 0583-AD32

Modernization of Poultry Slaughter Inspection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing a new inspection system for young chicken and turkey slaughter establishments that would replace the current Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), and the New Turkey Inspection System (NTIS). The Agency is also proposing several changes that would affect all establishments that slaughter poultry other than ratites, regardless of the inspection system under which they operate. This proposed rule is a result of the Agency's 2011 regulatory review efforts conducted under Executive Order 13563 on Improving Regulation and Regulatory Review.

DATES: Comments must be received by [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit relevant comments on the implementation of this proposed rule. The Agency specifically requests comment on whether it should phase-in the implementation of this proposed rule to provide additional time for small and very small establishments to adjust their operations to comply with the new requirements. If commenters believe that a phased implementation would mitigate the impact of this rule on small and very small establishments, FSIS requests comments on how the Agency can make the phased implementation most effective.

Comments may be submitted by either of the following methods:

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

• *Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Docket Clerk, Patriots Plaza 3, 355 E. Street SW, 8-163A, Mailstop 3782, Washington, DC 20250-3700. *Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2011–0012.

Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8 a.m. and 4:30 p.m., Monday through Friday.

All background documents referenced in this proposed rule are available for viewing by the public on the FSIS Website at: http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp

or in the FSIS docket room.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–3700, (202) 720–2709.

SUPPLEMENTARY INFORMATION:

Executive Summary

In January 2011, President Obama issued Executive Order (E.O.) 13563 on Improving Regulation and Regulatory Review. As part of this E.O., agencies were asked to review existing rules

that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them accordingly. FSIS is proposing to modernize poultry slaughter inspection as a result of its 2011 regulatory review efforts conducted under E.O. 13563. The Agency is taking this action to improve food safety and the effectiveness of poultry slaughter inspection systems, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources.

FSIS is proposing a new inspection system for young chicken and turkey slaughter establishments. The new inspection system would replace the current Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), and the New Turkey Inspection System (NTIS). Under this proposed rule, establishments that slaughter young chickens or turkeys would have to choose whether to operate under the traditional inspection system or under the proposed new inspection system. FSIS is proposing to limit the number of online inspectors in the traditional inspection system to two.

Key elements of the new inspection system include: (1) requiring establishment personnel to conduct carcass sorting activities before FSIS conducts online carcass inspection so that only carcasses that the establishment deems likely to pass

inspection are presented to the carcass inspector; (2) reducing the number of online FSIS carcass inspectors to one per line; (3) permitting faster line speeds than are permitted under the current inspection systems it replaces; and (4) removing the existing Finished Product Standards (FPS) and replacing them with a requirement that establishments that operate under the new system maintain records to document that the products resulting from their slaughter operations meet the regulatory definition of ready-to-cook poultry.

The proposed new inspection system may facilitate the reduction of pathogen levels in poultry products by permitting FSIS to conduct more food safety related offline inspection activities, will allow for better use of FSIS inspection resources, and will lead to industry innovations in operations and processing.

In addition to the New Poultry Slaughter Inspection System, FSIS is proposing changes to its regulations that will apply to all establishments that slaughter poultry other than ratites, regardless of the inspection system under which they operate. Because contamination by enteric pathogens and fecal material are hazards reasonably likely to occur in poultry slaughter operations unless they are addressed in a sanitation standard

operating procedure (SOP) or other prerequisite program, the Agency is proposing that all poultry slaughter establishments develop, implement, and maintain, as part of their HACCP plans, or sanitation SOPs, or other prerequisite programs written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller. FSIS is also proposing to require that all poultry slaughter establishments develop, implement, and maintain, as part of their HACCP plans, or sanitation SOPs, or other prerequisite programs written procedures to prevent contamination of carcasses and parts by enteric pathogens (e.g., Salmonella and Campylobacter) and fecal material throughout the entire slaughter and dressing operation. FSIS is proposing that, at a minimum, these procedures must include sampling and analysis for microbial organisms at the pre-chill and post-chill points in the process to monitor process control for enteric pathogens. FSIS is proposing to remove the current requirement that poultry establishments test for generic E. coli and to remove the codified Salmonella pathogen reduction performance standards for poultry.

Finally, FSIS is proposing to amend its regulations to provide for the use of certain poultry slaughter technologies that have been demonstrated to be successful through waivers of

the existing regulations, thus ending most current waivers. FSIS is proposing to remove the chilling requirements for ready-to-cook poultry, which now provide specific time and temperature parameters, and to require that establishments incorporate procedures for chilling poultry into their HACCP plans, or sanitation SOPs, or other prerequisite programs. This will give establishments greater flexibility to determine what chilling process is best suited to prevent outgrowth of pathogens on carcasses immediately after slaughter operations. The Agency is also proposing to permit poultry slaughter establishments to use (1) approved online reprocessing antimicrobial systems or (2) offline reprocessing antimicrobial agents including chlorinated water containing 20 ppm to 50 ppm available chlorine or other antimicrobial substances that have been approved as safe and suitable for reprocessing poultry. Establishments would be required to address the use of online or offline reprocessing of poultry in their HACCP plans, or sanitation SOPs, or other prerequisite programs.

Statutory Authorities

FSIS inspects and regulates the production of poultry prepared for distribution in interstate commerce under the authority of the Poultry Products Inspection Act (PPIA) (21

U.S.C. 451 et seq.). 21 U.S.C. 455(b) provides that the Secretary shall cause to be made by inspectors post-mortem inspection of the carcass of each bird processed, and at any time reinspection as he deems necessary of poultry and poultry products capable of use as human food. 21 U.S.C. 455(c) requires that all poultry carcasses and other poultry products found to be adulterated be condemned. Carcasses and parts that may be reprocessed to be made not adulterated are not required to be condemned if they are reprocessed under the supervision of an inspector and thereafter found to be not adulterated (21 U.S.C. 455(c)). Under the PPIA, a poultry product is adulterated, among other circumstances, if it bears or contains any poisonous or deleterious substance that may render it injurious to health; it is unhealthful, unwholesome, or otherwise unfit for human consumption; it was prepared, packaged, or held under insanitary conditions whereby it may have been rendered injurious to health; or if damage or inferiority has been concealed in any manner (21 U.S.C. 453 (g)(1),(3), (4), and (8)). Finally, 21 U.S.C. 463(b) provides that the Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of the PPIA. FSIS regulations and inspection programs are designed to verify that poultry products are unadulterated, wholesome, and properly marked, labeled, and packaged.

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a. Background

I. BACKGROUND

A. Poultry Slaughter Inspection Systems under Existing Regulations

1. Description of Inspection Systems under Existing Regulations

Under current regulations, FSIS employs four inspection systems for poultry other than ratites[1]: the Streamline Inspection System (SIS), the New Line Speed Inspection System (NELS), the New Turkey Inspection System (NTIS), and traditional inspection.[2] SIS, NELS, and NTIS are employed in official poultry slaughter establishments that utilize automated evisceration systems. Traditional inspection is typically employed at smaller, lower product volume establishments that eviscerate carcasses by hand. Automated evisceration allows establishments to run at faster line speeds than is possible when the carcasses are eviscerated by hand. Under all of the current inspection systems, the inspection process consists of online post-mortem inspection and offline reinspection.

[1] Ratites, including ostriches, can grow to exceed 600 lbs and typically weigh as much as 350 lbs when slaughtered. They are slaughtered and inspected under a system that is more similar to red meat than other poultry species. This rule would not affect ratite inspection.

[2] SIS, NELS, and NTIS are codified at 9 CFR 381.76; traditional inspection is codified at 9 CFR 381.67 and 381.76(a).

In all four of the existing inspection systems, one or more FSIS online inspectors inspect every carcass, with its viscera, at a fixed point along the slaughter and evisceration line immediately following the separation of the viscera from the interior of the carcass (9 CFR 381.76(b)). They examine each eviscerated carcass for visual defects and direct establishment employees to take appropriate corrective actions if the defects can be corrected through trimming or reprocessing. The online inspectors also identify and condemn carcasses with septicemic and toxemic animal diseases, which cannot be corrected through trimming or reprocessing. Establishment personnel then dispose of the condemned carcasses under FSIS supervision.

Under each of the existing inspection systems, establishments conduct no carcass sorting to determine which eviscerated carcasses appear eligible to bear the mark of inspection, which carcasses contain removable defects correctable through trimming or reprocessing, and which carcasses must be condemned because of septicemic and toxemic animal diseases. Rather, the existing regulations require establishments to assign a helper to take such actions as directed by the online post-mortem inspector after the inspector has conducted the initial sorting activities (9 CFR 381.76(b)).

Thus, under the existing inspection systems, establishments rely on FSIS online inspection personnel to effectively control and direct their processing. Moreover, because FSIS online inspectors are responsible for identifying unacceptable carcasses and parts, it takes online inspectors more time to conduct a carcass-by-carcass appraisal than would be necessary if establishments sorted and trimmed carcasses before they were inspected.

In addition to post-mortem inspection conducted by the online inspector, the existing inspection systems consist of reinspection activities conducted by offline inspectors (9 CFR 381.76(b)). During reinspection, FSIS inspectors apply various trim and processing standards, referred to as Finished Product Standards (FPS), designed to verify that the slaughter and evisceration process is under control (9 CFR 381.76(b)(3)(iv)(*c*). This is done by examining ten bird sample sets to determine compliance with the FPS. Under traditional inspection, all trim defects (e.g., breast blisters, bruises, fractures, and scabs) identified by the online carcass inspector must be removed at the online inspection station. Processing defects (e.g. ingesta, cloaca, and feathers) may be corrected further down the line, subject to reinspection. Under SIS, NELS,

and NTIS, all reinspection is conducted at separate reinspection stations located either before and after the chiller (SIS; 9 CFR 381.76(b)(3)(iv)(*a*)), or before the chiller only (NELS and NTIS; 9 CFR 381.76(b)(4)(i)(*b*) and 381.76(b)(5)(i)(*b*)).

In addition to applying the trim and dressing standards under FPS, offline inspection also consists of such food safety related activities as verifying Hazard Analysis Critical Control Point (HACCP) critical limits, verifying the effectiveness of sanitation SOPs, and collecting samples for pathogen testing.

2. Limitations of Current Inspection Systems under Existing Regulations and Need for Improvement

Traditional inspection is generally sufficient for low product volume establishments that operate at relatively slower line speeds; however, SIS, NELS, and NTIS are lacking in two important respects. First, they obscure the proper roles of industry and inspection personnel by assigning to FSIS online inspectors responsibility for sorting acceptable product from unacceptable product, finding defects, identifying corrective actions, and solving production control problems. Second, they require FSIS to allocate significant inspection personnel resources towards inspection activities to detect defects and conditions that present minimal food safety risks, thus limiting

the resources available for more important food safety-related inspection activities.

One limitation of the existing inspection systems is that they require online inspectors to conduct sorting activities. This necessitates a time-intensive online process that requires FSIS to allocate significant personnel resources to conduct activities that are more appropriately the responsibility of the establishment. The current systems thus limit line speeds, even if establishments can demonstrate that they are able to produce safe, unadulterated, wholesome products at more efficient rates. It also limits establishments' incentive to improve their processing methods and to develop more efficient slaughter and dressing technologies.

For example, under SIS, an establishment operating under optimal processing conditions is limited to line speeds of 35 carcasses per minute with one online inspector per line and 70 carcasses per minute with two online inspectors per line. Although NELS allows for a slightly faster maximum line speed – 91 birds per minute under optimal processing conditions – it requires three online inspectors per line. And under NTIS, an establishment operating under optimal processing conditions is limited to processing 32 light birds per minute with one online

inspector per line and 51 light birds per minute with two online inspectors per line. For heavy birds, those speeds decrease to 25 birds per minute and 45 birds per minute, respectively.

FSIS is proposing a new inspection system to improve food safety and the effectiveness of inspection systems, reduce the risk of foodborne illness in the United States, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources. If establishment personnel sorted the carcasses and took necessary corrective actions before the carcasses were presented for inspection, the online inspectors could be stationed later in the process and would be presented with carcasses that have fewer defects. Such a system would allow the online inspector to conduct a more efficient inspection, a carcass-by-carcass critical appraisal, to determine whether each carcass is not adulterated and therefore eligible to bear the mark of inspection. As a result, FSIS could assign fewer inspectors to online inspection, freeing up Agency resources to conduct offline inspection activities that are more important for food safety, such as verifying compliance with sanitation and HAACP requirements, or conducting Food Safety Assessments.

Moreover, the existing poultry slaughter inspection systems were designed before FSIS issued its HACCP regulations and began targeting its resources to address public health risks associated with foodborne pathogens. The existing systems were developed when visually detectable animal diseases were more prevalent and considered to be more of a concern than they are today. The line speed limits prescribed in SIS, NELS, and NTIS reflect the Agency's previous focus on the detection of visible defects and animal diseases and do not give establishments the flexibility to develop new technologies that would allow for a more efficient approach to address these conditions. For example, while FSIS inspectors are required to inspect and condemn carcasses for visual defects at one point in the slaughter process, poultry slaughter establishments could be given more flexibility to develop procedures to identify and condemn unacceptable carcasses and parts earlier and at various points in the slaughter and production process. An inspection system that provides flexibility for establishments to detect and remove visible defects and animal at point in the process before the carcasses are presented to the FSIS inspector would permit establishments to operate at faster line speeds if they are able to maintain process control.

Another limitation with SIS, NELS, and NTIS is that they focus substantial FSIS inspection resources on detecting visible trim and dressing defects that are less important to food safety, particularly in light of what is now known about the role microbial contamination plays in causing foodborne human illness. These inspection models need to be updated in light of the significant advances that have been made in the control or eradication of many animal diseases that were more prevalent and were considered to present a greater concern when the existing inspection systems were designed, particularly in generally healthy classes of animals such as young chickens.

Moreover, the analysis in the risk assessment conducted by FSIS suggests a significant correlation between increased unscheduled offline inspection services and lower levels of Salmonella and Campylobacter in young chicken and turkey slaughter establishments. This analysis indicates that reallocating inspection resources currently dedicated to online inspection under the existing inspection systems to offline, food safety related inspection activities, such as increased HACCP verification, sanitation SOP verification, pathogen sampling, and Food Safety Assessments, could potentially reduce pathogen levels. Additionally, FSIS could devote more resources

to inspection activities that focus on the areas of greatest risk in the poultry production system if establishments were required to assume greater responsibility for monitoring compliance with trim and dressing performance standards.

B. Regulations for Microbiological Testing under the Existing Inspection Systems

1. Generic E. coli Criteria for Measuring Process Control

The current regulations require that official poultry slaughter establishments conduct regular testing for generic Escherichia coli (E. coli) at the end of the chilling process or at the end of the slaughter line as a means to verify process control (9 CFR 381.94(a)). These regulations prescribe requirements for collecting the samples, obtaining analytical results, and maintaining records of such results (9 CFR 381.94(a)(2),(3), and (4)). They also include criteria for evaluating an establishment's generic E. coli testing results (9 CFR 381.94(a)(5)). The regulations provide that generic E. coli testing results that do not meet the criteria described in the regulations indicate that the establishment may not be maintaining process controls sufficient to prevent fecal contamination (9 CFR 381.94(a)(6)). If an establishment is not meeting the E. coli test results criteria, the regulations state

that FSIS will take further action as appropriate to ensure that all applicable provisions of the law are being met (9 CFR 381.94(6)).

In the preamble to the HACCP final rule (61 FR 38806, July 25, 1996), FSIS stated that microbial testing is an essential element for verifying process control of raw meat and poultry. Escherichia coli Biotype 1 (generic E. coli) was selected as the target organism for verifying process control for a variety of reasons, including: A strong association of E. coli with the presence of enteric pathogens and, in the case of slaughtering, the presence of fecal contamination; E. coli occurs at a higher frequency than Salmonella, and quantitative E. coli testing permits more rapid and more frequent adjustment of process control; and there is wide acceptance in the international scientific community of its use as an indicator of the potential presence of enteric pathogens. However, since the implementation of the HACCP final rule, and with respect to young chicken carcasses, the reliability of E. coli as an indicator of process control has been called into question. In its final report adopted February 13, 2004, "Response to the Questions Posed by FSIS Regarding Performance Standards with Particular Reference to Broilers (Young Chickens)," the National Advisory Committee

on Microbiological Criteria for Foods (NACMCF) stated that E. coli may no longer be as useful in broiler operations as originally thought. NACMCF recognized that FSIS viewed E. coli as a direct measure of control of fecal contamination and, by implication, Salmonella or other enteric pathogens. However, NACMCF stated that recent published information indicates that this assumption may not be valid for E. coli in young chickens. For example, in young chickens, its presence may also be a result of infectious process and air sacculitis, in addition to fecal contamination.[3]

Thus, FSIS has tentatively decided to remove the requirement that poultry slaughter establishments test for generic E. coli at post-chill and to allow establishments to use other, more relevant indicators of process control. FSIS is proposing that all poultry slaughter establishments collect and analyze carcass samples for microbiological analysis at the pre-

[3] Gomis, S.M., Riddell, C., Potter, A.A., and Allan, B.J., Phenotypic and genotypic characterization of virulence factors Escherichia coli isolated from broiler chickens with simultaneous occurrence of cellulites and other colibacillosis lesions. Can J Vet Res. 2001 Jan; 65(1):1-6.

Russell, S. M., *The effect of airsacculitis on bird weights, uniformity, fecal contamination, processing errors, and populations of* Campylobacter *spp. and Escherichia coli.* Poult. Sci. 2003; 82:1326-*1331.*

chill and post-chill points in the process. The basis for this decision and a discussion of the proposed testing requirements are set out later in this document.

2. Salmonella Pathogen Reduction/HACCP Performance Standards

In addition to generic E. coli criteria, the existing regulations contain Salmonella pathogen reduction performance standards for certain poultry slaughter establishments and establishments that produce certain raw ground poultry products (9 CFR 381.94(b)). The codified performance standards are based on the prevalence of Salmonella found by the Agency's nationwide microbiological baseline studies, which were conducted before the PR/HACCP rule was adopted. The regulations provide for FSIS to collect and analyze unannounced Salmonella samples sets in poultry slaughter establishments to detect whether these establishments are meeting the pathogen reduction performance standards (9 CFR 381.94(b)(2)). The performance standards set a maximum number of Salmonella-positive samples allowable per sample set and are defined on a product class basis so that an establishment operating at the baseline level would have an 80 percent chance of meeting the standard. Establishments are required to take corrective actions when FSIS determines that

they are not meeting the performance standards (9 CFR 381.94(b)(3)(i) and (ii)).

Under the regulations, an establishment's failure to take the corrective actions necessary to comply with the Salmonella performance standards, or an establishment's failure to meet the standards on the third consecutive series of FSIS-conducted tests for that product, constitutes a failure to maintain sanitary conditions and to maintain an adequate HACCP plan (9 CFR 381.94(b)(3)(iii)). The regulations provide that such failure will cause FSIS to suspend inspection services (9 CFR 381.94(b)(3)(iii)). However, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in Supreme Beef Processors, Inc. v. USDA. In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the Salmonella performance standards. Since that time, FSIS has used Salmonella failures as a basis to conduct an in-depth evaluation of the establishment's food safety systems, including its HACCP plan and sanitation SOPs.

In 2006, after an intensive review of the results of several years of Salmonella testing that showed a trend of increasing prevalence of Salmonella in young chicken

establishments, FSIS established three establishment performance categories for Salmonella based on the codified performance standards ("Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection," 71 FR 9772-9777, February 27, 2006). The new performance Category 1 represented the best performing establishments and was defined as no more than half of the regulatory standard. Category 2 was set at more than half but not exceeding the regulatory standard. Category 3 establishments were exceeding the regulatory standard and represent the worst performing establishments.

When FSIS announced the new performance categories, the Agency explained that it intended to track the performance of the different product classes it samples for Salmonella and publish on the FSIS Website the names of establishments in Categories 2 and 3 for any product class that did not have 90 percent of its establishments in Category 1. FSIS began publishing the names of young chicken establishments in Category 2 and 3 in March 2008. FSIS has continued to publish the names of these establishments on or about the 15th of each month since then.

Since it established the new Salmonella performance categories, FSIS has updated the year-long Nationwide Microbiological Baseline Data Collection Programs to better

measure improvements in pathogen reduction in all classes of raw product. Young chicken and young turkey microbiological baselines were completed in 2008 and 2009, respectively. On May 14, 2010, in response to a charge from the President's Food Safety Working Group, the Agency announced that it had developed new performance standards for Salmonella and Campylobacter for chilled carcasses in young chicken and turkey slaughter establishments based on the new baseline results ("New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments," 75 FR 27288).

On March 21, 2011, FSIS published a Federal Register notice to announce the forthcoming implementation of the new performance standards for Salmonella and Campylobacter ("New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule," 76 FR 15282). In the Federal Register notice, FSIS announced, among other actions, that Web-posting of young chicken and turkey establishments that fail the new Salmonella standards ("Category 3") for their last set will begin as sample sets scheduled for July 2011 are completed. In that notice, the Agency also explained that "[t]hese new Salmonella standards are to be applied to sample sets from establishments included in the

Agency's Salmonella Verification Program in the place of the performance standards for young chicken (as broilers) codified at 9 CFR 381.94 and the standards for young turkeys announced in a Federal Register Notice of 1995." FSIS also stated that "[t]he Agency intends to issue a proposed rule that would formally rescind the codified standards that are no longer in effect" (76 FR 15282).

Therefore, FSIS is proposing to eliminate the pathogen performance standard regulations in 9 CFR 381.94(b). FSIS can effectively address Salmonella through the actions discussed above and through the Salmonella Initiative Program described below.

C. Waivers of Regulatory Requirements

1. Regulations Providing for the Administrator to Waive Provisions of Inspection Regulations

The regulations in 9 CFR 303.2(h) and 381.3(b) provide for the Administrator to waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate definite improvements. Under these regulations, FSIS may only grant waivers from the provisions in the regulations

that are not in conflict with the purposes or provisions of the FMIA or PPIA (9 CFR 303.1(h) and 381.3(b)).

FSIS decides whether to grant requests for waivers based on proposals and documentation submitted by establishments to demonstrate that the use of a new technology is scientifically sound; that it will facilitate definite improvements; and that issuing the waiver will not conflict with the provisions of the FMIA or PPIA.[4] If FSIS determines that the information submitted by an establishment supports the requested waiver, the Agency will waive the appropriate provisions in the regulation for a limited period of time to allow the establishment to conduct an in-plant trial. The purpose of the in-plant trial is to gather data on the effects of the use of the new technology. FSIS reviews the data that is developed in the trial to determine whether they establish that the purpose of the waiver is being met.

Several poultry slaughter establishments are operating under waivers that allow them to use technologies that are not provided for in the regulations. As of April 2011, for example, FSIS had granted waivers to 144 poultry slaughter establishments

[4] For Agency New Technology waiver procedures, see http://www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp.

to allow these establishments to conduct online re-processing of poultry carcasses and parts accidentally contaminated with digestive tract contents. As discussed in detail later in this document, the current regulations only provide for reprocessing of accidentally contaminated poultry at a designated offline reprocessing station (9 CFR 381.91). Under the Salmonella Initiative Program (SIP)(76 FR 41186, July 13, 2011), the Agency has also granted six poultry slaughter establishments waivers from the specific time and temperature chilling requirements prescribed in 9 CFR 381.66. Any establishment that has been granted a waiver for on-line reprocessing, or any other slaughter process, and is continuing to operate under that waiver, must now participate in SIP and conduct testing as discussed in greater detail below.

The data generated from the in-plant trials conducted under the online reprocessing waivers and the waivers from the time and temperature chilling requirements have demonstrated that the technologies used in these studies have been successful and yielded definite improvements.(See "FSIS Analysis of On-line and Off-line Reprocessing Systems," available for viewing by the public in the FSIS docket room and on the FSIS Web site at: http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.) Therefore, FSIS is proposing to amend the regulations to provide

for the use of these technologies, which would end the need for these waivers. The proposed amendments are described under the headings “Proposed Changes to Time and Temperature Requirements for Chilling” and “Proposed Changes to Online and Offline Reprocessing Regulations,” below.

All establishments operating under waivers from any regulatory requirements, not just waivers for OLR and time and temperature regulations, will be participating in the Salmonella Initiative Program (SIP), described below. Thus, the SIP would continue after any final rule resulting from this proposal becomes effective.

2. The FSIS Salmonella Initiative Program (SIP)

Under SIP, meat and poultry slaughter establishments receive waivers of regulatory requirements on condition that they will conduct regular microbial testing and share the resulting data with FSIS. The Agency described preliminary details of SIP in a January 28, 2008, Federal Register notice (73 FR 4767-4774) and announced its final terms and conditions in the July 13, 2011, Federal Register notice (76 FR 41186). SIP benefits public health in that it encourages slaughter establishments to conduct testing for microbial pathogens, which is a key feature of effective process control, and to respond to

testing results by taking steps when necessary to regain process control. In addition, SIP enables FSIS to use establishment data to inform Agency policy aimed at enhancing public health protection.

SIP establishments test for Salmonella, Campylobacter (if applicable), and generic E. coli or other indicator organisms and share all sample results with FSIS. Establishments currently operating under regulatory waivers must participate in SIP or forfeit their waivers. All establishments operating under waivers will continue to operate under a SIP waiver and will continue to conduct testing under SIP if their waivers are not addressed in the final rule resulting from this proposal.

II. CONSIDERATION OF NEED FOR A NEW POULTRY SLAUGHTER INSPECTION SYSTEM

A. Early Development of the Inspection Models Program

In 1996, FSIS published its PR/HACCP final rule as the first step of a comprehensive initiative to target the Agency's resources to address the public health risks associated with foodborne pathogens, which cannot be detected by organoleptic inspection (61 FR 38868). Under FSIS's PR/HACCP regulations, establishments are required to develop and implement a system of preventive controls to ensure that their products are safe. This

approach gives establishments more flexibility to determine how they can best meet the Agency's regulatory requirements. FSIS verifies the adequacy and effectiveness of establishments' HACCP systems.

The existing poultry slaughter inspection systems were developed before HACCP was implemented and require that FSIS inspectors sort carcasses and direct establishments' corrective actions, rather than requiring establishments to sort, trim, and reprocess carcasses before they are inspected by FSIS. In 1997, in order to improve food safety and the effectiveness of inspection systems, reduce the risk of foodborne illness in the United States, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources, FSIS announced, in a Federal Register notice, that the Agency would be developing a new HACCP-based inspection models project (62 FR 31553). During the HACCP-based inspection models project, FSIS would design and test various new inspection models in a series of trials in volunteer meat and poultry slaughter establishments.

Under the initial inspection models approach, establishment personnel were responsible for identifying and removing normal from abnormal carcasses and parts, and FSIS inspection personnel

performed inspection activities that focused on the areas of greatest risk in the poultry products inspection system in each establishment.

In 1998, the American Federation of Government Employees, several FSIS inspectors, and a public interest organization filed a suit to enjoin FSIS from implementing the HACCP-based inspection model project ("HIMP"). The plaintiffs alleged that HIMP violated the requirement in the PPIA that government inspectors conduct a post-mortem inspection of each poultry carcass. Specifically, the PPIA provides that the Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post-mortem inspection of the carcass of each bird processed (21 U.S.C. § 455(b)). The district court upheld HIMP, finding that the word "inspection", as used in the statute, does not necessarily mandate a direct, physical examination of each carcass and that the model program was a rational policy judgment within the discretion afforded to the Secretary.

The plaintiffs appealed and the Court of Appeals for the District of Columbia Circuit reversed the district court's decision. The Court found that the PPIA requires Federal inspectors-rather than plant employees-to make the decision

about whether each carcass is adulterated within the meaning of the statute. The case was remanded to the district court for further proceedings.

In response to the Court of Appeals' opinion, FSIS modified HIMP to position one inspector at a fixed location near the end of the slaughter line in each poultry slaughter establishment. This inspector was responsible for examining each poultry carcass for adulteration after the carcasses had been eviscerated, sorted, washed, and trimmed by establishment employees, but before the carcasses entered the chiller. The modified models project also included FSIS off-line inspectors who were responsible for conducting HACCP and sanitation system verification activities and for closely examining a sample of carcasses for food safety defects to ensure that the establishment's process was under control and that adulterated birds were not getting past the establishment sorters. On remand, the district court found that HIMP, as modified, complied with both the applicable statutory provisions and the opinion issued by the Court of Appeals.

The plaintiffs again appealed to the Court of Appeals for the D.C. Circuit. Plaintiffs argued that the modified inspection procedures were not in compliance with the Court of

Appeals' opinion because FSIS had delegated some inspection duties to plant employees who were responsible for sorting defective carcasses and making preliminary decisions regarding adulteration. The court rejected this argument, finding that the PPIA does not prohibit plant employees from paring down the overall number of carcasses by sorting and removing carcasses before they reach the Federal inspector. The Court held that because the modified inspection model program required Federal inspectors to personally examine each poultry carcass leaving the slaughter line, FSIS was in compliance with the PPIA's requirement that "the carcass of each bird processed" be inspected for adulteration.

Plaintiffs also argued that the line speeds allowed in the HIMP plants were too fast to allow Federal inspectors to make a critical appraisal of each carcass. The Court found that FSIS's decision to allow higher line speeds was reasonable in light of the fact that establishment employees are required to sort defective carcasses prior to Federal inspection, resulting in fewer adulterated poultry carcasses being presented for Federal inspection. The Court also noted that although the PPIA delineates what must be inspected and by whom, it does not tell the reader exactly what an inspection is. The court concluded

that HIMP, as modified, reflected a reasonable design of an inspection system by the agency charged with responsibility for administering the PPIA and that it would rely on the agency's experience and informed judgment in evaluating the validity of the system under the law. Under these circumstances, the Court of Appeals upheld HIMP, as modified.

B. Existing HACCP-Based Inspection Models Program[5]

The revised HACCP-Based Inspection Models Project (HIMP) was initiated in 20 young chicken slaughter establishments and 5 turkey slaughter establishments on a waiver basis.

Under HIMP, post-mortem inspection, referred to simply as "carcass inspection," is conducted by a single online carcass inspector who visually inspects every carcass at a fixed location on the evisceration line immediately prior to the chiller. Carcass inspection takes place after establishment personnel have already sorted the eviscerated carcasses, disposed of carcasses that they have identified as having condemnable conditions, and conducted any trim and reprocessing they believe necessary to correct removable defects. Carcass inspection is conducted much more efficiently and effectively

[5] For a description of the performance standards used during the HIMP pilot, see Appendix A.

under HIMP than under the existing inspection systems because establishment personnel have already sorted, trimmed, and reprocessed the carcasses, thereby removing most visible defects, before the online carcass inspector appraises them.

Under HIMP, offline inspection is referred to as “verification inspection.” Verification inspection consists of system verification activities through which FSIS continuously monitors and evaluates establishment process control. FSIS conducts more offline, food safety related verification inspection activities under HIMP than under the existing inspection systems. Some examples of verification inspection activities include: HACCP, sanitation SOP, and other prerequisite program verification procedures, including verification checks specifically for septicemia and toxemia and for fecal contamination; verifying sanitary dressing requirements at multiple points in the inspection system; and sample collection for pathogen testing.

FSIS has concluded that the HIMP model has a number of benefits, such as focusing FSIS inspection personnel on the areas of greatest risk in the poultry production system and providing an incentive to establishments to improve and

innovate, while ensuring effective online inspection at line speeds of 175 birds per minute.

C. Analysis of HIMP

1. FSIS Evaluation of HIMP

FSIS has conducted a comprehensive analysis of data collected from the operation of HIMP in young chicken slaughter establishments and has prepared a written report (the "HIMP Report") that presents a thorough evaluation of the models tested. Based on this evaluation, FSIS has concluded that compared to inspection at non-HIMP establishments, HIMP has improved the safety of poultry products and increased overall consumer protection while still ensuring carcass-by-carcass inspection of each eviscerated carcass.

A detailed summary of the HIMP Report is provided below. The full HIMP Report is available for viewing by the public in the FSIS docket room and on the FSIS Website at: http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.

Prior to beginning HIMP, an independent consulting firm, Research Triangle Institute (RTI) conducted baseline organoleptic and microbiological data collection in 16 young chicken slaughter establishments that volunteered to participate

in the HIMP program. These baseline collection results reflect the performance of pre-HIMP poultry slaughter inspection systems and provided the basis to establish HIMP performance standards for septicemia and toxemia, for fecal contamination, and for five other consumer protection (OCP) concerns (see Appendix A for information about these performance standards). Prior to finalizing the standards, RTI conducted the same data collection after HIMP was implemented in 16 establishments and found improvement in various aspects of establishment performance after implementation of the HIMP system. The HIMP performance standards were finalized in November 2000. To participate in the program, establishments operating under HIMP are required to maintain process control plans to meet the performance standards for food safety and non-food safety OCP defects. The HIMP performance standards are a measure for comparing the performance of establishments operating under the new HIMP inspection system with performance when operating under the current non-HIMP inspection systems.

Following entry of a total of 20 young chicken slaughter establishments into the HIMP program, in 2002, FSIS collected FSIS verification data that show that HIMP establishments exceeded the performance standards for food safety and all but

one of the OCP standards. The HIMP Report contains the most recent data showing that the HIMP establishments continue to meet the HIMP performance standards. The HIMP Report also evaluates other measures to compare HIMP establishment performance with non-HIMP establishment performance. Therefore, based on these results, HIMP establishments have consistently performed better under HIMP than they did under non-HIMP inspection systems.

a. Overview of HIMP Report

The HIMP Report describes FSIS's microbiological and inspection findings in young chicken slaughter establishments participating in HIMP and compares them with the HIMP performance standards or with comparison sets of non-HIMP establishments. The first comparison set of establishments was a subset of 64 non-HIMP establishments selected to be comparable to HIMP establishments with respect to total slaughter volume, line speeds, and geographic distribution. The second comparison set was all 176 non-HIMP establishments that slaughtered young chickens in all 5 years considered in the study. The evaluation is based on data for the calendar years CY2006 through CY2010, with exceptions where only more recent data are available.

Across HIMP and non-HIMP establishments, analyses compared the number of offline inspection procedures, the rates of health-related regulatory noncompliances, fecal contamination noncompliances, and Salmonella positive rates. FSIS evaluated offline inspection procedures to determine whether comparable levels of inspection are being performed in HIMP establishments compared to non-HIMP establishments. FSIS looked at the other data to evaluate whether the HIMP system resulted in public health benefits and continued to ensure that FSIS inspected each carcass presented for inspection.

b. Inspection of Each Carcass by FSIS Inspectors to Determine Whether the Carcass is Not Adulterated and therefore Eligible to Bear the Mark of Inspection

The HIMP Report evaluates the ability of the FSIS online carcass inspector (CI) to detect carcasses affected with septicemia/toxemia and visible fecal contamination after the establishment has sorted the carcasses but before the carcasses enter the chiller. The purpose of this analysis is to demonstrate that even though CI’s in HIMP plants are presented with an extremely low number of carcasses affected with septecimia/toxemia and visible fecal contamination, they are

still able to detect carcasses with these visible food safety defects.

Data collected from April 1, 2009, to March 31, 2011, show that the CI in HIMP establishments found 125 carcasses affected with septicmia/toxemia and 26,815 carcasses with visible fecal contamination. The HIMP Report calculates the CI detection rates for both of these food safety defects by dividing the number of carcasses affected with them by the total number of carcasses presented to the CI inspector. For septicemia/toxemia, the CI detected affected carcasses at a rate of 0.000004 percent or 4 per 100 million carcasses slaughtered. For visible fecal contamination, the CI detected affected carcasses at a rate of 0.0009 percent or 9 per million carcasses slaughtered. The levels of these diseases and fecal contamination that are presented to the CI can be measured by the results of the FSIS off-line verification of the HIMP performance standards. Verification checks are conducted by the FSIS verification inspector (VI) before the CI and after the establishments has sorted the carcasses. The findings of those verification checks show that fewer than 8 per 1 million carcasses (0.0008 percent) processed in HIMP establishments were found to have septicemia/toxemia and that fewer than 0.8 per thousand carcasses (0.08 percent) processed in HIMP establishments were

found to have visible fecal contamination. These rates were lower than the HIMP performance standards of 0.1% carcasses for septicemia/toxemia and 0.8% carcasses for visible fecal contamination.

Therefore, levels of these diseases and fecal contamination presented to the CI are very low in HIMP establishments. Nevertheless, the CI in HIMP establishments further reduces the number of carcasses with septicemia, toxemia, or visible fecal contamination, thereby reducing food safety defects to levels lower than found in non-HIMP establishments. In conclusion, the most recent data demonstrates that the CI in HIMP establishments is able to identify carcasses affected with septicemia, toxemia, and visible fecal contamination.

c. Verification by Offline Inspectors of the Establishment Executing its HIMP Process Control Plan under which Establishment Employees Sort Acceptable and Unacceptable Carcasses and Parts

Because fewer inspectors are required to conduct online carcass inspection in HIMP establishments, FSIS inspection personnel are able to perform more offline food safety inspection activities. The HIMP study focuses on 11 offline inspection procedures identified by codes that apply to all poultry slaughter establishments. FSIS chose to focus on these

procedures because they are all related to food safety or production of wholesome product (with minimal defects). These inspection procedures determine the type of inspection activities that FSIS personnel perform to verify compliance with specific regulatory requirements. The 11 inspection procedure codes considered in the HIMP study are associated with procedures that FSIS inspection personnel perform to:

- Verify an establishment's compliance with the sanitation SOP regulations in 9 CFR 416.11-416.16 (procedure codes 01A01, 01B01, 01B02, 01C01, 01C02);
- Verify compliance the HACCP regulations in 9 CFR part 417 (procedure codes 03A01, 03J01, 03J02);
- Verify compliance with relevant regulations for finished product standards (FPS) and good commercial practices (procedure code 04C04);
- Verify compliance with generic E. coli testing requirements under 9 CFR 381.91 (procedure code 05A01); and
- Verify compliance with the Sanitation Performance Standards regulations in 9 CFR 416.1-416.6 (procedure code 06D01).

The HIMP Report compares the ratio of each inspection procedure performed per young chicken slaughter establishment for HIMP and non-HIMP establishments. The comparison shows that

in CY2010, FSIS offline inspection personnel performed 1.6 times more offline inspection procedures in HIMP establishments than in non-HIMP establishments. These procedures include verifying compliance with both OCP- and food safety-related regulations. This increased level of offline inspection activities ensures that HIMP establishments are maintaining OCP and food safety defects at levels that are less than in non-HIMP establishments and thereby producing a safer product.

Table 1 below presents the findings for each inspection procedure code.

Table 1 CY2010 Ratios of Inspection Procedures per Establishment in HIMP to Non-HIMP

Procedure Code	**20 HIMP Establishments (Procedures/Establishment)[6]**	**64 Non-HIMP Comparison Establishments (Procedures/Establishment)**	**HIMP/Non-HIMP Ratio**
Total	14135.9	8723.7	1.6
Sanitation SOP verification procedures			
01A01	3.4	3.7	0.9

01B01	140.3	148.7	0.9
01B02	98.0	110.9	0.9
01C01	259.2	272.5	1.0
01C02	294.8	299.0	1.0
HACCP verification procedures			
03A01	2.5	1.9	1.3
03J01	10296.1	3027.5	3.4
03J02	287.0	259.4	1.1
FPS and good commercial practices verification procedures			
04C04	2612.3	4447.4	0.6
Generic E. Coli testing verification procedures			
05A01	0.2	1.3	0.2
Sanitation Performance Standards verification procedures			
06D01	142.2	151.5	0.9

The number of 04C04 inspections in HIMP establishments appears to be less than in non-HIMP establishments. However, the number of 04C04 inspection procedures in HIMP and non-HIMP establishments is not directly comparable since they are counted differently. In HIMP establishments, during this procedure, a minimum of 2 OCP 10 bird sample sets are conducted in a single shift and are counted as a single 04C04 inspection procedure.

In non-HIMP plants, each 10 bird sample set is counted as a separate 04C04 inspection procedure.

d. Verification of the Establishment Executing its Sanitation SOPs and its HACCP System under 9 CFR parts 416 and 417

(1) Offline Inspection Procedures Performed

The Sanitation SOP regulations in 9 CFR 416 and the HACCP regulation in 9 CFR 417 are among the regulations most strongly related to public health. There are eight inspection procedures associated with activities that FSIS inspectors perform to verify compliance with the Sanitation SOP and HACCP regulations. These are the inspection procedures with codes in the 01 series and 03 series presented in Table 1 above. The HIMP Report found that in CY2010, FSIS inspectors performed approximately 2.8 more offline procedures to verify compliance with Sanitation SOP and HACCP regulatory requirements than inspectors did in non-HIMP establishments.

The HIMP Report also compares the rate at which inspectors in HIMP establishments performed the HACCP 3J01 procedure in HIMP establishments to the rate performed in non-HIMP establishments. The inspection activities under the 03J01 procedure include random verification of all HACCP requirements, and over 90 percent of these activities involve verifying an

establishment's compliance with FSIS's zero tolerance for visible fecal contamination. The HIMP Report found that in CY2010, inspectors in HIMP establishments performed 3.4 more 03J01 procedures overall than inspectors in non-HIMP establishments (see Table 3 above). These data show that under HIMP, compared to non-HIMP inspection systems, inspectors are able to spend more time in prevention-oriented inspections, which better protects the public from foodborne disease. This increased level of inspection ensures that HIMP establishments continuously satisfy food safety performance standards and HACCP regulations and are maintaining OCP- and food safety defects at levels that are less than in non-HIMP establishments and thereby producing a safer product.

(2) Public Health Related Non-Compliances

For purposes of data analysis and for targeting FSIS resources, FSIS categorizes each of its regulatory requirements based on how strongly non-compliance with that regulation could adversely affect public health. The categories are ranked from zero to three, and the FSIS regulations that are most strongly related to public health are classified as category 3 regulations. Category 3 regulations are those that if in non-compliance are most likely to endanger public health. A non-

compliance record or “NR” associated with a category 3 regulation is classified as a “W3 Non-compliance Record” or “W3NR.” These are also referred to as “health-related” NRs.

The HIMP Report summarizes and compares the health-related NR rates by inspection procedure for HIMP and the control set of non-HIMP establishments for the 5 years of combined CY2006 to CY2010 data. The health-related NR rate for an inspection procedure is calculated by dividing the total number of health-related NRs associated with that inspection procedure by the total number of inspection procedures performed under that inspection procedure. The comparison shows that health-related NR rates at HIMP establishments are not statistically different or are statistically lower for all inspection procedures considered. This information is presented in Table 2 below. These data demonstrate that HIMP establishments are satisfying all food safety, HACCP, and sanitation regulations designed to insure that establishments are producing safe product and wholesome products.

Table 2: Five Year Average Health-Related NR Rates for HIMP and Non-HIMP Broiler Establishments

Proc	HIMP Broiler	Non-HIMP Comparison

Code	Establishments	Broiler Establishments
01A01	0.00%	0.09%
01B01	0.21%	0.28%
01B02	1.33%	1.33%
01C01	0.38%	0.39%
01C02	1.27%	1.27%
03A01	0.00%	0.39%
03J01	0.90%*	1.41%
03J02	0.67%	0.75%
05A01	0.00%	0.00%
06D01	0.02%	0.03%

* indicates a statistically significant difference at the 0.05 level.

(3) Fecal Contamination: NRs Associated with Fecal Contamination

The HIMP Report analyzes NR rates for visible fecal contamination in HIMP and non-HIMP comparison establishments for CY2006 to CY2010. Because visible fecal contamination is a hazard reasonably likely to occur, poultry slaughter establishments address visible fecal contamination in their HACCP plans. The visible fecal NR rate was computed as the total number of fecal contamination NRs divided by the sum of the number of the HACCP verification 03J01 and 03J02 procedures

performed. This comparison found that fecal NR rates in HIMP establishments are statistically lower than those in both the control set of non-HIMP establishments and the all non-HIMP comparison set for all the years considered (see Table 3 below). This means that the rate of visible fecal material contamination in HIMP establishments is about half that of non-HIMP establishments. Thus, establishments operating under the HIMP inspection system had lower rates of visible fecal contamination than establishments operating under non-HIMP inspection systems. In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Based on these data, HIMP establishments likely have lower levels of pathogens than non-HIMP establishments. The fecal NR rates are presented in Table 3 below.

Table 3: Fecal NR Rates at HIMP and Non-HIMP Comparison Establishments

	HIMP	**Non-HIMP Comparison Establishments**	**All Non-HIMP Establishments**
2006	0.70%	1.10%	1.07%
2007	0.59%	1.21%	1.17%

2008	0.67%	1.25%	1.26%
2009	0.65%	1.25%	1.20%
2010	0.73%	1.49%	1.40%

Additional analysis conducted on the fecal NR rates in HIMP and non-HIMP establishments shows that that fecal NR rates in HIMP establishments are independent of production volume.

The HIMP Report also evaluates the effect of line speeds on fecal NR rates and found no statistical difference in either total fecal NR counts or fecal NR rates between establishments with different line speeds.

e. Verification of the Outcomes of the Establishment Process Control Plan, both Organoleptic and Microbiologic

(1) Food Safety Performance Standards

As discussed above, for the HIMP study, FSIS developed food safety performance standards for septicemic/toxemic animal conditions and visible fecal contamination. These performance standards allow the Agency to compare performance between HIMP and non-HIMP establishments in meeting the zero tolerance standard for these conditions. The HIMP Report compares the

findings of the offline FSIS verification inspectors (VIs) for the 2-year period April 1, 2009, to March 31, 2011, with the HIMP performance standards. The HIMP Report calculates the FSIS offline VI detection rates for carcasses affected with septicemia/toxemia or contaminated with visible fecal material by dividing the number affected carcasses identified by the VIs by the total number of carcasses examined by the VI. The total number of carcasses examined by VIs in HIMP establishments is 4 times greater than the number examined by offline inspectors in non-HIMP establishments.

The findings of the VIs verification checks show that fewer than 8 per 1 million carcasses (0.0008 percent) processed in HIMP establishments were found to have septicemia/toxemia. This rate is 125 times lower than the HIMP performance standard of 0.1% of the carcasses processed. The data also show that fewer than 0.8 per thousand carcasses (0.08 percent) processed in HIMP establishments were found to have visible fecal contamination, which is about 19 times lower than the HIMP performance standard. These findings are presented in Table 4 below.

Table 4: HIMP Achievement of Food Safety Performance Standards at Young Chicken Establishments

Defect Categories	HIMP Performance Standards (% of	HIMP Establishment Performance Based on

	carcasses)	FSIS Offline Inspector Verification Checks (% of carcasses)
Septicemia/Toxemia	0.1%*	0.0008% (± 0.002%) Range 0.0 – 0.008%
Visible fecal contamination	1.5% *	0.08% (± 0.05%) Range 0.008 – 0.17%

***** FSIS has a zero tolerance policy for Septicemia/Toxemia and Visible Fecal Contamination

Period of data collection: April 1, 2009 through March 31, 2011

(2) OCP Performance Standards

As discussed in the appendix to this proposal, FSIS developed OCP performance standards based on a tightening of the existing FPS for removable animal diseases and trim and dressing defects. The OCP performance standards allow the Agency to compare the performance of HIMP and non-HIMP establishments in

addressing these non-food safety defects. The Agency collected data on the number and type of OCP defects identified by the FSIS offline VIs from January 1, 2009, through December 31, 2010, and compared them with the corresponding OCP HIMP performance standard. A comparison of young chicken HIMP establishment performance with OCP HIMP performance standards is presented in Table 5 below.

Table 5: HIMP Achievement of OCP Performance Standards at Young Chicken Establishments

	Performance Standards Based on Non-HIMP Inspection (% of carcasses)	HIMP Establishment Performance Based on FSIS Inspector Verification Checks (% of carcasses)
OCP 1 Condition-Animal Diseases (e.g., airsacculitis)	1.7%	0.38% (± 0.36%) Range 0.0-1.25%
OCP 2 Condition-Miscellaneous (e.g., bruises, sores, and other processing defects)	52.5%	34.1% ± 9.3% Range 18.2- 49.9%
OCP 3 Contamination-Digestive Content (non-fecal)	18.6%	6.3% ± 4.3% Range 0.25 – 15.2%

(e.g., ingesta)		
OCP 4 Dressing Defects-Other (e.g., feathers)	80.0%	66.4% ± 10.4% Range 41.2 – 80.2%
OCP 5 Dressing Defects-Digestive Tract Tissue (e.g., bursa, cloaca)	20.8%	9.8% ± 4.0% Range 3.2 – 15.8%

Period of data collection: CY2009 through CY2010

The data show that OCP defects identified on carcasses processed in HIMP establishments average about half the corresponding OCP HIMP performance standard. The analysis found no statistically significant difference in OCP2 – OCP5 rates between HIMP establishments with different line speeds. This shows that these establishments are effectively addressing OCP standards.

(3) Salmonella Positive Rates

The HIMP Report compares the Salmonella percent positive rates for HIMP young chicken slaughter establishments and the control set of 64 non-HIMP establishments for the years CY2006 to CY2010. This comparison is presented in Table 6.

Table 6: Salmonella Percent Positive Rates for HIMP and Non-HIMP Broiler Establishments

	2006	2007	2008	2009	2010
20 HIMP Broiler Establishments	9.0%	5.8%	4.2%	4.9%	4.7%
64 Non-HIMP Comparison Broiler Establishments	10.8 %	8.5%	7.3%	4.3%	4.0%
176 All Non-HIMP Broiler Establishments	11.1 %	8.1%	7.6%	6.8%	4.7%

Analysis of these rates found that in CY2006-CY2008 the Salmonella positive rate in HIMP establishments was statistically significantly lower than in the non-HIMP comparison set and that the difference in CY2009 and CY2010 was not statistically significant. The Salmonella positive rate in HIMP establishments was statistically significantly lower than in the all non-HIMP comparison set for CY2006 to CY2009. There was no statistically significant difference in CY2010, which most likely reflects the effects of the Salmonella initiatives that FSIS implemented in 2006 to reverse the multi-year trend of

persistently higher percent positive rates for Salmonella detected through FSIS's HACCP verification testing each year. As a result of these initiatives, the entire industry was forced to reduce the incidence of positive Salmonella results, particularly those establishments with the highest Salmonella positive rates.

The analysis in the HIMP Report also found that, after adjusting for production volume, the difference in the Salmonella positive rate between establishments with different line speeds is not statistically significant. This analysis is based on the 10 HIMP establishments with Salmonella testing during CY2010. The line speeds for these 10 establishments ranged from annual average of 98 to 162 birds per minute.

f. Conclusion

Based on its evaluation of the HIMP study, FSIS has concluded that establishments operating under the HIMP inspection system performed better than establishments operating under non-HIMP inspection systems with respect to rates of food safety and OCP defects. Also, fecal contamination rates and Salmonella positive rates are lower in HIMP than in non-HIMP establishments. HIMP establishments have higher compliance with sanitation SOP and HACCP prevention regulations. Based on the

data discussed in the HIMP Report, FSIS has concluded that more offline food safety inspections results in greater compliance with sanitation and HACCP regulations and birds with lower levels of fecal and Salmonella contamination. In aggregate, the findings support that the HIMP inspection system results in public health benefits, allows FSIS to conduct inspection more efficiently, and ensures that HIMP inspectors perform in a manner that properly enables them to inspect each carcass.

2. 2001 Government Accountability Office Report on HIMP

On December 17, 2001, the Government Accountability Office ("GAO") issued a report on HIMP entitled "Food Safety: Weaknesses in Meat and Poultry Inspection Pilot Should Be Addressed Before Implementation."[7] The following describes FSIS's current thinking regarding the GAO's 2001 recommendations for executive action that that specifically pertain to elements of this proposed rule. FSIS requests comment on these aspects of the proposed rule.

[7] GAO, 2001. Food Safety: Weaknesses in Meat and Poultry Inspection Pilot Should Be Addressed Before Implementation, http://www.gao.gov/new.items/d0259.pdf

1. GAO recommended that only establishments with a good history of regulatory compliance be eligible to participate in the inspection program.

Response: The GAO recommendation was made in the context of HIMP as a pilot program. The pilot program is now completed and FSIS has conducted a comprehensive evaluation of the HIMP inspection system, which is described in the HIMP Report. Thus, FSIS believes that this gradation among establishments recommended by GAO is no longer relevant to the implementation of the New Poultry Inspection System.

2. GAO recommended that establishments operating under the new inspection system be required to implement statistical process controls to manage and control production and that FSIS monitor and verify the efficacy of these systems.

Response: FSIS believes that statistical process control (“SPC”) systems, which help to determine whether an establishment’s production processes are performing within established performance standards with regard to non-food-safety related defects, are effective tools for establishments to use to manage and control their production. However, instead of specifically mandating the use of SPC in this proposal, FSIS is proposing to allow establishments operating under the new

inspection system to implement the process controls that they have determined will best allow them to produce ready-to-cook poultry that is wholesome and not adulterated. FSIS is proposing that the establishments document that they are meeting the standard for ready-to-cook poultry. Establishments could, but would not be required to, use SPC systems to meet this requirement. FSIS expects that most establishments will choose to use SPC systems as part of their effort to meet this requirement, but the Agency believes that it is more appropriate and more in keeping with HACCP requirements to provide each establishment the flexibility to determine how best to meet the requirement within the context of its unique production environment.

3. GAO recommended that FSIS, in conjunction with industry, develop a training and certification program for establishment sorting activities, and that only trained and certified establishment personnel be permitted to perform these duties.

Response: FSIS agrees that proper training is important to establishment sorters' ability to make accurate decisions on how to address animal disease conditions and trim and dressing defects. If sorters do not make these decisions correctly, inspection personnel will be required to take actions such as

stopping the production line to remove contaminated carcasses, issuing non-compliance records, and directing the establishment to reduce the line speed to ensure that the establishment is able to maintain process control, and that inspectors are able to conduct a proper inspection. Training of sorters is vitally important to ensure that sorting procedures are properly performed. Lack of effective sorter training would cause FSIS to initiate action to ensure that plant employees are properly trained.

FSIS is not proposing to require specific, formalized sorter training. However, FSIS will develop guidance documents to assist establishments in the training of their sorters. The Agency intends to post draft guidance materials on the FSIS Website and announce the availability of such materials in the Federal Register and through the FSIS Constituent Update. The Agency will seek public comment on these draft materials to inform the development of the final guidance documents to ensure they are as useful as possible. The Agency will make the final guidance documents available to the public on the FSIS Website before the final rule resulting from this proposal becomes effective. The guidance that the Agency is planning to develop would be based on the training that FSIS provides to on-line

inspection personnel that are responsible for sorting carcasses under the existing inspection system. Under this proposed rule, establishments would have the flexibility to select the training program that best assist them to meet the requirements of this proposed rule.

D. Public Health Benefits Projected from Allocating More Inspection Resources to Food Safety-Related Inspection Activities

1. Risk Assessment

In June 2011, FSIS completed a quantitative risk assessment to determine how performing a greater number of sanitation, sampling, and other offline inspection procedures in young chicken and turkey slaughter establishments might affect the number of human illnesses from Salmonella and Campylobacter. These offline inspection procedures primarily involve activities that FSIS inspection personnel perform to verify the effectiveness of establishment sanitary operations and other health and safety-related activities. The HIMP Report, discussed above, found that FSIS inspectors performed more offline inspections to verify compliance with Sanitation SOP and HACCP regulations in HIMP establishments than they do in in non-HIMP establishments. The risk assessment is available for

viewing by the public in the FSIS docket room and on the FSIS Web site at: http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.

FSIS developed the risk assessment to help the Agency determine how it could help reduce risks to public health associated with processed poultry by improving its approach to inspection. To give the Agency the information it needed, the risk assessment focused on four risk management questions: (1) Can FSIS redeploy its inspection activities within official establishments without causing an increased prevalence of microbial pathogens in the establishments? (2) Will redeploying inspectors to offline duties have an effect on the prevalence of microbial pathogens, and hence on human illness? (3) Where in a poultry establishment will redeployed inspection activities have the greatest effect in reducing the prevalence of microbial pathogens and thus, in reducing human illness? (4) What is the quantitative uncertainty of the pathogen prevalence and illness reductions?

2. Model

FSIS developed a risk assessment model for examining relationships between current variations in inspection personnel assignments and prevalence of Salmonella and Campylobacter on

young chicken and turkey carcasses and subsequent human illnesses attributable to those pathogens. FSIS paired inspection data with Salmonella and Campylobacter prevalence data for the same establishments and timeframes.[8]

FSIS employed a stochastic simulation model using multi-variable logistic regressions to identify correlations between the numbers of offline food-safety inspection procedures, both scheduled and unscheduled, along with numbers of non-compliances and scheduled-but-not-completed procedures, and contamination of poultry with Salmonella or Campylobacter. (Scheduled procedures are assigned to inspectors at an establishment by the Agency's automated management system. Unscheduled procedures are performed according to inspector needs at an establishment and may include fecal checks for compliance with the zero-tolerance requirement, or they may be a response to unforeseen hazards or unsanitary conditions arising from sanitation SOP failures, or the need to verify corrective actions taken under the

[8] The prevalence of Salmonella on young chickens came from the USDA/FSIS Salmonella PR/HACCP verification testing program from July 2007 to September 2010 and the most recent young chicken baseline study (2007-2008). Data for prevalence of Campylobacter on young chickens came from the young chicken baseline study (2007-2008). Data for inspection procedures performed in an establishment came from the FSIS performance-based inspection system (PBIS) data base (July 2007-September 2010). Data for turkey establishments comprise results of the FSIS "Young Turkey Baseline" (August 2008 through July 2009, 9) and PR/HACCP Salmonella verification program (July 2007 through September 2010).

establishment's HACCP plan.) The correlations were used to predict the effect that devoting more resources to these procedures would have on human illness attributable to the consumption of young chicken. Stochastic simulations were used to account for uncertainty in the estimates relating inspection procedures in an establishment to detection of Salmonella and Campylobacter in poultry. Illness estimates were based on CDC data, and uncertainty distributions were used to account for the variability in annual Salmonella and Campylobacter illnesses and uncertainty about the relationship between the pathogen prevalence levels at the establishments and the corresponding annual number of illnesses that could be attributed to the pathogens.

3. Conclusions of the Risk Assessment

The results of the risk assessment show that redeployment of Agency resources from on-line inspection activities to unscheduled off-line activities to verify compliance with Sanitation SOPs, HACCP requirements, and other requirements that are important to food safety, is correlated with lower prevalence of carcasses contaminated with Salmonella and Campylobacter and may result in a reduction in the number of human illnesses.

Regarding the first risk-management question, the risk assessment showed that establishments with more unscheduled offline inspection activities have lower Salmonella and Campylobacter prevalence than establishments with fewer unscheduled offline activities. The assessment also suggested that there may be fewer illnesses attributable to both Salmonella and Campylobacter when additional unscheduled offline inspection procedures are performed.

In answer to the second risk-management question, the lower prevalence of Salmonella and Campylobacter on poultry at establishments where additional unscheduled offline procedures were performed could lead to as many as 4286 fewer Salmonella-related illnesses and 986 fewer Campylobacter-related illnesses per year. FSIS has estimated that 174,686 expected annual Salmonella illnesses could be attributed to both young chicken and turkey consumption, and an estimated 169,005 expected annual Campylobacter illnesses attributable to young chicken or turkey consumption. Thus, a reduction of 4,286 expected Salmonella illnesses annually, reflects a 2.5% reduction in attributable illnesses. A reduction of 986 expected Campylobacter illnesses annually reflects a 0.6% reduction in attributable illnesses.

Responding to the third question, the risk assessment showed that the greatest effect on Salmonella and Campylobacter prevalence and related illness would occur when inspection activities were concentrated on increased unscheduled off-line procedures. These could include additional unscheduled sanitation procedures, additional unscheduled sampling procedures, or additional unscheduled HACCP procedures.

In answer to the fourth risk-management question, on the uncertainty of the results for pathogen prevalence and illness reductions, FSIS analysts reflected the uncertainty of illness estimates by reporting not only expected values but also the upper and lower bounds of an 80-percent confidence band around the estimates. Thus, for example, they calculated the annual averted Salmonella illnesses to be as few as 1514 and as many as 7682, and the averted Campylobacter illnesses as few as 26 and as many as 2865. Table 7 presents total estimated reductions in human illnesses relating to increased offline inspection procedures.

Table 7: Total potential reductions in annual human illnesses relating to better offline inspection procedure performance in young chicken and turkey slaughter establishments

	What happens if unscheduled offline inspection procedures increase in young chicken and turkey establishments?[1]		
		Confidence Interval	
	Expected value	10th%	90th%
Annual Salmonella illnesses prevented:	4286	1514	7682
Annual Campylobacter illnesses prevented:	986	26	2865

[1] Risk assessment scenario assumes that all unscheduled inspection activities could change by as little as no increase to as much as a 60% increase

III. PROPOSED NEW POULTRY INSPECTION SYSTEM FOR YOUNG CHICKENS AND TURKEYS

A. Replacement of SIS, NELS, and NTIS with the New Poultry Inspection System

Based on the Agency's experience under HIMP and the improved performance related to food safety and non-food-safety standards and especially in reducing pathogen levels, FSIS is proposing to eliminate SIS, NELS, and NTIS and to replace them with the New Poultry Inspection System. All young chicken and

turkey slaughter establishments would be required to operate under either the new inspection system or the traditional inspection system.

Establishments that slaughter classes of poultry other than young chickens and turkeys would be permitted to operate under the New Poultry Inspection System under a waiver through the SIP. FSIS would consider the data collected in poultry slaughter establishments operating under a SIP waiver to determine whether to expand the New Poultry Inspection System to other classes of poultry.

B. Carcass Sorting and Online Carcass Inspection

Under the new inspection system, establishments will be required to sort carcasses, to dispose of carcasses that must be condemned, and to conduct any necessary trimming or reprocessing activities before carcasses are presented to the online FSIS carcass inspector. After these sorting activities have been completed, the online carcass inspector will conduct a carcass-by-carcass inspection before the carcasses enter the chiller. If the online carcass inspector observes any food safety defects on any of the carcasses, such as the presence of septicemic or toxemic animal disease or fecal material, he or she will stop the line to prevent the contaminated carcass from entering the

chiller. Under this new inspection system, the inspector will not restart the line until establishment personnel have removed the contaminated carcass from the line. The online carcass inspector will notify the inspector-in-charge if the presence of excessive food safety related or non-food-safety related conditions, poor presentation of carcass for inspection by the carcass inspector, or other indications that there may be a loss of process control. Under such conditions, the inspector-in-charge will take appropriate remedial action and will be authorized to require that the establishment slow the line speed.

Establishments' responsibility for carcass sorting under the proposed new inspection system would include removing carcasses that exhibit septicemic and toxemic conditions from the processing line. Carcasses that exhibit septicemic and toxemic conditions are likely to contain infectious agents, such as bacteria, virus, richettsia, fungus, protozoa, or helminth organisms, which can be transmitted to humans. For this reason, they present a food safety risk if they are permitted to enter the chiller.

Because establishments operating under the proposed new inspection system would be required to identify and remove

carcasses affected by septicemic and toxemic conditions before FSIS carcass inspection, FSIS is proposing that establishments under the new system address, as part of their HACCP plan, or sanitation SOP, or other prerequisite program, procedures for ensuring that septicemic and toxemic carcasses are prevented from entering the chiller. These procedures must cover, at a minimum, establishment sorting activities for these conditions.

Under this proposal, FSIS would maintain its zero tolerance for septicemic and toxemic carcasses. Carcasses exhibiting septicemic and toxemic conditions would be condemned, if not removed by the establishment, by the online carcass inspector, as under the existing regulations (9 CFR 381.83). A noncompliance record (NR) would be issued for every carcass affected by septicemia and toxemia that reaches the online carcass inspection station. Moreover, because establishments would be required to address this food safety hazard in their HACCP plan, or sanitation SOP, or other prerequisite programs, the Agency continuously would assess the effectiveness of an establishment’s HACCP system if FSIS inspection personnel observed septicemic or toxemic carcasses.

Under the proposed new inspection system, because the online carcass inspector will be positioned immediately before

the chiller and will not conduct a carcass inspection until after sorting, trimming, and reprocessing has been completed by establishment employees, viscera will not be presented together with the carcasses as in the current inspection systems. FSIS has determined that not presenting the viscera will not prevent the online carcass inspector from ensuring that all carcasses are unadulterated and wholesome. With the exception of one condition, i.e., visceral leukosis, observing the outside of the carcass is sufficient to determine whether the carcass should be condemned. Systemically affected carcasses are darker in color from dehydration and hemorrhaging and may be smaller or have less body fat because of inappetence or increased metabolic rate. There may be an obvious cause of the systemic involvement such as a large tumor, bruise, or infected joint. Although observing the viscera provides additional assurance that the decision to condemn is correct and may help determine the specific category for recording the reason for condemnation, observing the viscera is not required to identify the presence of a condemnable condition, with the exception of visceral leukosis.

Avian visceral leukosis can only be detected by observing the viscera. Avian visceral leukosis, a rare manifestation of

the viral disease leukosis, is not transmissible to humans and does not present a human health concern. However, it may render poultry unwholesome or otherwise unfit for human food.

Avian leukosis can be identified by observing the viscera of the first 300 birds of each flock because if avian visceral leukosis is present, it will be present throughout the entire flock. In general, a flock constitutes birds raised under similar circumstances on the same premises. It is common commercial practice to vaccinate each flock of chickens for viral leukosis. Nationwide data from 1984 revealed that all forms of leukosis (skin, visceral, other viral leukoses) resulted in the condemnation of 0.017 percent of the approximately 7.4 billion young chickens slaughtered. On rare occasions, the vaccine is not effective. If it is not, visceral leukosis is present on a flock basis. Accordingly, FSIS is proposing that an offline inspector will observe the viscera of the first 300 birds slaughtered of each young chicken flock under the New Poultry Inspection System to determine whether the disease is present in the flock. FSIS has followed this practice in young chicken HIMP establishments, and it has been shown to be effective. (See HIMP Report, available for viewing by the public in the FSIS docket room and on the FSIS Web site

at: http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp). Turkeys do not typically display liver lesions associate with leukosis, therefore, the 300 bird viscera check is not performed on turkeys.

To allow FSIS to properly inspect viscera for avian leukosis, FSIS is proposing to require that establishments that slaughter young chickens notify the FSIS IIC prior to the slaughter of each new flock. Under this proposed rule, if the inspector identifies a carcass affected with visceral leukosis, he or she may expand the sample beyond 300 birds. The decision to designate a flock as leukosis positive would be made by the FSIS inspector-in-charge (IIC). In case of a positive flock, the IIC would position an inspector to inspect each viscera for visceral leukosis only, at a location where viscera and carcass can be identified together. This activity would be for the duration of the slaughter of the flock.

C. Offline Verification Inspection

In addition to the online carcass inspector, FSIS is proposing that one offline verification inspector be assigned for each evisceration line in establishments operating under the New Poultry Inspection System. As in HIMP, verification

inspectors under the new inspection system will conduct food safety related inspection activities and will continuously monitor and evaluate establishment process control. Verification inspectors will conduct inspection activities including HACCP, sanitation SOP, and other prerequisite program verification procedures; verification checks for septicemia and toxemia, and fecal contamination; checks to verify and ensure that sanitary dressing requirements are being met; ante-mortem inspection; and sample collection for pathogen testing. The offline verification inspector will work with the inspector-in-charge to ensure that food safety related or non-food-safety related conditions do not impair the online carcass inspector's ability to conduct the inspection of each carcass or will notify the inspector-in-charge whenever circumstances indicate a loss of process control. Under such conditions, the inspector-in-charge will take appropriate remedial action and will be authorized to require that the establishment slow the line speed.

D. Finished Product Standards to be Replaced with Requirement that Establishments Maintain Records to Document that the Products Resulting from their Slaughter Operations Meet the Definition of Ready-to-Cook Poultry

1. Establishment Requirements

FSIS is proposing to eliminate SIS, NELS, and NTIS, which would include eliminating the current “Finished Product Standards” (FPS) under 9 CFR 381.76 that address trim and dressing defects. FSIS is proposing to replace these FPS with a requirement that establishments operating under the New Poultry Inspection System document that the products resulting from their slaughter operations meet the definition of ready-to-cook poultry.

FPS are criteria applied to processed birds before and after chill to ensure that the product being produced is consistently wholesome and unadulterated. The FPS address defects that are less important to food safety than conditions such as septicemia/toxemia or visible fecal contamination. However, the conditions addressed in the FPS may render a carcass unwholesome or adulterated.

Ready-to-cook poultry is “… any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down) from which the head, feed crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without giblets, and which is suitable for cooking without need for further processing” (9 CFR 381.1). All

poultry slaughter establishments are required to prepare all eviscerated carcasses as “ready-to-cook poultry” (9 CFR 381.76(a)). Carcasses affected with removable animal diseases or that contain numerous trim and dressing defects are not “suitable for cooking without the need for further processing,” and thus do not meet the definition for ready-to-cook poultry.

Examples of removable animal diseases include airsacculitis, arthritis, ascites, avian leukosis complex, avian tuberculosis, cadaver, enteritis, erysipelas, generalized inflammatory process, generalized keratoacanthomas, neoplasms, nephritis, osteomyelitis, pericarditis, salpingitis, tenosynovitis, and tumors (e.g., carcinoma or sarcoma). Although these conditions are less important to food safety than conditions such as septicemic/toxemic carcasses or visible fecal contamination do, they do render carcasses unwholesome and unfit for human food at levels above those provided for in the regulations. Moreover, under 9 CFR 381.81-90, carcasses and parts affected with these conditions must be condemned unless the condition can be removed.

Examples of trim and dressing defects include extraneous material, such as, feathers, lung, oil gland, trachea, and bile; digestive tract tissue defects, such as bursa of fabricius,

cloaca, crop, esophagus, and intestine; non-fecal digestive content contamination, such as ingesta; and other miscellaneous defects, such as breast blisters, bruises, external mutilation, fractures, overscald, scabs, trimable keratoacanthomas, and localized inflammatory process. Like removable animal diseases, poultry carcasses or parts that contain a large number of trim or dressing defects would not be “suitable for cooking without the need for further processing” and therefore would not meet the definition of ready-to-cook poultry.

As discussed above, under HIMP, removable animal diseases and trim and dressing defects addressed in the FPS are referred to as “OCPs.” There are five categories of OCPs addressing removable animal diseases and various types of trim and dressing defects that account for 29 specific defects addressed under the existing FPS.

To develop the OCP categories FSIS first determined baseline performance levels for establishments operating under the FPS. To do this, a private consulting firm, Research Triangle Institute, collected thousands of samples from 16 young chicken slaughter establishments operating under the existing inspection systems. The sampled carcasses had passed FSIS online inspection, undergone trimming by establishment personnel to

remove visible defects, and been determined by FSIS offline inspectors to be in compliance with the FPS. As such, these carcasses were suitable for cooking without the need for further processing, and thus met the definition of ready-to-cook poultry.

FSIS ranked the 16 establishments based on their performance under each of the five OCP categories. The performance standard for each OCP category was then established based on the performance level of the establishment representing the 75th percentile for that category (i.e., the performance level of the fourth-best performing establishment of each category). Thus, the OCP performance standards represent a reduction from the highest prevalence of defects found in ready-to-cook poultry that had passed the FPS.

Data collected from young chicken and turkey establishments operating under HIMP show that for the two year period CY2009 through CY2010, HIMP establishments maintained OCP defect levels that average about half the corresponding OCP performance standards derived from the performance of non-HIMP establishments. Thus, the data show that establishments operating under both HIMP and non-HIMP inspection systems perform well in controlling for OCP defects, but that

establishments operating under the HIMP system do exceptionally well. Accordingly, FSIS has concluded that it is not necessary to adopt prescriptive OCP requirements as a condition for establishments to participate in the New Poultry Inspection System. Under this proposal, establishments operating under the New Poultry Inspection System will be allowed to implement the process controls that they have determined will best allow them to produce ready-to-cook poultry that is wholesome and not adulterated.

Under this proposed rule, establishments will have the flexibility to design and implement measures to address OCP defects that are best suited to their operations. They will also be responsible for determining the type of records that will best document that they are meeting the ready-to-cook poultry definition. FSIS expects that most establishments will implement some type of statistical process control to address removable animal diseases and trim and dressing defects and use the statistical control charts associated with such procedures to document that the resulting products are ready-to-cook poultry.

If they choose to do so, establishments operating under the New Poultry Inspection System could incorporate procedures to

address removable animal diseases and trim and dressing defects into their HACCP plans, or sanitation SOPs, or other prerequisite programs, and rely on the records generated under these programs to document that the resulting products are ready-to-cook poultry. Establishments would most likely address these defects in their sanitation SOPs or other prerequisite programs. However, an establishment could address these defects in its HACCP plan if its hazard analysis determined that one or more of these removable diseases presented a food safety hazard. Establishments could also address removable animal diseases and trim and dressing defects as part of a quality control program and rely on the records generated under that program to document that they are meeting the ready-to-cook poultry definition.

2. FSIS Verification

Under this proposed rule, FSIS would verify that an establishment's poultry products comply with the ready-to-cook poultry definition by reviewing the records maintained by the establishment to document that its products are ready-to-cook poultry. In addition to inspecting for food safety defects, the FSIS on-line carcass inspector will also inspect carcasses for trim and dressing defects and removable animal diseases. The presence of persistent, unattended trim and dressing defects or

removable animal diseases would indicate that the plant is not producing ready-to-cook poultry. Furthermore, an establishment's inability to consistently produce product that meets the ready-to-cook poultry definitions may indicate a general lack of control in an establishment's overall slaughter and dressing process. Thus, if the establishment or FSIS inspection personnel observe the presence of persistent, unattended removable animal diseases or trim and dressing defects on poultry carcasses or parts, FSIS would require the establishment to take appropriate actions to ensure that it is operating under conditions needed to produce safe, wholesome, and unadulterated products. Under this proposal, if inspection personnel see evidence that an establishment is not producing products that meet the definition of ready-to-cook poultry, then inspector-in-charge would be authorized to require that the establishment reduce its line speed and remedy the defects.

E. Maximum Line Speeds under the New Poultry Inspection System

Based on FSIS's experience under HIMP, the Agency is proposing that the maximum line speed for young chicken slaughter establishments be 175 birds per minute, and that the maximum line speed for turkey slaughter establishments be 55 birds per minute.

Establishments operating under HIMP have demonstrated that they are capable of consistently producing safe, wholesome, and unadulterated poultry products while operating at these line speeds. Moreover, they have consistently met pathogen reduction and other performance standards operating at these line speeds. The new inspection system is modeled on HIMP and, as discussed later in this document, also incorporates additional measures that will apply to all poultry establishments. These measures, which include testing for microbial organisms at pre-chill and post-chill, are designed to ensure that establishments maintain process control.

To gather additional data on the effects of line speeds on the worker safety and the ability of establishments to maintain process control, the Agency will select a maximum of five non-HIMP establishments that applied through the SIP to receive waivers of existing regulations restricting line speeds. The Agency limited the number of non-HIMP establishments that would receive SIP waivers for line speed requirements to five because FSIS inspectors rather than establishment personnel would continue to be responsible for conducting carcass sorting. Thus, these non-HIMP plants would need additional inspectors to ensure that faster line speeds do not affect product safety.

FSIS recognizes that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety. To obtain preliminary data on this matter, FSIS asked the National Institute for Occupational Safety and Health (NIOSH) to evaluate the effects of increased line speed by collecting data from the five non-HIMP plants that have been granted waivers from line speed restrictions under the SIP. NIOSH has expressed its willingness to evaluate the effects of increased production volume on employee health, with a focus on musculoskeletal disorders and acute traumatic injuries (76 FR 41186, 41189). NIOSH will prepare a report based on its findings of short-, intermediate-, and long-term effects from the process modifications. NIOSH will make recommendations as needed. FSIS has made cooperation with NIOSH a condition for the five non-HIMP plants to operate at faster line speeds under the SIP waiver. FSIS will consider the available data on employee effects collected from NIOSH activities when implementing any final rule resulting from this proposal.

F. Facilities Requirements for Establishments Operating Under the New Poultry Inspection System

1. General

As discussed above, the new inspection system would replace SIS, NELS, and NTIS. FSIS anticipates that most, if not all, of the establishments that will choose to use the proposed inspection system are establishments that operate under one of those inspection systems. Accordingly, the following discussion of the facilities requirements associated with the proposed new inspection system highlights the differences between the proposed system and the existing inspection systems.

The proposed regulatory text describing the facilities requirements under the new inspection system is organized differently than the existing regulatory text. Whereas the existing regulations describe facilities requirements under Sections 9 CFR 381.36 and 381.76, the proposed regulatory text incorporates all facilities requirements relating to the new inspection system under proposed 9 CFR 381.36(c). The requirements are subdivided into four paragraphs: Paragraph (1) describes facilities requirements for the online carcass inspection station; Paragraph (2) describes facilities requirements for the offline verification inspection stations; Paragraph (3) describes facilities requirements pertaining to inspection of the viscera of the first 300 carcasses of each flock; and Paragraph (4) describes a facilities requirement for

a trough extending beneath the processing line from the point of evisceration to the point where trimming is performed.

2. Online Carcass Inspection Stations

Under the proposed inspection system, one online carcass inspection station will be provided on each processing line. If this proposal is adopted, it will be located at the end of the processing line, immediately before the chiller and after the establishments has conducted sorting, trimming, and reprocessing activities and has applied all pre-chill interventions. This location for the online inspection station differs from the existing inspection systems, which require several online inspection stations to be located after evisceration has occurred but before any trimming or pre-chill interventions have been applied. Based on its experience under HIMP, FSIS expects that when establishments operating under SIS, NELS, or NTIS convert to the new inspection system, they will use their existing online inspection stations to conduct required establishment sorting activities.

Under the proposed inspection system, as under the existing inspection systems, the conveyor line will be level for the entire length of the online carcass inspection station, and the vertical distance from the bottom of the shackles to the top of

the platform will be at least 60 inches. Other requirements for the proposed online inspection station that are the same as those under the existing inspection systems include requirements for a conveyor line start/stop switch, for proper lighting, for a clipboard holder, for receptacles to be used for condemned carcasses and parts, and for hangback racks.

FSIS is proposing that the platform for the online carcass inspection station be of the same dimensions and include the same safety features as under the existing inspection systems except that under the proposed system, the platform need only be four feet long instead of eight feet long. The inspection platform can be shorter under the proposed inspection system because, unlike the existing inspection systems, the new inspection system does not require an establishment helper to flank each online carcass inspector. Also unlike the existing inspection systems, the platform need not be height-adjustable under the proposed inspection system because the inspection procedure under the proposed system does not require the online carcass inspector to handle every carcass.

As under the existing inspection systems, FSIS is proposing that establishments equip each online carcass inspection station with hand rinsing facilities to prevent cross-contamination from

occurring when the online carcass inspector is required to touch carcasses with his or her hands. However, the carcass inspection method under the proposed inspection system does not require the carcass inspector to touch every carcass; such hand contact will be infrequent. Therefore, the Agency is not proposing to require that establishments equip the online inspection station with continuous flow hand rinse facilities as under the existing regulations. Instead, the Agency is proposing that establishments provide either continuous flow hand rinse facilities or hand rinse facilities capable of being activated in a hands-free manner (e.g., by placing the hands in front of a motion sensor or by stepping on a foot pedal). This flexibility will allow establishments to conserve water. As is the case now, under this proposal, all online hand rinse facilities must operate in a sanitary manner that minimizes splashing and the risk of cross-contamination, and the hand rinse facilities must provide water that is at least 65 degrees Fahrenheit to ensure effective sanitation.

FSIS is proposing that the water provided by the hand rinse facilities at online carcass inspection stations may not exceed 120 degrees Fahrenheit. The current regulations do not provide a maximum temperature. FSIS is proposing this change to prevent

the risk of scalding. According to the U.S. Consumer Product Safety Commission (CPSC), most adults will suffer third-degree burns if exposed to 150 degree Fahrenheit water for two seconds, to 140 degree water for six seconds, to 130 degree water for 30 seconds, and 120 degree water for five minutes.[9] Carcass inspectors wear latex gloves, and it is possible for water to become trapped underneath the gloves and remain in contact with inspectors' hands even after their hands are removed from the water source. FSIS has granted some establishments waivers to install non-continuous flow online hand rinsing facilities in order to conserve water. These facilities are referred to as "water savers." However, inspection personnel have identified that water provided by water savers is oftentimes too hot due to build-up of water in the pipes, causing burning of forearms while contacting the water and/or metal railings at the inspection station. Inspection personnel have also identified that water pressure from water savers is uneven, causes splattering, and does not provide water in a manner that allows inspectors to wash their hands quickly between birds presented for inspection. Inspection personnel have filed grievances against FSIS management for not stopping the use of these hand

[9] US Consumer Product Safety Commission Document #5098, "Tap Water Scalds." Available at: http://www.cpsc.gov/cpscpub/pubs/5098.html.

rinsing facilities or for not getting establishments to correct these problems. Therefore, to ensure that inspectors are protected from scalding and to encourage maximum use of hand rinsing facilities as needed to prevent cross contamination from occurring, FSIS is proposing that hand rinsing facilities provide water at a minimum temperature of 65 degrees Fahrenheit and a maximum temperature of 120 degrees Fahrenheit. The Agency requests comment on the efficacy and safety of this proposed temperature range and on the hand rinsing facilities requirement in general.

The online inspection station under the proposed inspection system must also be equipped with a buzzer within reach of the on-line inspector that the inspector can use when necessary to alert the inspector-in-charge, offline inspectors, or establishment management of the need to correct a deficiency that require their attention.

3. Offline Verification Inspection Stations

FSIS is proposing to require that establishments operating under the proposed inspection system provide offline verification inspection stations that are similar to the offline inspection stations required under the existing inspection systems. As under the existing inspection systems, FSIS is

proposing that at least one offline verification inspection station be located at a pre-chill location and at least one be located at a post-chill location. For establishments having more than one processing line or more than one chiller, the Agency will determine how many offline verification inspection stations are required under the specific processing conditions of the establishment concerned.

FSIS is proposing to require that the offline verification inspection stations under the new system consist of the same dimensions as the offline stations under the existing inspection systems. The dimensions and features of the offline inspection tables would also be the same. The requirements for lighting, hangback racks, and accessibility to hand washing facilities would also be the same as under the existing inspection systems. The requirement for a clipboard holder is the same except FSIS is also proposing to allow establishments to elect to provide offline verification inspectors with electronic means of recording inspection results.

4. Location to Inspect the Viscera of the First 300 Carcasses of Each Flock

Under the proposed inspection system, an offline inspector in young chicken slaughter establishments will inspect the

viscera of each of the first 300 birds slaughtered in each flock. Accordingly, FSIS is proposing to require that young chicken establishments operating under the proposed inspection system provide a location along the processing line after the carcasses are eviscerated at which the viscera inspection can safely and properly be conducted. The viscera must be presented at this location either uniformly trailing or leading. Based on FSIS's experience under HIMP, most establishments choosing to operate under the new inspection system will provide this location where establishment sorting activities take place.

5. Drainage from Processing Line

FSIS is proposing no change to the existing requirement that a trough or other drainage and collection facilities must extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where trimming has been performed.

G. Eligibility to Operate under the New Poultry Inspection System

FSIS is proposing that young chicken and turkey slaughter establishments may use the new inspection system if they apply to do so, and if the Administrator determines that they are

eligible. To be eligible, the establishment must agree to meet all facilities requirements and to maintain records to document that the products resulting from their slaughter operations meet the definition of ready-to-cook poultry.

Because FSIS is proposing to eliminate SIS, NELS, and NTIS, and to end HIMP, the Agency is also proposing to require that all young chicken and turkey slaughter establishments that do not operate under the new inspection system operate under traditional inspection.

In addition, FSIS is proposing to allow establishments that slaughter poultry classes other than young chicken and turkey to operate under the New Poultry Inspection System if they request and are granted a waiver through the SIP.

IV. OTHER PROPOSED CHANGES TO POULTRY SLAUGHTER REGULATIONS

A. Proposed Changes to Traditional Inspection System

FSIS is proposing to limit to two the number of online inspectors per line in all poultry slaughter establishments operating under traditional inspection, with an exception for existing establishments other than young chicken and turkey that are currently operating with more than two online inspectors. Under traditional inspection, online carcass inspectors would

continue to use the current traditional inspection methods. The Agency anticipates that it will assign approximately one offline inspector for every six online inspectors under traditional inspection. Additionally, the Agency would continue to provide oversight of workforce through veterinarians.

Most poultry slaughter establishments operating under traditional inspection are currently staffed with two online inspectors. As of September 2011, all of the very small establishments that slaughter young chickens or turkeys under the traditional inspection were staffed with two or fewer on-line inspectors However, there is a small number of poultry slaughter establishments that slaughter species other than young chickens and turkeys that have more than two online inspectors. FSIS will continue to staff these establishments with the number of online inspectors they currently have. FSIS has tentatively concluded that doing so will ensure that this rule change does not have an adverse impact on these establishments. FSIS is proposing that this exception will not apply to new establishments after a final rule is published because the Agency anticipates that new establishments would be aware of the requirements of the rule and would factor this into their decisions to operate. Also, this exception would not apply to

young chicken and turkey slaughter establishments because doing so would undercut the efficiencies that are presented by this proposal.

B. Proposed Changes Affecting All Poultry Slaughter Establishments

1. Procedures to Address Contamination by Fecal Material and Enteric Pathogens as Hazards Reasonably Likely to Occur

a. Contamination of Poultry Carcasses and Parts by Fecal Material and Enteric Pathogens are Hazards Reasonably Likely to Occur in Poultry Slaughter Establishments

The Centers for Disease Control and Prevention collects data on laboratory-confirmed human foodborne illness cases through the Foodborne Diseases Active Surveillance Network (FoodNet), an active, population-based, sentinel surveillance system for the United States.[10] Several FoodNet case-control studies have examined the link between chicken and human infection with Salmonella or Campylobacter and have found that poultry products are an important vehicle for human Salmonella and Campylobacter infections in the United States (CDC memo:

[10] For more information on FoodNet see http://www.cdc.gov/foodnet/

Foodborne illness from Salmonella and Campylobacter associated with poultry, United States, available at: http://www.fsis.usda.gov/PDF/Salmonella_Campylobacter_011811.pdf).

In addition to FoodNet case-control studies, CDC collects outbreak data reported by State and local health departments through the Foodbome Disease Outbreak Surveillance System (FDOSS). Outbreak data collected through FDOSS provides important evidence linking sources of Salmonella and Campylobacter to human illness.[11]

Fecal contamination is a major vehicle for spreading enteric pathogenic microorganisms, such as Salmonella, to raw poultry. Accordingly, contamination of poultry carcasses and parts by fecal material and enteric pathogens (e.g., Salmonella and Campylobacter) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP or other prerequisite program.

In order to ensure that establishments properly address the food safety hazards associated with contamination of poultry carcasses by fecal material and enteric pathogens, FSIS is

[11] For more information on CDC's FDOSS see: http://www.cdc.gov/outbreaknet/surveillance_data.html

proposing to amend the poultry slaughter inspection regulations as described in the following two sections.

b. Procedures Addressing Zero Tolerance for Visible Fecal Material before Chilling

In 1997, FSIS codified its zero tolerance policy for poultry carcasses contaminated with visible fecal material entering the chiller (62 FR 5139, February 4, 1997). At that time, the Agency published a final rule that removed "feces" from the list of nonconformance elements under the FPS and provided that "Poultry carcasses contaminated with visible fecal material shall be prevented from entering the chilling tank" (9 CFR 381.65(e)). The preamble to that final rule emphasized that the "zero tolerance policy for visible fecal contamination is an important food safety standard because fecal contamination is a major vehicle for spreading pathogenic microorganisms, such as Salmonella, to raw poultry."

Later the same year, FSIS published a second Federal Register document entitled "Notice on complying with food safety standards under the HACCP system regulations" (62 FR 63254, November 28, 1997). The purpose of the second document was to ensure that establishments understood the Agency's zero tolerance policy for visible fecal material as a food safety hazard as establishments prepared to comply with the then newly

enacted HACCP system regulations. The notice first cited the zero tolerance policy for visible fecal contamination before the chiller that had recently been codified at 9 CFR 381.65(e). Then, the notice explained that, "to meet the zero tolerance standard, an establishment's [HACCP] controls must (among other things) include limits that ensure that no visible fecal material is present … before poultry carcasses enter the chilling tank" (citing 9 CFR 417.2(c)). Finally, the notice explained that "Under the HACCP system regulations, critical control points to eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' HACCP plans."

Thus, in February 1997, FSIS codified the requirement that all poultry slaughter establishments must prevent carcasses contaminated with visible fecal material from entering the chiller (9 CFR 381.65(e)); and in November 1997, FSIS specified in a Federal Register notice that procedures for doing so must be incorporated in establishments' HACCP systems. As a result, all poultry slaughter establishments' HACCP plans currently include critical control points for preventing carcasses contaminated with visible fecal material from entering the chiller. Accordingly, FSIS is proposing to amend 9 CFR 381.65 to require poultry slaughter establishments to develop, implement,

and maintain as part of their HACCP plans, or sanitation SOPs, or other prerequisite programs, written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chilling tank. Such a requirement will ensure that establishments maintain the records to verify that that they have implemented the necessary measures and, when necessary, have taken appropriate corrective actions to prevent carcasses contaminated with visible fecal material from entering the chiller.

c. Procedures to Prevent Contamination of Carcasses and Parts by Enteric Pathogens and Fecal Material throughout the Entire Slaughter and Dressing Operation

Background

Although the existing requirement for establishments to prevent visible fecal material from entering the chiller, and the proposed clarification described above that establishments must have procedures addressing how they do so, are important safeguards, those safeguards will not be fully effective if an appropriate effort is not made to prevent contamination from occurring throughout the slaughter and dressing operation. Fecal material is a major vehicle for spreading pathogenic microorganisms, such as Salmonella and Campylobacter, to raw

poultry, and therefore it is vital for establishments to maintain sanitary conditions and to prevent, to the maximum extent possible, contamination from occurring before slaughter and throughout the slaughter and dressing process.

Under HACCP, establishments are responsible for identifying food safety hazards that are reasonably likely to occur in the production process and for implementing preventive measures to control those hazards. However, FSIS's experience with HACCP shows that instead of implementing controls to prevent contamination from occurring early in the production process, some poultry slaughter establishments rely on interventions applied at the end of the process to remove contamination after it occurs. This may be due in part to the fact that FSIS inspectors perform verification checks for zero visible fecal contamination and Salmonella and Campylobacter testing at the end of the slaughter and chilling processes. Failure to implement preventive measures throughout the slaughter and dressing process can lead to the creation of insanitary conditions in the establishment and increases the potential for carcasses and parts to become contaminated with enteric pathogens and fecal material. Interventions with chemical antimicrobials applied at the end of the process are less likely to be fully effective on carcasses that contain high levels of

pathogens, and these chemical treatments are not effective in preventing insanitary conditions throughout the slaughter establishment.

Information that FSIS has collected from comprehensive Food Safety Assessments (FSA's) it has conducted in establishments that have failed to meet the Agency's Salmonella performance standards demonstrate the need for establishments to adopt preventive measures to control contamination throughout the entire production process, as well as the need to maintain documentation to verify the effectiveness of those measures on an on-going basis.

For example, FSIS conducted an FSA at a young chicken slaughter establishment that failed its Salmonella set in 2007. For the FSA, FSIS reviewed the establishment's Salmonella testing data, controls, and records associated with the establishment's sanitary dressing procedures and microbial interventions, and observed the establishment's implementation of these controls and procedures. The Agency's review found that the establishment had high levels of Salmonella on incoming birds. The high levels of Salmonella sustained throughout the process appeared to have overwhelmed any subsequent in-process interventions. As a result of the FSA findings, FSIS notified

the establishment in writing that the Agency would withhold or suspend inspection unless the establishments provided a written response within 72 hours on the actions it would take to achieve compliance. In response, the establishment gave a written description of immediate corrective actions it would take, including removing debris and repositioning equipment, retraining of employees in the HACCP and Sanitation SOP methodology prescribed in the establishments control programs, and reassessing the establishments HACCP plan to incorporate a new antimicrobial treatment for the chill tank and similar antimicrobial interventions applied during the dressing operation. FSIS then put in place a verification plan in which inspectors in that establishment were expected to routinely verify the corrective actions proffered by the establishment. Since implementation of these corrective actions, the establishment has passed all of its Salmonella performance sets.

In another example, FSIS conducted an FSA in an establishment that had failed a Salmonella set in 2005. From the FSA, the Agency found that the establishment failed to: (i) identify Salmonella as a significant hazard, (ii) control hazards it did identify, (iii), identify corrective actions in its sanitation SOPs, (iv) perform verification, (v) perform all

corrective actions, and (vi) monitor pre-shipment records sufficiently. As a result, FSIS notified the establishment in writing that the Agency would withhold or suspended inspection unless the establishment provided a timely response on how it would achieve compliance. Consequently, the establishment reassessed and redesigned its HACCP plan for slaughter; revised its preoperational plan; and conducted remedial training of personnel in HACCP and sanitation SOPs. Because the establishment did not previously have defined verification activities for its employees to perform and document, the establishment instituted hourly checks for sanitary dressing at evisceration. FSIS issued a Notice of Deferral on August 8, 2005, and a Closeout Letter of Warning on March 3, 2006. FSIS then put in place a verification plan in which inspectors in that establishment were expected to routinely verify the corrective actions proffered by the establishment. Since implementation of these corrective actions, the establishment has passed all of its Salmonella performance sets.

Proposed Regulatory Requirements

To ensure that establishments implement appropriate measures to prevent carcasses from becoming contaminated with pathogens, and to ensure that both FSIS and establishments have

the documentation they need to verify the effectiveness of these measures on an on-going basis, FSIS is proposing to require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation. FSIS is proposing that establishments incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs, and that they maintain records sufficient to document the implementation and monitoring of these procedures. These proposed requirements are necessary to fully implement the existing HACCP regulations.

Many establishments have in place process control measures to address the prevention of contamination by enteric pathogens and fecal material, but are not maintaining documentation to verify the effectiveness of these procedures on an on-going basis. If this rule becomes final, establishments may choose to incorporate those measures into their procedures addressing how they prevent contamination from occurring during slaughter and dressing operations. Examples of such measures include: monitoring of evisceration equipment to ensure it is properly adjusted to the size of birds within a particular flock; purchase specification agreements requiring feed withdrawal; and

employee hygiene and hand washing policies. Under this proposed rule, establishments will be required to incorporate these procedures into their HACCP plans, or Sanitation SOPs, or other prerequisite programs, and to maintain on-going documentation to demonstrate that the procedures are effective. This on-going documentation will allow both the establishment and FSIS to identify specific points in the production process where a lack of process control may have resulted in product contamination or insanitary conditions, which will allow the establishment to take the necessary corrective actions to prevent further product contamination.

FSIS is not proposing to prescribe the specific procedures that establishments must follow to prevent carcasses from becoming contaminated by enteric pathogens or fecal material because the Agency believes that establishments should have the flexibility to implement the most appropriate measures that will best achieve the requirements of this proposed rule. However, on-going verification and documentation to demonstrate that an establishment's process controls are effective in preventing food safety hazards are critical components of the HACCP system. FSIS believes that microbiological test results that represent levels of microbial contamination at key steps in the slaughter

process, are necessary for establishments to provide comprehensive, objective evidence to demonstrate that they are effectively preventing carcasses from becoming contaminated with pathogens before and after they enter the chiller.

As discussed in detail earlier in this document, the current regulations require that official poultry slaughter establishments conduct regular testing for generic E. coli at the end of the chilling process as a means of verifying process control(9 CFR 381.94(a)). The regulations include performance criteria that are intended to represent the highest expected microbial loads on carcasses when the slaughter process is in control (9 CFR 381.94(a)(5)(1)). However, FSIS's experience with using post-chill testing for generic E. coli to monitor process control for fecal contamination and sanitary dressing has led the Agency to conclude that such testing is not the most effective way to prevent contamination from occurring throughout the slaughter and dressing operation. As noted above, recent studies indicate that E. coli levels may not be a valid measure of fecal contamination. This finding was also supported by a 2004 report issued by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Additionally, while post-chill testing may be useful for identifying microbial

levels on carcasses after they have been subjected to antimicrobial chemicals in the chiller, it does not necessarily reflect the effectiveness of the preventive measures implemented earlier in the process to address contamination at points in the process before the chiller.

Given these limitations, FSIS is proposing to rescind the generic E. coli testing requirements in 9 CFR 381.94 and to replace them with a new testing requirement that will provide establishments the flexibility to sample for other, potentially more useful indicator organisms. Under this proposal, establishments would continue to conduct sampling and analysis of carcasses for microbial organisms at the post-chill location, but in addition the Agency is proposing a second testing location at the pre-chill position in order to ensure establishments will be able to monitor the effectiveness of process control for enteric pathogens throughout the slaughter and dressing operation.

Although FSIS has tentatively concluded that verification testing conducted at two proposed points, i.e., pre-chill and post-chill, will provide the evidence establishments need to verify that their process control measures are effective in preventing carcasses from becoming contaminated with pathogens,

the Agency also considered two alternatives approaches. FSIS considered requiring a third verification test at the re-hang position to monitor the incoming load of pathogens but does not believe it is necessary to impose the additional costs that would be associated with testing at this point. FSIS also considered requiring only one verification test at any position along the production line to provide maximum flexibility but concluded this approach may not be sufficient to monitor the effectiveness of an establishment's procedures to prevent contamination throughout the slaughter and dressing operation. The Agency requests comments on these alternatives.

Under this proposed rule, instead of following a prescribed microbiological testing program, each establishment would be responsible for developing and implementing its own microbiological sampling plan, which would be required to include carcass sampling at pre-chill and post-chill. The establishment would be responsible for determining which microbiological organisms will best help it to monitor the effectiveness of its process control procedures. Because FSIS is proposing that an establishment's microbiological sampling plan be part of its HACCP plan, sanitation SOP, or other prerequisite program, each establishment would be required to provide

scientific or technical documentation to support the judgments made in designing its sampling plan (see 9 CFR 417.4(a)). Under this proposal, establishments could develop sampling plans to test carcasses for enteric pathogens, such as Salmonella and Campylobacter, at pre-chill and post chill, or they could test for an appropriate indicator organism. FSIS intends to provide sampling guidance to assist small and very small establishments develop sampling plans that meet the Agency's expectations for testing designs and sampling frequency.

This proposed rule does not prescribe how frequently establishments must sample and test poultry carcasses for microbiological organisms at pre-chill and post-chill. Instead, FSIS is proposing to require that an establishment's sampling frequency be adequate to monitor the effectiveness of the establishment's process control for enteric pathogens. The frequency with which establishments would need to conduct such testing will depend on a number of factors, including their production volume, the source of their flocks, their slaughter and dressing process, and the consistency of their microbial test results over time. Because the testing frequency would be an integral part of an establishment's HACCP system verification procedures, establishments would need to collect and maintain

data to demonstrate that their testing frequency is adequate to verify the effectiveness of their process control procedures.

This proposed rule does not mandate that establishments meet specific performance standards for microbial testing. Rather, because establishments would be required to incorporate their procedures for preventing contamination by enteric pathogens and fecal contamination into their HACCP plans, or sanitation SOPs, or other prerequisite programs, establishments would be required to take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures are not effective in preventing carcass contamination throughout the entire slaughter and dressing process. Establishments would also need to routinely evaluate the effectiveness of their procedures in preventing carcass contamination.

Small and very small, low-volume establishment[12] that choose to operate under the revised traditional inspection system rather than the New Poultry Inspection System may not need to conduct testing at two points in the slaughter process to

[12]Low-volume establishments would include those classified as very low volume establishments under the existing generic E. coli testing regulations, e.g., establishments that slaughter no more than 440,000 young chicken or no more than 60,000 young turkeys on an annual basis (9 CFR 381.94(a)(2)(v)).

adequately monitor process control. Therefore, FSIS is considering permitting these establishments to conduct testing for microbial pathogens at one point in the process if they can demonstrate that they are maintaining adequate process control. Under this proposal, if the Agency had evidence to indicate that an establishment conducting testing at a single point in the process was having difficulty maintaining process control, such as not meeting FSIS's pathogen performance standards, the establishment would need to conduct additional testing or implement additional measures to ensure that its process remains in control. The Agency request comments on this aspect of the proposed rule.

If this proposal is finalized, FSIS will issue guidance to assist establishments in developing procedures for controlling contamination throughout the slaughter and processing operation and for developing appropriate sampling plans to verify the effectiveness of their procedures. This guidance will include a default sampling frequency for small and very small establishments.

Under this proposed rule, FSIS would verify the effectiveness of an establishment's process control procedures in preventing carcasses from becoming contaminated with enteric

pathogens and fecal material by reviewing the establishment's monitoring records, including the establishment's microbial testing results, observing an establishment implementing its procedures, and inspecting carcasses and parts for visible fecal contamination when conducting both online carcass inspection and offline verification inspection procedures. FSIS personnel would consider both the establishment's testing results, as well as the results of the Agency's testing for Salmonella and Campylobacter to determine young chicken and turkey establishment's compliance with the Agency's Salmonella and Campylobacter performance standards, to help assess how well the establishment is controlling its slaughter and dressing processes.

If inspection personnel determine that an establishment's process control procedures are not effective in preventing contamination by enteric pathogens or fecal contamination, the Agency would take appropriate regulatory action to ensure that the establishment's production process is in control, and that product is not being adulterated. Such action could include performing additional visual inspections of products or equipment and facilities, increasing offline verification inspections, initiating Food Safety Assessments (FSAs),

conducting hazard analysis verification procedures, conducting intensified product sampling for Salmonella and Campylobacter under the Agency's performance standard sampling program, and retaining or condemning product.

2. Impact Considerations for Small/Very Small Low Volume Establishments

As noted in the Preliminary Impact Analysis (PRIA) for this proposed rule, FSIS projects that all 51 of the very small establishments that operate under the existing traditional inspection system will chose to operate under the proposed revised traditional inspection system. However, this proposed rule will impose certain costs on establishments regardless of the proposed inspection system under which they chose to operate. Therefore, because FSIS is interested in implementing this proposed rule in a manner that will minimize the impact on small and very small establishments, the Agency requests comments on the following measures to help mitigate the impact on to small and very small establishments.

- Phase-in for small businesses: FSIS requests comments on whether a phased implementation would help to mitigate the impact of this proposed rule on small and very small

establishments. The Agency also requests comments on the type of phased implementation that would be most effective in mitigating the impact on very small establishments. For example, would a phased implementation that establishes separate effective dates for large, small, and very small establishments be effective in mitigating the impact of this proposed rule on small and very small establishments?

- Allow small and very small plants that operate under the modified traditional inspection system to test for microbial pathogens at one point in the slaughter process instead of two. As noted above, this proposed rule requires that all young chicken and turkey slaughter establishments conduct testing for microbial pathogens at two points in the slaughter process regardless of the inspection system that the operate under. However, FSIS believes that it may not be necessary for very small, low-volume establishments that operate under the revised traditional inspection system to conduct testing at two points in the process to effectively monitor process control. Therefore, FSIS requests comments on whether it should revise this provision in the proposed rule to permit very small, low volume establishments to conduct testing

for microbial pathogens at one point in the process if these establishments can demonstrate that they are maintaining adequate process control through other means.

- Number of on-line inspectors permitted for revised traditional inspection: As discussed earlier in this document, this proposed rule would limit the number of on-line inspectors for the revised traditions inspection system to two, with an exception for existing establishments other than young chicken and turkey that are currently operating with more than two online inspectors. FSIS is proposing to continue to staff establishments that slaughter poultry other than young chickens and turkeys with the number of online inspectors that they currently have to mitigate the impact of this proposed rule on these establishments. FSIS has tentatively decided that this exception would not apply to young chicken and turkey slaughter establishments because doing so would undercut the efficiencies that are presented by this proposal. However, because the young chicken and turkey slaughter establishments that operate under the existing traditional inspection system are classified as either small or very small, FSIS requests comments on it should permit these establishments to retain more than two inspectors if they

are currently operating with more than two inspectors under the existing traditional inspection system.

In addition to the proposed mitigations discussed above, FSIS intends to adopt the following measures to assist small and very small establishments meet the requirements of this proposed rule.

- Provide FSIS outreach training programs to small and very small establishments to help them comply with the proposed requirements to address enteric pathogens and fecal contamination. FSIS intends to provide training to small and very small establishments to assist them to develop, implement, and maintain written procedures for the prevention of contamination by enteric pathogens and fecal material and for preventing carcasses contaminated with fecal material from entering the chill tank. To ensure that very small plant operators have access to such training, FSIS is considering providing computer-based training or using a webinar format.
- Provide guidance on measures small establishments can take to control for enteric pathogens. As discussed above, under both the New Poultry Inspection System and the revised traditional inspection system, establishments will

be required to conduct testing for microbial pathogens at pre-chill and post-chill to verify process control. The frequency with which establishments conduct testing under this proposed rule will depend on, among other things, the production volume, source of flock, and the plants slaughter and dressing process. FSIS believes that very small, low volume establishments that have slower line speeds and that do not use automated evisceration equipment will likely not need to conduct frequent testing to demonstrate that their process is in control. Therefore, FSIS intends to develop guidance to assist small plants implement measures other than testing to demonstrate that their process is in control. FSIS believes that this will help to minimize the amount of testing (and the associated costs) that small plants will need to conduct to comply with the proposed rule. The guidance would provide for an increase in testing frequency if an establishment is having difficulty maintaining process control, such as not meeting FSIS's pathogen performance standards.

FSIS requests comments on these and other possible measures that that the Agency can implement to minimize this proposed rule's impact on small and very small, low volume establishments.

3. Proposed Changes to Time and Temperature Requirements for Chilling

a. Background

As discussed earlier in this document, FSIS has granted SIP waivers from the time and temperature chilling regulations to six poultry slaughter establishments. The current poultry chilling regulations (9 CFR 381.66) require ready-to-cook poultry, except for ratites, to be chilled immediately after evisceration unless the poultry is to be frozen or cooked immediately at the establishment. The purpose of these regulations is to ensure prompt removal of body heat and to prevent the incubation and rapid growth of bacterial populations on or within the carcasses, thereby preserving the conditions and wholesomeness of the poultry and preventing adulteration (9 CFR 381.66(a); 35 FR 15739, October 7, 1970).

Under the current regulations, poultry slaughtering establishments must ensure that the internal temperature of poultry carcasses weighing 4 to 8 pounds is reduced to 40°F or below within 4 hours; carcasses weighing 4 to 8 pounds, within 6 hours; and those weighing over 8 pounds, within 8 hours (9 CFR 381.66(b)). Once chilled, poultry to be packaged and shipped must be stored at 40°F or less. FSIS believes that a chilling

process satisfying the present requirement results in no outgrowth of bacteria.

During further processing and packaging operations, the internal temperature of the poultry carcass may be allowed to rise to 55°F, provided that immediately after packaging, the poultry is chilled to 40°F or placed in a freezer. The regulation requires that any poultry that is to be held at the establishment in packaged form longer than 24 hours must be held in a room at a temperature of 36°F or lower (9 CFR 381.66(c)(3)). This requirement provides assurance that no bacterial outgrowth occurs before the package leaves the establishment.

9 CFR 381.66(c)(4) requires the chilling of giblets to 40°F or lower within two hours of the time that they are removed from the inedible viscera. But when the giblets are cooled with the carcass from which they are drawn, the giblets are subject to the same chilling time as the carcass. 9 CFR 381.66(e) requires that the temperature of air-chilled, ready-to-cook poultry be reduced to 40°F or lower within 16 hours.

The temperature limits in these regulations were based on the fact that most relevant foodborne bacteria have not been reported as being capable of multiplying at temperatures below

40°F (35 FR 15739). Thus, any bacteria would be in a suspended state, if not actually killed. Chilling ready-to-cook poultry and keeping it at sufficiently low temperatures inhibits the multiplication of spoilage organisms as well as foodborne pathogens on the poultry and permits the poultry to be sold in markets at great distances from the processing establishment.

Most poultry slaughtering establishments in the United States chill eviscerated poultry by immersion in vats of water and ice. Where the chilling operation has been identified as a CCP in an official establishment’s HACCP plan, FSIS inspectors verify that the establishment is monitoring at that CCP, and that the establishment’s process is meeting the critical limits for the CCP. For raw poultry products, the chilling operation must meet the 40°F temperature and time requirement, no matter what other limits the establishment may have identified in its hazard analysis. FSIS inspectors may determine whether products are compliant with the regulatory requirements by taking the temperatures of fresh and frozen poultry products -— including carcasses, parts, and giblets —- or by observing establishment employees conducting monitoring, by verification procedures, or by reviewing establishment records.

The regulation limiting chilling operations to specific time-and-temperature combinations is at odds with the PR/HACCP regulations. Additionally, FSIS has two long pending petitions requesting that the Agency repeal the prescriptive time and temperature chilling requirements. The American Meat Institute (AMI) petitioned the Department to amend the regulations governing moisture absorption and retention in certain raw meat and poultry products. AMI also requested other changes, including repeal of the regulations requiring poultry carcasses to be chilled below 40°F within a specified time. The National Turkey Federation (NTF) has requested that FSIS waive the time and temperature requirements for poultry carcass cooling. FSIS has carefully considered the AMI and NTF requests in developing this proposal.

FSIS has concluded that alternative approaches to chilling are effective and safe. As discussed above, under SIP, the Agency has granted six poultry slaughter establishments waivers from the specific time and temperature chilling requirements prescribed in 9 CFR 381.66. FSIS will review the data provided through these waivers to ensure that these alternative approaches to chilling poultry are effective at controlling levels of bacteria and ensuring food safety. The Agency will

take this data into consideration before issuing a final rule in this proceeding.

Based on the foregoing, FSIS is proposing to eliminate the time and temperature requirements for chilling ready-to-cook poultry carcasses and giblets. The existing requirements prescribe both the time and temperature parameters to be used in the chilling process and do not allow for alternative approaches that the establishment can use to control levels of bacteria. The regulation gives an establishment producing ready-to-cook poultry no flexibility to use procedures other than those in the regulations, even if alternative procedures achieve the same results. Because the objective of the current chilling regulations is to prevent microbial multiplication, establishments should have the option of choosing the means to do so, instead of being required to use a prescribed method of chilling that achieves a specific temperature limit, 40°F, that applies to ready-to-cook poultry products.

In addition, the time and temperature regulations are inconsistent with the Agency’s regulations on retained water (9 CFR 441.10) in that they tend to prevent poultry establishments from making full use of available options for reducing retained

water in their products, such as the option of reducing the dwell time of products in immersion chillers.

b. Proposed Rule

FSIS is proposing to replace these prescriptive time and temperature requirements with a requirement that poultry slaughter establishments develop and maintain procedures that control the levels and prevent the multiplication of spoilage organisms and pathogenic bacteria in the product after evisceration. Establishments would have to include these procedures in their HACCP plans, or sanitation SOPs, or other prerequisite programs. Establishments would be required to maintain a chilling process so that at the end of slaughter operations, no pathogen outgrowth occurs.

Additionally, establishments would be required to keep previously chilled poultry carcasses and major portions chilled so that there would be no outgrowth of the pathogens, unless such poultry is to be packed and frozen immediately at the official establishment. And establishments would be required to chill giblets after processing so that there is no outgrowth of pathogens. Giblets could either be chilled with the carcass or separately.

Under this proposed rule, unless poultry are to be frozen or cooked immediately at the establishment after evisceration, poultry establishments would be required to identify those conditions at the establishment affecting carcass chilling and pathogen outgrowth afterwards. These conditions could include the amount of agitation of the chiller medium, the concentration of anti-microbial substances in the chiller medium, the temperature of the chiller medium, the rate of temperature reduction of the carcasses, and the internal temperature or microbial condition of the carcasses exiting the chiller.

Establishments would have to incorporate procedures for chilling into their HACCP plans, or Sanitation SOPs, or other prerequisite programs. These written procedures would include the conditions of use affecting carcass chilling and microbial multiplication identified by the establishment.

FSIS would consider the present chilling requirements as safe harbors. If an establishment uses a chilling and subsequent storage process different from the present requirements, the establishment would be required to specify the point where chilling has been completed and to validate that at that point any residual microbial population is inhibited from growing. The establishment would also be required to validate that the

bacterial population does not increase during storage at the establishment.

To ensure that the bacterial population does not multiply during storage (after chilling), the establishment could take into account any of several effects of temperature on microbial growth. For example, at temperatures of 48°F (10°C) or below, the multiplication of microorganisms of concern is very slow and has no significant effect on the microbiological quality of the carcass. At temperatures below 50°F, spoilage bacteria generally multiply faster than pathogens, and meat or poultry kept below 50°F will tend to spoil before excessive pathogen multiplication could occur. Gram negative pathogens, such as salmonellae, tend not to multiply below 45°F (7°C).

Removal of the time and temperature chilling requirements is unlikely to lead to a significant change in carcass chilling methods or long-established packaging and shipping practices that the poultry products industry considers necessary to meet both regulatory and market requirements to maintain raw products in a sanitary condition. It would, however, eliminate a prescriptive requirement and give establishments greater flexibility to manage how they chill poultry. Processors must ensure good temperature controls at the establishment and during

shipment to maintain product quality during transport and ensure a usable shelf life for the products after delivery to retail establishments.

More than half of the raw poultry products destined for the retail market are shipped using the chill-pack method of refrigeration, under which the products are quickly chilled after packaging and held at temperatures of from 28°F to 32°F. The rapid chilling limits the growth of pathogenic and spoilage bacteria on the carcass. Almost a third of the products are packed in containers filled with shaved or crushed ice (the ice-pack method) or dry ice (dry-ice pack) and held at temperatures between 30°F and 35°F and shipped to distributors, grocers, and fast-food chains. Other raw poultry products are shipped either in the frozen state or under other forms of refrigeration. This proposal would not affect these practices and the resulting consumer protections. The Agency has, therefore, concluded that consumers would be fully protected without the very prescriptive requirements that this proposed rule would eliminate.

Time and temperature requirements are intended to remove animal heat and inhibit the multiplication of bacteria, including food-poisoning organisms, on ready-to-cook poultry products. But time and temperature combinations other than those

in the current regulations and technologies other than chilling are available to reduce bacterial levels and control bacterial multiplication on products at the processing establishment.

FSIS would verify that establishments are controlling levels of bacteria through verifying an establishment's chilling procedures in its HACCP plan or Sanitation SOP or other prerequisite programs. Consistent with current regulations, once the product is chilled, the establishment would be required to continue to inhibit the outgrowth of such organisms as long as the product remains at the establishment.

c. Air chilling

Under this proposal, air-chilled poultry would be required to meet the same regulatory requirements for pathogen control as poultry chilled by immersion. FSIS is proposing to amend the regulations to clarify what constitutes the air chilling of poultry carcasses and parts. Air chilling is a production method that rapidly cools poultry carcasses and parts by moving them through cold air chambers. In immersion chilling, by contrast, the carcasses are dipped into ice cold water containing one or more antimicrobial agents. Regardless of the method used, establishments would need to define when the chilling process is complete.

The Agency is taking this step because industry is using “air chilling” and “air chilled” as label claims on packages of ready-to-cook poultry and parts. Moreover, many consumers apparently believe that air-chilled poultry is superior in taste and in wholesomeness to poultry that is chilled by conventional methods.

Because of the perceived marketing advantage in air chilling poultry, the industry has asked FSIS exactly what constitutes air chilling. Consequently, the Agency has decided to propose a definition of air chilling. Based on FSIS’ knowledge of industry practices and consumer expectations, the Agency is proposing to define ”air chilling” as the method of chilling raw poultry carcasses and parts exclusively with air. Under this proposed definition, an anti-microbial intervention that is applied with water may be used for a short duration if its use does not result in any pick-up of water or moisture, and if it does not assist the chilling process by lowering the product temperature (cooling effect).

By contrast, so-called evaporation chilling does not qualify as air chilling. Evaporation chilling consists of using a mist to chill poultry carcasses and parts and then using air to further chill the poultry.

FSIS is also proposing that ready-to-cook poultry may bear an “air chilled” or “air chilling” claim on the label if the chilling process used with the poultry carcasses and parts meets the definition of air chilling.

FSIS would verify that establishments that use air chilling and include “air chilled” or “air chilling” on their product labels use procedures that meet all the regulatory requirements, i.e., no water is used to aid the chilling process, and, if water is used to apply an anti-microbial, the product retains no water.

4. Proposed Changes to Online and Offline Reprocessing Regulations

a. Background

As noted earlier in this document, 144 poultry slaughter establishments are operating under waivers that allow them to use online antimicrobial systems to reprocess carcasses accidentally contaminated with digestive tract contents. On December 1, 2000, FSIS issued a proposed rule to permit the use of online reprocessing in poultry slaughter establishment (“Performance Standards for On-line Antimicrobial Reprocessing of Pre-chill Poultry Carcasses” (65 FR 75187)). FSIS initiated

this rulemaking in response to petitions submitted by two companies that have developed online reprocessing systems, Rhodia, Inc. and Alcide Corporation. Rhodia's online reprocessing system uses trisodium phosphate (TSP) rinse in combination with a chlorinated water system to treat carcasses pre-chill. Alcide's system uses acidified sodium chlorite as pre-chill antimicrobial treatment. Both systems are among those used in establishments operating under online reprocessing waivers.

The Agency proposed to amend its regulations to allow establishments to reprocess contaminated carcasses online by applying a pre-chill antimicrobial intervention if such carcasses met pre-chill performance standards for Salmonella and generic E. coli that would be significantly lower than the current generic E. coli regulatory criteria for verifying process control and the codified pathogen reduction Salmonella performance standards (65 FR 75192). At that time, FSIS had determined that it was necessary to hold poultry contaminated with digestive tract contents to a more rigid pathogen reduction standard than product that is not visibly contaminated because digestive tract contents are a source of pathogens and other microorganisms. The available data evidenced that physical

removal of visible contamination does not necessarily remove significant levels of pathogens and other microorganisms. However, although both the Rhodia and Alcide petition included data from in-plant trials that demonstrated that each company's pre-chill online reprocessing system is effective in reducing pathogens and other microorganisms on visibly contaminated poultry carcasses, Rhodia's data were quantitative and focused on absolute levels of reduction (e.g., less than 0.5 percent of the treated samples were positive for Salmonella), while Alcide's data documented degrees of reduction (e.g., there was an average reduction by 27.27 percent of the prevalence of Salmonella on the treated samples).

Therefore, because the various antimicrobial treatments used in the in-plant online reprocessing trials had differing effects with respect to pathogen reduction, FSIS did not include specific pre-chill standards in the proposed rule. Instead, the December 2000 proposed rule requested comments, especially in the form of additional data, on the specific performance standards that establishments that use pre-chill online antimicrobial reprocessing systems should be required to meet.

Most of the comments submitted in response to the proposed rule supported the use of online reprocessing. Some commenters

recommended different kinds of performance standards that could be associated with online reprocessing but did not include microbiological data to support the suggested standards. There was also a general lack of consensus on the type of performance standard the Agency should adopt. Other commenters said that FSIS should not require a performance standard specifically for the use of online reprocessing.

As discussed above, FSIS enforces a zero tolerance standard for contamination by visible fecal material on poultry carcasses and parts pre-chill. Under the current regulations, the Agency permits the reprocessing of carcasses contaminated on their inner surfaces with visible digestive tract material before they enter the chilling tank. The regulations require that all reprocessing of poultry occur at an approved reprocessing station away from the processing line. Contaminated surfaces that are cut must be reprocessed only by trimming. Contaminated inner surfaces that are not cut may be reprocessed by trimming alone or in combination with other methods, such as washing and vacuuming. If the inner surfaces of carcasses are reprocessed other than solely by trimming, all surfaces of the carcass must be treated with chlorinated water containing 20 ppm available chlorine (9 CFR 381.91 (b)). The Agency estimates that

approximately 2 to 3 percent of inspected poultry carcasses is reprocessed offline.

There are concerns that offline reprocessing of poultry carcasses may spread pathogenic organisms because the technique involves a significant amount of product handling and provides ample opportunity for cross contamination. As mentioned earlier in this document, FSIS has experience with industry use of online reprocessing in poultry slaughter establishments through approved experimentation conducted under waivers from the current regulations. Although the data generated from these in-plant trials demonstrated that various online antimicrobial treatments have differing effects with respect to pathogen reduction, the results indicate that online reprocessing, when properly employed, is safe and effective. The results of 11 online reprocessing system waivers show that on the aggregate, online reprocessing reduces APC, E. coli, Coliforms, and Salmonella on treated carcass.

The Agency also has experience with industry use of offline reprocessing using antimicrobial agents other than chlorinated water containing 20 ppm available chlorine through approved experimentation conducted under waivers. The results from four offline reprocessing system waivers show that on the aggregate,

offline reprocessing using antimicrobial agents other than chlorine reduces APC, E. coli, and Salmonella at a level equal to or better than chlorine. These waivers have also demonstrated that the use of chlorinated water containing between 20 and 50 ppm available chlorine is safe and effective when properly employed.

b. Proposed Rule

FSIS is re-proposing to amend its regulations to permit the use of online reprocessing of poultry carcasses. However, the Agency has decided not to propose performance standards specifically associated with the use of online reprocessing. As noted above, data generated from in-plant trials show that various online antimicrobial treatments have differing but equally effective results with respect to pathogen reduction. The comments submitted on this issue did not provide any new data on the type of performance standard that the Agency should adopt. Therefore, instead of proposing performance standards, FSIS has decided to permit establishments to use online reprocessing antimicrobial interventions if the parameters for use of the antimicrobial intervention system have been approved by the FSIS, and the establishment incorporates procedures for

online reprocessing into its HACCP plan, or sanitation SOP, or other prerequisite programs.

Establishments choosing to use online reprocessing would be required to comply with the same standards and regulations addressing digestive tract contents that are applicable to all poultry slaughter establishments. Establishments using online reprocessing would still be required to ensure that poultry carcasses contaminated with visible fecal material do not enter the chilling tank.

Permitting establishments the option of online reprocessing would allow visibly contaminated poultry carcasses to remain online for treatment by a system of automatic bird washers and antimicrobial spraying or drenching equipment, rather than have to be moved off the line to an offline reprocessing station. All carcasses would remain on the line to be treated with the on-line anti-microbial agent, whether they are contaminated or not. However, carcasses that are mutilated or entirely contaminated are adulterated and would not be permitted to be reprocessed online or offline.

Online reprocessing of pre-chill young poultry carcasses offers substantial benefits –it will reduce the potential of cross-contamination, reduce digestive tract contamination for

all carcasses because all carcasses would pass through the same system of automatic bird washers and antimicrobial spraying or drenching equipment, and will maintain a continuous flow of carcasses down the processing line.

This proposed rule would not require establishments to use online reprocessing. Establishments that elect to use online reprocessing would have to incorporate procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs for applying an online antimicrobial intervention to all carcasses after evisceration and before the carcasses enter the chiller.

FSIS will list all antimicrobial agents that have been approved for use in online reprocessing, together with the specific parameters of use under which the antimicrobial agents have been approved, in FSIS Directive 7120.1: “Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products.” As under current regulations, the safety of antimicrobial substances will be determined by the FDA. The suitability of those substances as reprocessing agents will be determined by FSIS. Establishments opting to use online reprocessing would be permitted to use online reprocessing systems and antimicrobial agents that have been approved by FSIS

under the specific conditions of use for which they have been approved. Establishments would not need to request a waiver to use these approved online reprocessing systems. If deficiencies occur with the use of online reprocessing, an establishment would be required to take corrective actions.

FSIS would verify that establishments were properly using online reprocessing by verifying an establishment’s online reprocessing procedures as detailed in its HACCP plan, sanitation SOP, or other prerequisite programs.

FSIS is also proposing to amend the current regulations pertaining to offline reprocessing to allow establishments that reprocess inner surfaces other than solely by trimming to use chlorinated water containing 20 ppm to 50 ppm available chlorine or another approved antimicrobial substance in accordance with the parameters approved by the Agency. As with the methods of online reprocessing described above, approved methods of offline reprocessing will be listed in FSIS Directive 7120.1, “Safe And Suitable Ingredients Used in the Production of Meat, Poultry, And Egg Products,” and establishments would be required to incorporate their procedures for offline reprocessing into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

FSIS is proposing to revise the offline reprocessing regulations to remove the provisions that provide for the Agency to withdraw approval for an establishment to conduct offline reprocessing. As noted above, under this proposal, FSIS would ensure the effectiveness of an establishment's procedures for online or offline reprocessing through its HACCP verification activities.

Finally, even though a poultry product has been subjected to anti-microbial treatments as part of online reprocessing, it may still qualify for a certified organic claim, depending on the anti-microbial agent that was used. The use of "organic" labeling for such poultry products is determined on a case-by-case basis. Two treatments permitted for use in poultry products labeled as "organic" are Hydrogen Peroxide and Peracetic Acid. In addition, Orange Pulp and Acidified Sodium Chlorite have been formally recommended for use in organic handling in an Agricultural Marketing Service (AMS) National Organic Program (NOP) proposed rule.

V. Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that

maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an “economically significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Introduction

The Food Safety and Inspection Service (FSIS) is proposing to implement a new system for inspecting the slaughter of young chickens and turkeys. Furthermore, other proposed actions include a revised traditional inspection system for inspecting the slaughter of all poultry; and proposed requirements that would apply to all establishments that slaughter poultry, other than ratites (e.g., ostriches, emu, and rhea).

Need for the Rule:

Given technological advances in the production of poultry, the current inspection system’s line speed restrictions result in higher-than-necessary costs per bird. The new system described in this document makes available a new voluntary

inspection system that would enable producers to decrease production costs by increasing line speeds in a manner that does not compromise the safety of the production process. Based on our experience with the HIMP program, FSIS expects the new inspection system to improve food safety and the effectiveness of inspection systems, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources.

Furthermore, FSIS has determined that contamination of poultry carcasses and parts by fecal material and enteric pathogens (e.g., Salmonella and Campylobacter) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP or other prerequisite program.

Therefore, to ensure that all establishments that slaughter poultry properly address the food safety hazards associated with contamination of poultry carcasses by fecal material and enteric pathogens, FSIS is proposing that all poultry establishments develop, implement and maintain written procedures to 1) prevent poultry carcasses contaminated with visible fecal material from entering the chiller and 2) prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. FSIS is proposing that establishments incorporate these procedures into

their HACCP plan, or sanitation SOP, or other prerequisite program.

Proposed Actions

Table 8 compares the components or requirements of the actions of the proposed rule with a comparison to the current regulatory environment for the approximately 289 federally inspected establishments that slaughtered all poultry other than ratites in 2010 (FSIS Animal Disposition Reporting System (ADRS)). Actions include requirements for young chicken and turkey establishments and requirements for all poultry slaughter establishments excluding ratites. Table 8 includes information for SIS and NELS inspection systems and SIS Automated Evisceration Equipment Systems, referred to as MAESTRO, which is an acronym for “Meyn’s Automatic Evisceration System Total Removal of Organs”, and Nu-Tech Nuova. These automated poultry evisceration systems were introduced in the late 1990s. For young chicken establishments, four inspectors are stationed on the same side of a processing line that runs at a maximum of 140 bpm or 35 bpm per inspector—the same per-inspector line speed as under SIS. The evisceration equipment used in SIS or NELS must be supported by establishment employees who manually complete carcass and viscera presentation. In contrast, the automated evisceration systems do not require that support.

Table 8: Comparison of Key Components of the Baseline Regulatory Environment and Proposed Rule

Key Features or Provisions of the Proposal	Very Small and Small Establishments Traditional		Small and Large Non-Traditional		
	Baseline	**Proposed**	**Non-HIMP Baseline**	**HIMP Baseline**	**Proposed**
Number of Establishments	70		194	25	
Carcass Sorting Activities	FSIS	FSIS	FSIS	Establishment	Establishment
Online Inspector per Line	1-4	1-2[a]	2-4	1	1
Online Inspector Limit	No	Yes	No	Yes	Yes
Addition of Online Establishment Workers because of Relocation of Online IPP	No	Yes	No	Yes	Yes
Line Speed Maximum Birds per minute for Young Chickens	16-25	16-25	70-140	175	175
Line Speed Maximum Birds per minute for Mature Chickens	16-25	16-25	70		SIP Waiver determined
Line Speed Maximum Birds per minute for Turkeys	21-51	21-51	45	55	55
Line Speed Maximum Birds per minute for Other Poultry	16-25	16-25	Na	Na	SIP Waiver determined
Records to document that products meet the definition of ready-to-cook poultry	No	No	No	No	Yes
New Facilities Requirements:	No	No	No	Yes	Yes
New carcass inspection station online for each evisceration line	No	No	No	Yes	Yes
New carcass inspection station offline for each evisceration line	No	No	No	Yes	Yes
New carcass inspection area online for avian	No	No	No	No	Yes

leukosis for each evisceration line					
Underline Trough for each evisceration line	No	No	No	Yes	Yes
HACCP System - written to prevent contamination by enteric pathogens and fecal material & testing	No	Yes	No	No	Yes
HACCP System - written to prevent carcasses contaminated with fecal material from entering the chill tank	No	Yes	No	No	Yes
Replace Requirement to Test for Generic E. coli and Salmonella performance standards with 2-point testing	No	Yes	No	No	Yes
End Waivers for: Chilling Requirements for RTC Time and Temp Eliminated	No	Yes	No	No	Yes
End Waivers for: Use Online Reprocessing (OLR) Antimicrobial Systems or Offline Antimicrobial Agents	No	Yes	No	No	Yes

Na Does not apply.
a Establishments that already have more than two Inspection Program Personnel (IPP) per evisceration line will get to keep all of them.

As shown in Table 8, online inspectors in the Very Small and Small establishments currently range from 1 to 4 per line. Under the revised traditional inspection system, this range will decrease to 1 to 2 (except that establishments that already have more than two IPP per evisceration line will be allowed to keep them). The Small and Large Establishments, all of which FSIS expects to adopt the proposed new inspection system, will have 1 online inspector per line, down from the current 2 to 4 online inspectors per line under the current non-traditional systems (SIS, NELS, and NTIS) and equal to the number of online inspectors per line under HIMP.

Summary of the proposed rule's provisions

A. Elements of the new system for the slaughter of young chickens and turkeys:

(1) Requirements by establishment personnel to conduct carcass sorting activities before FSIS inspection program personnel (IPP) conduct online carcass inspection so that only carcasses that the establishment deems likely to pass inspection are presented to the FSIS carcass IPP, expected to impact 194 establishments;

(2) A limit of one FSIS online carcass inspector per evisceration line, expected to impact 194 establishments;

(3) Faster slaughter and evisceration line speeds than are permitted under the current inspection systems. Existing evisceration line speeds in the non-traditional inspection systems are currently operating below capacity, expected to impact 194 establishments;

(4) Development, implementation, and maintenance of written procedures to ensure that young chicken and turkey carcasses contaminated with septicemic and toxemic conditions do not enter the chilling tank. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs, expected to impact 219 establishments;

(5) Removal of the existing Finished Product Standards (FPS) and subsequent replacement with a requirement to maintain records

that document finished products meet the definition of ready-to-cook poultry. Establishments will have the flexibility to design and implement measures for producing ready-to-cook poultry that are best suited to their operations. In addition to inspecting for food safety defects, the FSIS on-line carcass inspector will also conduct a carcass inspection for defects that are less important to food safety. The presence of persistent, unattended defects would indicate that the plant is not producing ready-to-cook poultry, expected to impact 219 establishments; and

(6) Requirement that facilities in the establishment include: (a) an online carcass inspection station for each evisceration line; (b) one or more offline carcass inspection stations for each evisceration line; (c) an online area for the online inspection of carcasses for avian leukosis; and (d) an underline trough for each evisceration line in order to prevent the contamination of online carcasses by removed poultry waste or inedible products of the evisceration process. FSIS projects that this action would affect about 219 establishments of about 270 official federally inspected establishments that slaughter young chickens and turkeys and that would adopt this proposed new inspection system. This 219 total includes HIMP

establishments, though they will have already installed this equipment, meaning that 194 establishments are affected.

B. Elements that would affect all 289 poultry, non-ratite slaughter establishments:

(1) Development, implementation, and maintenance of written procedures to prevent contamination of carcasses and parts by fecal material and enteric pathogens (e.g., Salmonella spp. and Campylobacter spp.) as part of an establishment's HACCP plans, sanitation SOP, or other prerequisite programs. FSIS is proposing that, at a minimum, these written procedures include sampling and analysis for microbial organisms at the pre-chill and post-chill points in the process to verify process control.

(2) Development, implementation, and maintenance of written procedures to ensure that carcasses and parts with visible fecal contamination do not enter the chiller as part of an establishment's HACCP plans, sanitation SOP, or other prerequisite programs.

(3) Removal of current requirement to test for generic E. coli and the codified Salmonella pathogen reduction performance standards for poultry.

(4) Removal of the chilling requirements for ready-to-cook (RTC) poultry, which now provide specific time and temperature parameters.

(5) Requirements regarding the use of approved online reprocessing antimicrobial systems or offline reprocessing approved antimicrobial agents, if these procedures for reprocessing are incorporated into their HACCP plans, sanitation SOPs, or other prerequisite programs.

Among the 70 establishments that are expected to use the revised traditional inspection system, the maximum number of FSIS IPP per poultry evisceration line will be set to two unless the establishment is already operating with more than two online IPP per line under the current traditional poultry inspection system.[13] FSIS projects that this action would affect about 51 establishments of about 270 official federally inspected establishments that slaughter young chickens and turkeys; and all 19 official federally inspected establishments that slaughter other chicken and other poultry and that would choose to switch to the proposed revised traditional inspection system.

Analysis of the Benefits and Expenditures (Costs) of the Proposed Action

Baseline

[13] Under the revised traditional inspection system, only establishments that currently have more than two inspectors per line will be allowed to retain more than two inspectors per line.

Table 9 shows the baseline characterization of the U.S. poultry market other than ratites in 2010. Domestic federally inspected establishments slaughtered and dressed about 9.0 billion birds other than ratites in 2010, including about 8.4 billion young chickens; about 140 million other chickens (e.g., fowl and capon); about 252 million turkeys; and about 27 million other poultry (e.g., ducks, geese, quail, pheasants, and squab).

Table 9. Baseline Characterization of the U.S. Poultry Market

	Young Chickens	Other Chickens	Turkey	Other Poultry
Market price ($/bird)[a]	$ 3.38	$ 1.34	$ 22.74	$ 9.02
Market quantity [b] (thousand birds/year)				
Domestic production	8,386,671.6	139,499.2	251,787. 8	26,781.1
Exports	1,314,710.8	14,675.8	18,428.9	903.4
Imports	9,314.1	0	229.8	243.2

A summary of the types of young chicken and turkey operations and the sizes of these official establishments is in Table 10 (FSIS ADRS 2010). Table 10 summarizes the 270 federally inspected establishments that slaughtered young chickens (231 establishments) and turkeys (39 establishments) and excludes the 19 other establishments that slaughtered only other chickens (such as fowl and capon) (6 establishments) and only other poultry (such as squabs, pheasants, quail, ducks or

geese) (13 establishments) in 2010 along with the 19 that slaughtered other chicken and other poultry.

Table 10. Summary of HACCP Establishment Size of the 289 Official Establishments that Slaughtered All Poultry under Federal Inspection in 2010 (FSIS ADRS, 2010)

Type of Operation		Very Small	Small	Large	Total	Percent of all est.
Young Chicken*	Young Only	7 (4%)	33 (20%)	124 (76%)	164	(57%)
	Young and Mature	11 (42%)	14 (54%)	1 (4%)	26	(9%)
	Young Chicken and Other Poultry	26 (63%)	13 (32%)	2 (5%)	41	(14%)
Turkey	Young Only	7 (23%)	6 (20%)	17 (57%)	30	(10%)
	Young and Mature	0	4 (44%)	5 (56%)	9	(3%)
Total Young Chicken and Turkeys		**51 (19%)**	**70 (26%)**	**149 (55%)**	**270 (100%)**	**(93%)**
Other Chicken		0	4 (67%)	2 (33%)	6	(2%)
Other Poultry		3 (23%)	10 (77%)	0	13	(4%)
Total Poultry		**54 (19%)**	**84 (29%)**	**151 (52%)**	**289 (100%)**	**(100%)**

*Establishments that slaughter primarily young chickens.

Projected number of establishments that will opt for the revised traditional system

FSIS is proposing that all establishments that slaughter poultry other than ratites and are not participating in the new inspection system must switch to the proposed revised traditional inspection system.

FSIS projects that about 70 federally inspected establishments will switch from their current traditional inspection system to the proposed revised traditional system for the slaughter of poultry, other than ratites.

The basis for this projection is that these 70 establishments consist of 51 HACCP Very Small establishments, or about 19 percent, of the 270 official federally inspected establishments that slaughter young chickens and turkeys and 19 establishments that slaughter poultry other than young chicken or turkey (or ratites). The Very Small young chicken and turkey establishments do not have sufficient output volume over which to spread the initial set-up costs of the proposed new system or the training and maintenance costs resulting from this system.

These 70 establishments represent about 24 percent of the 289 official federally inspected establishments that slaughtered

one or more classes of poultry other than ratites,[14] under all poultry inspection systems in 2010. In addition, based on FSIS's ADRS records, the 70 establishments slaughtered less than 1 percent of all poultry (other than ratites) of the domestic poultry industry, in 2010. Furthermore, based on FSIS's Animal Disposition Reporting System (ADRS) records of 2010, the approximately 219 official federally inspected establishments slaughtered about 99.9 percent of the young chickens and turkeys of the domestic poultry industry in 2010.

Projected changes in the number of lines and shifts under the revised inspection system

FSIS ADRS 2010 records indicated that there were 663 line shifts in 270 establishments that slaughter young chickens and turkeys, as shown in Table 11.[15] In these establishments, one shift is defined as about 8 hours per day and two shifts as about 16 hours per day. Approximately 55 percent of the 270 establishments operated two slaughter shifts per day in 2010. For this analysis, the 663 line-shifts of production results

[14] Based on FSIS's Animal Disposition Reporting System (ADRS) of 2010, 289 establishments slaughtered all classes of poultry, under all poultry inspection systems in 2010, other than ratites. Of the 289 establishments, about 270 establishments slaughtered young chicken and young turkey in 2010.

[15] The very small establishments that slaughter annually a relatively small number of young chickens and turkeys by methods that do not use a high-speed line are included.

from multiplying the number of lines by the number of shifts. Table 11 shows the details of the FSIS ADRS 2010 information on the 270 young chicken and turkey establishments, classified by current inspection system. FSIS maintains this type of information because staffing patterns in current inspection are determined based on the number and type of slaughter lines. These 663 lines operate daily in the 270 young chicken and turkey establishments with one or two 8-hour-shift(s), on about 5 or 6 days of the week.

Table 11 also summarizes the transition of the young chicken and turkey industry to the proposed new inspection system. This table shows distribution of the 270 establishments that slaughtered young chickens and turkeys in 2010.

Of the 187 young chicken establishments (not under the traditional inspection system) with 542 high-speed lines, there were 117 establishments under SIS inspection, 50 under NELS inspection, and 20 under the HIMP inspection. Of the 32 turkey establishments (not under the traditional inspection system) with 56 high-speed lines, there were 27 establishments under NITS inspection, and 5 under the HIMP inspection. Therefore, 219 of the 270 young chicken and turkey establishments, or 81 percent, have about 598 lines that are high speed.

Table 11. Transition of 270 Official Establishments and Line-shifts that Slaughtered Young Chickens and Turkeys under Federal Inspection Systems to the New Inspection Systems and the Revised Traditional Inspection System (source: FSIS ADRS, 2010).

<table>
<tr><th colspan="6">Inspection Systems Before the Rule</th></tr>
<tr><td colspan="6">Slaughter Processing – with Lines in 2010
270 Establishments
663 Line-shifts</td></tr>
<tr><td colspan="5">High-Speed Lines
219 Establishments
598 Line-shifts</td><td>Low-Speed Lines
51 Establishments
65 Line-shifts</td></tr>
<tr><td colspan="3">Young Chickens
187 Establishments
542 Line-shifts</td><td colspan="2">Turkeys
32 Establishments
56 Line-shifts</td><td>Young Chickens and Turkeys
51 Establishments
65 Line-shifts</td></tr>
<tr><td>SIS

117 Estab.
346 Line-shifts</td><td>NELS

50 Estab.
153 Line-shifts</td><td>HIMP

20 Estab.
43 line-shifts</td><td>NTIS

27 Estab.
42 line-shifts</td><td>HIMP

5 Estab.
14 line-shifts</td><td>Traditional

51 Establishments
65 Line-shifts</td></tr>
<tr><th colspan="6">Expected Inspection Systems After the Proposed Rule is Implemented</th></tr>
<tr><td colspan="5">New Inspection System (Young Chickens and Turkeys)
219 Establishments
598 Line-shifts</td><td>Revised Traditional
51 Establishments
65 Line-shifts</td></tr>
</table>

Notes: The number of line shifts is the number of slaughter lines in establishments that operate one shift plus two times the number of lines in establishments that operate two shifts. Each shift is about 8 hours of operation per day.

Table 12 shows that of the 187 young chicken establishments (not under the traditional inspection system) with 542 high-speed lines, 127 were HACCP large establishments and 60 were HACCP small establishments. Of the 32 turkey establishments (not under the traditional inspection system) with 56 high-speed lines, 22 were HACCP large establishments and 10 were HACCP small establishments. None of the HACCP very small establishments is known to have high-speed line systems.

Table 12. Number of Lines of 289 Establishments that Slaughtered Young Chickens, Other Chickens, Turkeys, and Other Poultry under Federal Inspection Systems (FSIS ADRS, 2010).

Numbers of Evisceration Lines in Active Federally Inspected Establishments that Slaughter All Classes of Poultry Other than Ratites

Establishment HACCP Size	Number of Establishments	Number of Evisceration Line-shifts	Number of Establishments - 1-shift	Number of Establishments - 2-shifts
Very Small	54	68	54	0
Small	84	99	82	2
Large	151	531	0	151
Total	289	698	136	153

Numbers of Evisceration Lines in Active FederallyInspected Establishments that Slaughter Primarily Young Chickens

Establishment HACCP Size	Number of Establishments	Number of Evisceration Line-shifts	Number of Establishments - 1-shift	Number of Establishments - 2-shifts
Very Small	44	58	44	0
Small	60	60	60	0
Large	127	482	0	127
Total	231	600	104	127

Numbers of Evisceration Lines in Active Federally Inspected Establishments that Slaughter Primarily Turkeys

Establishment HACCP Size	Number of Establishments	Number of Evisceration Line-shifts	Number of Establishments - 1-shift	Number of Establishments - 2-shifts
Very Small	7	7	7	0
Small	10	15	10	0
Large	22	41	0	22
Total	39	63	17	22

Numbers of Evisceration Lines in Active Federally Inspected Establishments that Slaughter OnlyOther Chickens (e.g., Fowl)

Establishment HACCP Size	Number of Establishments	Number of Evisceration Line-shifts	Number of Establishments - 1-shift	Number of Establishments - 2-shifts
Very Small	0	0	0	0
Small	4	4	4	0
Large	2	8	0	2
Total	6	12	4	2

Numbers of Evisceration Lines in Active Federally Inspected Establishments that Slaughter Primarily Other Poultry (e.g., Ducks)

Establishment HACCP Size	Number of Establishments	Number of Evisceration Line-shifts	Number of Establishments - 1-shift	Number of Establishments - 2-shifts
Very Small	3	3	3	0
Small	10	20	8	2
Large	0	0	0	0
Total	13	23	11	2

Notes:
(1) Source: FSIS PBIS, March 2011. These federally inspected establishments have 03J HACCP codes for slaughter operations
(2) Source: FSIS ADRS, March 2011. These federally inspected establishments slaughtered poultry in 2010.
(3) 1-shift is about 8 hours of slaughter operation; 2-shifts are about 16 hours of slaughter operation, each workday.

Expected Benefits associated with the voluntary portion of the proposed action-- Consumer and producer benefits from increased line speed:

Reducing current restrictions on line speeds will result in more birds being processed per minute. For this analysis, we used a conservative increase of an average of 6 percent for the line speed and measured as increased birds per minute (BPM), for young chickens.[16] FSIS requests comments on the precision of this estimate for increased line speed. At this relatively low marginal increase in line speed or BPM, we expect that the affected establishments would process an average of 6 percent more BPM with no additional online labor cost on the evisceration line. This is because we expect that the establishments would do some of their sorting and removal of defective birds before rehang. Then there should be few if any empty shackles as can happen when FSIS inspection program personnel remove defective birds after the rehang process. Furthermore, the additional adoption of online reprocessing under these actions would keep additional birds in the evisceration shackles instead of being sent to the rework area. These changes with the new inspection system would increase the

[16] This estimate is very conservative because the current maximum speed allowed is 140 BPM for young chickens (45 for turkeys), while the proposed rule increases this maximum speed to 175 BPM for young chickens (55 for turkeys), which represents a 25 percent increase in line speed for young chickens (22 percent for turkey).

number of birds populating the evisceration shackles and thus increase the throughput or BPM under the new inspection system. For the private sector (e.g., industry and consumer groups) of the economy, FSIS projects that the proposed rule will result in lower costs of production, which will lead to more industry profits and lower consumer prices. The lower production costs may also lead to increased sales of domestic and exported products in the long run. We estimate these economic benefits to be at least $258.9 million (3 cents per bird for 99.9 percent of 8.64 billion birds) annually. This is the expected annual net increase in consumer and producer surplus and does not take into account either the increased long-term production or expanded exports. This increase in well-being from the lower cost will benefit both consumers and producers. Given the estimates of own price elasticity of demand and elasticity of supply for both chicken and turkey,[17] the expectation is that, with the relatively high (in absolute terms) estimate for own price

[17] The 3 cents per bird cost reduction will be divided between producers and consumers. The own price elasticity of demand estimates are -0.43 for chicken and -0.58 for turkey and estimates of elasticity of supply are 0.22 and 0.26 for chicken and turkey, respectively. Muth, M.K., R.H. Beach, C.L. Viator, S.A. Karns, and J.L. Taylor. 2006. "Poultry Slaughter and Processing Sector Facility-Level Model." Prepared for U.S. Department of Agriculture, Food Safety and Inspection Service. Research Triangle Park, NC: RTI International. ERS has estimates of own price elasticity of demand for chicken ranging from -0.602 (1985) to -0.841 (1975-80) (see USDA Economic Research Service at http://www.ers.usda.gov/Data/Elasticities/Query.aspx). The greater value, in absolute terms, for elasticity of demand suggests that the division of the cost reduction between producers and consumers will be weighted toward producers.

elasticity of demand, 2 to 2.4 cents of the 3 cents per bird will go to producer surplus and the remaining 0.6 to 1 cent will go to consumer surplus.Assuming an increase of 6 percent in line speed allows for an estimate of the decrease in processing cost per bird. This means that, for a given unit of a worker's time, 6 percent more birds will be processed. Assuming that labor is 15 percent of the total cost of processing a bird[18], then this increase of 6 percent in the number of birds per period of time means a decrease of 0.85% in the processing cost of a bird. Using a wholesale price of ready-to-cook poultry of $1.35 per kilogram and a ready-to-cook poultry wholesale cost of $1.23 per kilogram[19], then the mark-up from wholesale is 10 percent ((1.35-1.23)/1.23 = 9.8%). With a weighted average wholesale price per bird for young chicken and turkey of $3.94[20], the wholesale cost, using the mark-up margin of 10.0%, is $3.58. With the 0.85% reduction in cost, the wholesale cost will decline by 3 cents ($3.58 x 0.0085). This reduction of 3 cents will be divided

[18] Structural Change in U.S. Chicken and Turkey Slaughter. By Michael Ollinger, James MacDonald, and Milton Madison. Economic Research Service, U.S. Department of Agriculture. Agricultural Economic Report No. 787

[19] See p. 269 of Watkins,B, YC Lu, and YR Chen. Economic feasibility analysis for an automated on-line poultry inspection technology. Poultry Science 2000 79: 265-274.

[20] Muth, M.K., R.H. Beach, C.L. Viator, S.A. Karns, and J.L. Taylor. 2006. "Poultry Slaughter and Processing Sector Facility-Level Model." Prepared for U.S. Department of Agriculture, Food Safety and Inspection Service. Research Triangle Park, NC: RTI International.

between producers and consumers, based on the relative absolute values of the elasticities of demand and supply.

Expected Benefits associated with the voluntary portion of the proposed action—Public health benefits from reallocating FSIS inspection activities:

FSIS hypothesizes that switching existing FSIS IPP activities towards more off-line verification activities (such as sanitation performance standards, sampling, other inspection requirements, and fecal inspections) may reduce pathogen levels in poultry slaughter establishments. This is supported in the findings from the FSIS Risk Assessment (October, 2011), which found a significant correlation between more off-line inspection activities and lower levels of Salmonella and Campylobacter in certain poultry products. It is possible that these reductions may lead to a corresponding reduction in illnesses.

Using results from this risk assessment (Table 7), FSIS estimates that the proposed rule is expected to reduce the number of human illness attributed to young chicken and turkey products by an average of about 4,286 (with a range of 1,514 to 7,682) Salmonella spp. illnesses and about 986 (with a range of 26 to 2,865) Campylobacter spp. illnesses. Annual *Salmonella*

spp. cost savings from an averted case is $18,000 (74 FR 33030)[21]; and the annual Campylobacter spp. cost savings from an averted case is $2,067[22]. Thus, FSIS projects that the monetized value of the human illness reductions is an expected annual average of about $79.19 million (with a range of $27.3 million to $144.2 million).

[21] Food and Drug Administration, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, July 2009. Batz et. al estimate an averted Salmonella illnesses is $3,220. This would reduce the estimated cost savings from 4,286 averted cases from Salmonella, from $77.15 million to $13.8 million. The final economic analysis will provide estimates for Salmonella and Campylobacter based on consistent methodology.

[22] Batz, Michael B., Sandra Hoffman, and J. Glenn Morris, Jr. 2011. Ranking the Risks: The 10 Pathogen-Food Combinations with the Greatest Burden on Public Health. University of Florida Emerging Pathogens Institute.

Table 13: Expected Total potential reductions in human illnesses or illnesses averted and Projected Cost Savings due to better inspection procedure performance in young chicken and turkey slaughter establishments

	What happens if all young chicken and turkey establishments have increased unscheduled offline inspection procedures?[1,2,3]		
		Range	
	Expected value	10th percentile	90th percentile
Annual Salmonella spp. cost savings[a] and averted illnesses:	$77.15 million (4,286 illnesses averted)	$27.25million (1,514 illnesses averted)	$138.28million (7,682 illnesses averted)
Annual Campylobacter spp. cost savings[b] and averted illnesses:	$2.04 million (986 illnesses averted)	$0.05 million (26 illnesses averted)	$5.92 million (2,865 illnesses averted)
Annual Total Cost savings	$79.19 million	$27.30 million	$144.20 million

[1] The number of establishments in each size category throughout the economic analysis is different from the number used in the risk assessment. The risk assessment uses the most recent data for the correlation between baseline and inspection data (2008) and participating establishments, while the economic analysis uses 2010 size categories to reflect the most up-to-date size distribution.
[2] The reported expected reductions in illnesses represent the unscheduled inspection procedures scenario from the risk assessment ;
[3] Totals may not add up due to rounding.
a Average cost savings from an averted Salmonella spp. cost case is $18,000. This estimate is based on the FDA estimate (74 FR 33030)
b Average cost savings from an averted Campylobacter spp. is $2,067. This estimate is based on Batz, Michael B., Sandra Hoffman, and J. Glenn Morris, Jr. 2011

Thus, FSIS estimates that the total annual average private sector benefit from this proposed rule is approximately $338.1 million ($258.9 + $79.19).

Unquantifiable benefits associated with the mandatory portion of the proposed action-- public health benefits resulting from preventing contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation

In addition to the benefits listed in the previous section, FSIS expects public health benefits from the mandatory component of the proposed rule, which is proposed to apply to all poultry slaughter establishments. FSIS is proposing to require that all

poultry slaughter establishments develop, implement, and maintain, as part of their HACCP plans, sanitation SOPs, or other prerequisite programs, written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. FSIS is proposing that, at a minimum, these procedures must include sampling and analysis for microbial organisms at the pre-chill and post-chill points in the process to monitor process control for enteric pathogens.

Effective sanitary dressing and process control procedures are crucial to an establishment’s ability to produce a clean, safe, and wholesome product. The existing regulations require that establishments prevent poultry carcasses contaminated with visible fecal contamination from entering the chiller (9 CFR 381.65(a)). To clarify the existing requirements, FSIS is proposing to require that that establishments develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chilling tank. However, because this proposed requirement reflects existing practices, it is unlikely to have a significant effect on the poultry industry.

While preventing poultry carcasses contaminated with visible fecal material from entering the chiller is an important

safeguard for reducing the prevalence of pathogens on poultry carcasses, it cannot be fully effective unless establishments implement appropriate measures to prevent contamination from occurring throughout the slaughter and dressing operation. Although many establishments do have in place process control measures to prevent contamination of carcasses by enteric pathogens and fecal material throughout the slaughter and dressing process, they are not required to maintain written procedures that describe their process control measures or to maintain records to verify the effectiveness of their process controls. In addition, under the existing regulations, official poultry slaughter establishments are required to comply with prescriptive requirements for testing for generic E. coli at the end of the chilling process as a means of verifying process control.

As discussed earlier in this document, FSIS's experience with using post-chill testing for generic E. coli to monitor process control for fecal contamination and sanitary dressing has led the Agency to conclude that such testing is not the most effective way to prevent contamination from occurring throughout the slaughter and dressing operation. Therefore, FSIS is proposing to remove the prescriptive generic E. coli testing and

replacing it with a more flexible microbiological testing scheme that provides for testing at the points in the process where contamination is most likely to occur, i.e., pre-chill and post-chill. Such a testing scheme has the benefit of allowing poultry slaughter to have the flexibility they need to determine which microbiological organisms will best help them to monitor the effectiveness of their process control procedures. It will also allow establishments to identify the points in their production process where microbial levels are the highest and to implement controls at the points where contamination is most likely to occur.

FSIS is proposing to require that establishments incorporate their procedures for preventing contamination of carcasses with enteric pathogens and fecal material into their HACCP systems, and that they maintain records sufficient to document the implementation and monitoring of their procedures. These records will improve the establishment’s overall HACCP system by providing additional documentation that the establishment and FSIS can use to verify the effectiveness of the establishment’s process control procedures. The records that would be required under this proposed rule, including the records of the establishment’s testing results, will provide

establishments and FSIS with on-going information on the effectiveness of the establishment's process controls, and allow establishments to identify situations associated with in an increase in microbial levels so that they can take the necessary corrective actions to prevent further potential contamination. The documentation that would result from this proposed rule could also limit the scope of a product recall if the establishment maintains records sufficient to allow it to identify the point when a lack of process control could have resulted in product contamination.

Summary of estimated costs and cost savings of the proposed rule

Items 1-7 are costs and cost savings associated with the voluntary component of the proposed new rule:

1. Addition of Online Establishment Workers Because of the Relocation of Online Inspection Program Personnel and Online Sorters – Annual Cost associated with the voluntary component

FSIS expects, based on information provided by establishments participating in the HIMP pilot program, that young chicken and turkey establishments initially would expand their labor resources by employing about 0.8 staff-years of online sorters and carcass-inspection helpers that substitute for every 1.0 staff-year of FSIS online inspection program personnel. For example, in one shift, an establishment that had

ten FSIS online inspection program personnel would add eight online sorters and carcass-inspection helpers in response to the proposal. This substitution rate is based on survey results of young chicken and turkey establishments that are in the HIMP pilot program. As the line speed is increased, however, the substitution rate is expected to increase to 1.0 FTE or even higher.

In the 219 establishments that will slaughter young chickens and turkeys under the new inspection system, FSIS expects between 663 and 750 FSIS online inspection program personnel will be shifted from online inspection to verification inspection activities and online inspection of carcasses (carcass inspection, after the final wash and before the chiller). FSIS estimates that this shifted number of 750 FSIS online inspection program personnel is the upper bound of the expected range for the 219 establishments that would transition to the new inspection system, if the proposed rule is put into effect.

Using the expected substitution rate of 0.8 (8 for 10), the 219 establishments would initially need about 600 (750 x .8) additional trained personnel to do the online sorting of young chickens and turkeys, and helping carcass inspection program personnel for all shifts. This implies that about 750

inspection program personnel would be reassigned to other inspection activities within the establishment (e.g. carcass inspection, verification inspection, and relief coverage). The 750 inspection program personnel, however, may be an over estimate, because of attrition.

The Bureau of Labor Statistics indicated that the expected standard rate for establishment labor is about $13.95 per hour[23], and including benefits and related costs, the wage cost is taken for this analysis to be about $27,900 per staff-year (for about 2000 hours[24] per staff-year). Therefore, the average cost to 219 establishments for the initial additional 600 staff-years of online sorter labor is about $16.7 million annually (600 x $27,900). The cost is expected to decrease on a per-bird basis, because of the expected labor productivity increase associated with increased line speed and more cost-effective evisceration equipment.

2. Training Online Sorters, under the New Inspection system – One-time Cost associated with the voluntary component

Initial training costs are expected, based on information provided by establishments participating in the HIMP pilot program, to be about $200 to $600 per employee (sorter), or an

[23] Based on the 2008 Bureau of Labor Statistics employment cost index.

[24] This is a simplifying assumption.

average cost of about $400 per employee. Additional training costs accrue for the extra establishment employees (sorters) needed to cover for task rotation patterns and scheduled and unscheduled leave of trained establishment employees. FSIS projects, based on information provided by establishments participating in the HIMP pilot program, that rotation schedules would be about three times per shift. FSIS did not report costs in the official HIMP Report. FSIS, however, obtained information on establishment costs and practices from site visits to the HIMP project establishments and non-HIMP establishments that slaughter poultry. The HIMP establishments (20 young chickens and 5 turkeys, as shown in Table 11) reported a range of costs for their implementation of the FSIS's requirements of the HIMP inspection system. Based on this information, FSIS made assumptions on costs and practices of the poultry establishments that would be affected by this proposed rule. We are requesting information on the expected costs to the plants that will be affected by the proposal.

FSIS assumes that the 219 establishments will need about 3.5 to 4 times the replacement staff-hours, or about 2,100 (600 x 3.5) to 2,400 (600 x 4) establishment employees who are trained to perform online sorting and CI helper activities. Therefore, initially, an average of about 2,250 establishment

employees will need to be trained at a one-time average cost of about $400 each, or a total for 219 establishments, of about $0.9 million (2,250 x $400). FSIS is requesting comments on these assumptions for staff turnover in the official establishments.

3. Training, Annually - for Replacement Sorters Due to Labor Turnover – Annual Cost associated with the voluntary component

Annual labor costs are estimated based on information provided by establishments participating in the HIMP pilot program, in order to account for the expected labor turnover rates in young chicken and turkey establishments and the need to train and educate replacement establishment personnel for sorting young chickens and turkeys.

FSIS projects that if the annual turnover rate of trained sorters is taken to be between 5 and 20 percent, or an average of 12.5 percent over a five-year period, then about 281 (.125 x 2250) new establishment sorters will need to be trained annually. FSIS projects that the initial training costs are expected to be about $200 to $600, or an average of about $400 per employee (sorter), then the additional training costs will average about $0.11 million (281 x $400), annually.

4. Continuing Education & Training, Annually - for Existing Sorter Labor – Annual Cost associated with the voluntary component

After the initial training, the establishments will have additional costs to provide ongoing annual education and training (formalized). This education and training is for the knowledgeable establishment staff (sorters) of an average of about 2,250 persons who need to maintain a sufficiently high correlation of agreement with FSIS on regulatory compliance for dressing performance standards. The annual training cost, based on information provided by establishments participating in the HIMP pilot program, was about $150 to $200 per sorter, or an average of $175 per sorter, then the total average cost would be about $0.39 million (2250 x $175), annually.

5. Additional Facilities: Online Carcass and Offline Inspection Stations, Avian Leukosis Inspection Area, and Underline Troughs associated with the voluntary component

Under the proposal, all of the poultry establishments participating in the new poultry slaughter inspection system will need to add capital investments to install a carcass inspection station except for the establishments participating in the HIMP pilot.

Establishments operating under SIS, NELS, and NTIS are currently required to have an underline trough but they will need an additional new trough at the end of the evisceration line. The 25 establishments (20 young chicken and 5 turkey)

that operate under HIMP will not need new trough installations under the proposed new rule. This means that of the 219 establishments projected to adopt the proposed new system, 194 will need installations that will require inspection stations that will cost about $5,000 to $6,000, or an average of about $5,500, for most establishments, based on information provided by establishments participating in the HIMP pilot program. FSIS assumes installations will require a stainless steel underline trough (or equivalent) that will cost about $8,000 to $12,000, or an average of about $10,000, for most establishments, based on information provided by commercial construction guidelines of costs for purchasing (or constructing) and installing such systems.

For the carcass inspection station, this cost is for the construction of a stainless steel elevated stand that has stairs and a surrounding guardrail. This carcass inspection stand must have a floor area large enough to allow sufficient space to accommodate the carcass inspection program person and an establishment employee, that is, a helper for removal of defective or rejected birds from the line. This inspection station would contain plumbing for hot and cold water, and a stainless steel hand-washing basin.

Furthermore, electrical service must be installed for powering bright lights (200 foot-candles of illumination at the level of the bird) required for inspection, and control switches must be installed to allow the starting and stopping of the eviscerating line. The verification inspection station typically is already in place in most young chicken and turkey, and other poultry slaughter establishments. Therefore, in most cases, there would be no additional cost for a verification inspection station near the end of the eviscerating line. The verification inspection station is typically a stainless steel table illuminated with bright lights (200 foot-candles).

These capital investments for the carcass inspection stations are necessary for each of the about 566 eviscerating lines now installed in the 194 non-HIMP establishments that will implement the new inspection system. Therefore, the calculated cost for adding carcass and verification inspection stations for the 194 establishments is about $8.8 million (566x $15,500).

6. Carcass Dressing for Meeting the Definition of Ready-to-Cook (RTC) Poultry and the Removal of the Finished Product Standards (FPS) under the New Inspection System associated with the voluntary component

FSIS is proposing to remove the existing Finished Product Standards (FPS) and replacing them with a requirement that establishments maintain documentation to demonstrate that the

products resulting from their slaughter operations meet the definition of ready-to-cook poultry. Establishments will have the flexibility to design and implement measures for producing ready-to-cook poultry that are best suited to their operations. FSIS on-line carcass inspectors will inspect each carcass for defects that are important for food safety, such as septicemia and toxemia, as well as for defects that are less important to food safety but that may render carcasses or parts unwholesome or adulterated, such as persistent, unattended removable animal diseases and trim and dressing defects.

FSIS seeks comments on these carcass dressing issues - products resulting from their slaughter operations would meet the definition of ready-to-cook poultry. Based on meeting the definition of ready-to-cook poultry, how many additional birds would go to the salvage and reprocessing area? How many additional establishment employees would be added to the eviscerating line to do online trimming and reprocessing? What are the relationships between salvage and reprocessing activities (online and offline) and eviscerating line speeds? For example, for every 20 to 25 percent increase in line speed, would the establishment require a five percent increase in labor time for extra trimming and cleaning activities (online and offline)? FSIS also seeks comments on the requirement that

establishments maintain documentation to demonstrate that the products resulting from their slaughter operations meet the definition of ready-to-cook poultry.

7. Elimination of Some Line Speed Restrictions – Annual Cost Savings associated with the voluntary component;

Based on information provided by establishments participating in the HIMP pilot program, establishments will marginally increase their line speeds given the opportunity to take advantage of the flexibility provided by the proposal and relocation of inspection program personnel. This will reduce their dressing costs, as discussed in the benefits section above. To gradually increase line speeds, some establishments will not need to purchase additional equipment, until they reach their slaughter and eviscerating-line system capacity limit (i.e., re-hang, chilling, or cold (chilled and frozen) storage capacity). Some establishments will need to purchase more automated evisceration and dressing equipment, or eliminate bottlenecks. Eliminating bottlenecks of production could include the establishment's additional capital investments (facilities or equipment) of upgrading the capacity of transfer and re-hang stations; straightening the run of slaughter and eviscerating lines; increasing cut-up or deboning capacity;

adding chillers or increasing chilling capacity; or increasing cold (chilled and frozen) storage capacity.

FSIS solicits information on how the elimination of some line speed restriction in the proposed rule would affect cost saving per dressed carcass, such with greater throughput of dressed carcasses and a lower unit cost per dressed carcass or per pound of product for labor, materials, water, and energy per bird or per pound of dressed poultry carcass. FSIS also solicits information on planned investments in the domestic poultry industry in order to increase evisceration line speed within the next few years.

The estimated costs and costs savings to establishments from the voluntary portion of the proposed regulation are summarized in table 14a. Annualized costs are calculated using a discount rate of 7% over a ten year planning period.

Table 14a. Estimated annual cost (cost savings) of the proposed rule to establishments: Elements associated with the voluntary component of the proposed new rule (millions of dollars)

	One-time costs	Recurring annual costs
Additional annual sorting labor		16.7
Additional knowledge costs (human capital)		
Initial one-time training of sorting workers	0.9	
Training annual sorting labor-turnover rate of 12.5%		0.11
Continuing annual education and training		0.39
Additional one-time capital expenditure for inspection stations and underline troughs	8.8	

Total costs to establishments from voluntary component	9.7	17.2
Average cost to establishments from voluntary component	18.49	

Items 8-13 are costs and cost savings associated with the mandatory component of the proposed new rule:

8. Sampling and Analysis for Microbial Organisms Pre-chill and Post-Chill to monitor Process Control for Enteric Pathogens– one-time and annual cost associated with the mandatory component

New sampling is required for a one-time baseline and for recurring microbial testing to monitor process control for enteric pathogens. Such testing is required as part of the written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. FSIS is proposing that establishments incorporate these procedures into their HACCP plan, or sanitation SOP, or other prerequisite program, and that they maintain records sufficient to document the implementation and monitoring of these procedures.

The baseline sampling would be done in a relatively short period of time and only sample a few events. Thus it would require less labor for collection compared to the ongoing sampling that would extend over a year with multiple sampling events. Therefore, the estimated cost per sample for the one-time baseline is lower than for the ongoing sampling. The baseline was calculated by multiplying 150 samples collected for

the baseline by the prorated hourly pay of $29.03 for a QC technician for 25 minutes needed to collect the samples and a cost of $33.75 for analytical cost of the samples. This was done for all 289 firms.

For annual costs, the same salary and analytical costs were applied and multiplied by the estimated number of samples, which was calculated by assuming 319,332 chicken samples (8.526 billion chickens divided by 26,700 chickens for the number of sampling events) plus 83,929 turkey samples (251.787 million turkeys divided by 3,000 for sampling events number) multiplied by a wage rate of $29.03 times 5/60.[25]

FSIS projects this cost for testing samples and collection of the samples to be about $2.0 million one-time for the baseline and about $12.6 million annually for the poultry industry.[26]

[25] Samples are assumed to be collected for every 26,700 chickens and every 3,000 turkeys. The sampling event refers to sampling at pre-chill and post-chill. This ensures that sampling is based on volume of output and does not impose unnecessary burdens on small businesses.

[26] The baseline sampling has less labor for collection because it is done in a relatively short period of time (a few sampling events) versus ongoing sampling that extends over a year with multiple sampling events. Therefore, the cost per sample for the one-time baseline is lower than for the ongoing sampling. The baseline was calculated by multiplying 150 samples collected for the baseline by the prorated hourly pay of $29.03 for a QC technician for 25 minutes needed to collect the samples and a cost of $33.75 for analytical cost of the samples. This was done for all 289 firms. For annual costs, the same salary and analytical costs applied and were multiplied by the estimated number of samples assuming 1 for each 26,700 chickens and 3,000 turkeys.

Furthermore, FSIS expects costs for the “ready-to-cook” proposed requirements would be offset by the present costs to industry for the Finished Product Standards, and that additional cost, if any, to industry would be minimal. Thus FSIS did not include costs associated with the requirement.

9. Additional Labor Due to Increased Line Speed associated with the mandatory component

Young chicken and turkey, and other poultry slaughter establishments that can increase line speed with their existing eviscerating line equipment, would probably also need to add additional labor to the line in order to handle the additional birds per minute that need to be sorted and trimmed, salvaged, or reprocessed, online and offline. In this scenario, the establishment does not replace its existing eviscerating line equipment with newer technology. More labor is applied to the line but the labor per bird would decrease due to the increase in throughput from the increase in the line speed.

FSIS solicits information on the additional labor that might be needed.

10. Additional Recordkeeping, Monitoring, and Record Storage associated with the mandatory component

Establishments are required to maintain written documentation of sample results for verifying their process

controls. The proposal that all poultry slaughter establishments monitor their systems through microbial testing and recordkeeping implies more information than presently required to be monitored. Thus, FSIS includes only recurring costs associated with record keeping. FSIS assumed that the time spent for a QC technician salaried at $29.03 per hour for recording results keeping (including review) for each sample event is 5 minutes. FSIS estimates the time spent presently is about 2.5 minutes. From these, FSIS estimated recordkeeping costs for this proposed requirement to be $975,600 per year, based on an assumption of 5 minutes to record each of the over 403,300 samples[27] under the new system. This replaces $568,500 for recordkeeping for the generic E. coli testing, based on an estimate of 2.5 minutes per sample for recording. Since FSIS does not specify required testing frequencies, establishments may test with lower frequency than the one assumed and would therefore have lower costs. FSIS does not dictate the frequency of testing that is assumed in the cost estimates. A lower frequency would result in lower costs.

[27] Calculated by assuming 319,332 chicken samples (8.526 billion chickens divided by 26,700 chickens for the number of sampling events) plus 83,929 turkey samples (251.787 million turkeys divided by 3,000 for sampling events number) multiplied by a wage rate of $29.03 times 5/60. For eliminated E. coli recordkeeping, 470,000 samples were recorded in 2.5 minutes at $29.03 per hour.

11. a.) Modification of the HACCP Plans and Process Control Plans - One-time Cost associated with the mandatory component

The establishments would need to modify their HACCP plans, Sanitation SOPs, or other Pre-requisite programs so as to address septicemic and toxemic carcasses and food safety hazards that are reasonably likely to occur. Establishments would also be required to maintain records to document that their product meet the definition for ready-to-cook poultry. Under the proposed rule, establishments will have the flexibility to design and implement measures to address OCP defects that are best suited to their operations. They will also be responsible for determining the type of records that will best document that they are meeting the ready-to-cook poultry definition. The FSIS estimates based on information provided by establishments participating in the HIMP pilot program, that these initial costs (for developing and verifying the plan) would average about $5,000 for a HACCP small and about $9,000 for a HACCP large establishment; and FSIS projected about $2,000 for a HACCP very small establishment for process control implementation costs in response to the requirements for the new inspection system in the first year; or a one-time average cost of about $1.9 million ((83 x $5000) + (151 x $9000) + (55 x $2000)) in total for 289 establishments.

11. b.) Written procedures to ensure that carcasses and parts with visible fecal contamination do not enter the chiller, after evisceration operations associated with the mandatory component

FSIS is proposing that all of the 289 federally inspected establishments that slaughtered poultry other than ratites in 2010 develop, implement, and maintain, as part of their HACCP plans, or sanitation SOPs, or other prerequisite programs, written procedures to ensure that carcasses and parts with visible fecal contamination do not enter the chiller, after evisceration operations. The one-time cost to develop the plan and ongoing cost of implementation and maintenance of the plan are included in the costs of changing the HACCP system as discussed in cost item number 5 above. FSIS solicits information on added costs that are associated with the proposed requirement for written procedures, and then the implementation and maintenance costs of the procedures to ensure that carcasses and parts with visible fecal contamination do not enter the chiller, after evisceration operations.

11. c.) Written procedures to ensure that young chicken and turkey carcasses contaminated with septicemic and toxemic conditions do not enter the chilling tank, for the new inspection system associated with the mandatory component

FSIS is proposing that the 219 federally inspected establishments that would slaughter young chickens and turkeys under the new inspection system develop, implement, and maintain

written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chilling tank. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. The one-time cost to develop the plan and ongoing cost of implementation and maintenance of the plan are included in the costs of changing the HACCP system as discussed in cost item number 5 above. FSIS solicits information on added costs that are associated with this proposed requirement.

12. Elimination of Generic E. coli Standards – Annual Cost Savings associated with the mandatory component

FSIS proposes the removal of the current requirement that poultry establishments test for generic E. coli and to remove the codified Salmonella pathogen reduction performance standards for poultry. For the poultry industry, this would mean about 77,000 fewer samples collected and tested for generic E. coli. FSIS projects that this action would affect about 289 official federally inspected establishments that slaughter all poultry other than ratites. FSIS projects that this would have a cost savings of approximately $11.71 million per year for the 289 official federally inspected establishments that slaughter all poultry other than ratites. This is the cost saving of labor for sampling event collection; materials; shipping; and

laboratory testing from eliminating about 470,000 E. coli samples and testing. The estimated cost per sampling avoided is about $57.10 per sampling event. For 470,000 sampling events at $30, the annual total would be about $11.71 million.

13. Elimination of Carcass Cooling Standards – possible cost savings associated with the mandatory component

FSIS projects that the proposed elimination of carcass cooling standards will remove some of the “bottleneck” restrictions of the chilling system. FSIS projects that the birds may take less time to cool to meet this new requirement of no microbial growth. FSIS projects that the establishments will be able to increase the output from the chiller in order to accommodate increased line speed. FSIS solicits information on any added costs and any cost saving associated with the proposed elimination of carcass cooling standards.

Table 14b shows the considered additional one-time, first-year, and annual average expenditures for the proposed rule for the 289 affected poultry establishments of complying with the mandatory actions of the proposal. Again, annualized costs are calculated using a discount rate of 7% over a ten year planning period.

Table 14b. Estimated annual cost (cost savings) of the proposed rule to establishments: Elements associated with the mandatory component of the proposed new rule (millions of dollars)

	One-time costs	Recurring annual costs
Additional PC microbial testing – plate counts, collection, packaging, shipping		
One-time baseline	2	
Annual recurring testing		12.6
Additional annual recordkeeping, monitoring, and record storage		0.98
Eliminated generic E. coli testing recordkeeping		-0.57
Additional one-time HACCP system plans (additions and modifications) and ProcessControl (PC) plan development	1.9	
Reduced annual microbial testing - generic E. coli plate counts, collection, packaging, and shipping		-11.7
Total costs to establishments from mandatory component	3.9	1.3
Average costs to establishments from mandatory component	1.82	

For the poultry industry, as shown in Tables 14a and 14b,

the one-time costs are about $13.6 million, consisting of $9.7 million in one-time costs incurred by the establishments that adopt the proposed new inspection system and $3.9 million in one-time costs for all firms in the industry with the requirements of the proposed new rule. The on-going annual average net expenditure to the poultry industry would be about $18.5 million, with $17.2 million from adopting the proposed new rule and $1.3 million in costs for all firms with this proposed rule. These cost figures annualize to $20.3 million over 10 years at 7%. In addition, however, FSIS projects a cost savings for the poultry industry. FSIS projects that the dressing costs per bird will be lowered for about 99.9 percent of the RTC young chicken and turkey production of the poultry industry. FSIS projects a net cost savings with the proposed regulation of about $258.9 million annually for companies that slaughter poultry (see Table 16 below). The initial one-time expenditure and on-going annual expenditures are more than offset by these savings due to the increased line speed. These net savings are included in the expected benefits.

The proposed new rule will have mandatory costs for all firms, whether they adopt the proposed new rule or go to the revised traditional inspection system. FSIS expects the 51 very

small establishments that slaughter young chicken and turkey to adopt the revised traditional inspection system instead of the proposed rule yet still incur the mandatory costs listed in Table 14b. To assess the impact on these very small establishments, Table 14c lists these estimated mandatory costs.

As mentioned, the baseline was calculated by multiplying 150 samples collected for the baseline by the prorated hourly pay of $29.03 for a QC technician for 25 minutes needed to collect the samples and a cost of $33.75 for analytical cost of the samples for all 289 establishments. This comes to about $6,900 per firm and $351,000 for the 51 very small establishments. For annual recurring costs, the same salary and analytical costs applied and were multiplied by the estimated number of samples, as before, and adjusted for volume so that the cost of annual recurring testing for very small establishments is 0.1 percent of the cost for recurring testing in Table 14b. For annual recording and storage, the samples are based on volume and this is adjusted to 0.1 percent of the costs in Table 14b, or about $1,000 annually, to be balanced by the savings from eliminated generic E. coli testing recordkeeping of 0.1 percent of the estimated $568,500 annually. The cost of the additions and modifications to the HACCP plans and the process control (PC) plan development are

estimated at $2,000 per very small establishment, for a total cost of $102,000 for the 51 very small establishments. The cost savings for very small establishments from reduced annual microbial testing is volume-based and is 0.1 percent of the $11.7 million in annual savings to the industry.

Table 14c. Estimated annual cost (cost savings) of the proposed rule to very small establishments: Elements associated with the mandatory component of the proposed new rule (millions)

	One-time costs	Recurring annual costs
Additional PC microbial testing – plate counts, collection, packaging, shipping		
One-time baseline	0.351	
Annual recurring testing		0.013
Additional annual recordkeeping, monitoring, and record storage		0.001
Eliminated generic E. coli testing recordkeeping		-0.001
Additional one-time HACCP system plans (additions and modifications) and ProcessControl (PC) plan development	0.102	
Reduced annual microbial testing - generic E. coli plate counts, collection, packaging, and shipping		-0.012
Total costs to establishments from mandatory component	0.453	0.001
Average costs to very small establishments from mandatory component	0.061	

These costs are estimated at about $0.453 million in one-time costs and about $0.001 million for annual costs. This is over $8900 per very small establishment in one-time costs,

primarily for establishing the baseline testing required for all firms under the proposed rule, and very low costs per very small establishment in annual costs. These costs are based on the mandatory elements of the proposed new rule that apply to all establishments that slaughter young chicken and turkey, whether they adopt the proposed new rule or move to the revised traditional system of inspection. These estimates include the reduction in costs from the elimination of the generic E. coli testing. The annualized costs of these requirements for very small establishments are $0.061 million, or about $1,200 per establishment for the 51 very small establishments. This represents an average annual cost per bird of less than 0.9 cents (and less than 0.25 cents per pound), based on the assumption that very small establishments slaughter one-tenth of one percent of the nearly 9 billion birds slaughtered annually.

These costs are estimated at about $0.45 million in one-time costs and about $0.02 million for annual costs. This is over $8800 per very small establishment in one-time costs, primarily for establishing the baseline testing required for all firms under the proposed rule, and about $400 per very small establishment in annual costs. These costs are based on the mandatory elements of the proposed new rule that apply to all

establishments that slaughter young chicken and turkey, whether they adopt the proposed new rule or move to the revised traditional system of inspection. These estimates include the reduction in costs from the elimination of the generic E. coli testing. The annualized costs of these requirements for very small establishments are $0.08 million, or about $1,600 per establishment for the 51 very small establishments. This represents an average annual cost per bird of less than 0.9 cents (and less than 0.25 cents per pound), based on the assumption that very small establishments slaughter one-tenth of one percent of the nearly 9 billion birds slaughtered annually.

Expected FSIS Budgetary Effects:

Table 15 shows the expected FSIS budgetary net savings effects from the proposed rule for the slaughter of all poultry other than ratites and including the new inspection system for the slaughter of young chickens and turkeys.

FSIS used the following scenario assumptions in its financial cost model to project the FSIS budgetary effects of the proposed rule:

- 175 establishments (150 young chicken establishments and 25 turkey establishments)

- 1,498 food inspector grade increases (from GS7 to GS8) (1,436 inspectors in young chicken establishments and 62 inspectors in turkey establishments)
- 375 CSI (Consumer Safety Inspector) upgrades (from GS8 to GS9) (354 in young chicken establishments and 21 in turkey establishments)
- A reduction in the number of inspector positions (between approximately 500 and 800) through managing vacancy or refill rates, a reduction of approximately 190 positions will be affected in the following way:.
    - Of the 190 positions, 100 will be relocated to livestock slaughter establishments
    - 90 inspectors will be relocated to jobs in the Agency for which their skills and experience qualify them.
- A reduction of approximately 140 SCSI (Slaughter Consumer Safety Inspector) positions – potentially all of the personnel involved to be relocated
- 150 fewer OTP staff years required for relief – no severance or relocation impact
- Training costs for approximately 3,300 employees
- Relocation costs for approximately 350 CSI employees
- Travel savings with fewer number of relief inspectors

FSIS projects that the 25 young chicken and turkey establishments currently under HIMP inspections would switch to the new inspection system. The equipment used in the HIMP, as well as in the other current non-traditional inspection systems, can be used in the proposed new inspection system. Furthermore, FSIS projects that about 19 other poultry establishments may enter the program under the SIP waiver. FSIS projects that these establishments will choose to make the capital and labor investment, when they see that their economic competitiveness may diminish. FSIS did not include the impact from these additional establishments in the financial cost model of Table 15 that projects the FSIS budgetary effects of the proposed rule because we expect it to be very small. Establishments that change operations but continue to produce will continue to have FSIS inspectors.

Table 15. Estimated annual cost (cost savings) of the proposed rule to FSIS: Elements associated with the voluntary component of the proposed new rule (millions of dollars)

	First year costs (cost savings)[28]	Recurring costs (cost savings) after first year
Cost from Grade Increases (Salary & Benefits)	$5.1	$8.26

[28] First year cost savings are lower than for the following years because the rule will not be in effect for the full first year.

Training Costs	$4.78	$0
Relocation Costs	$3.79	$0
Savings From Position Elimination	($26.4)	($47.62)
Savings from reduced Relief Inspector Travel	($.14)	($.22)
Total Costs (Savings)	($12.9)	($39.58)

The expected FSIS budgetary savings effects are cost savings to the FSIS related to position elimination of about $47.6 million, after the first year of implementation. Furthermore, FSIS projects cost savings annually from expected reduction in travel expenses for relief IPP. FSIS projected total Relief Inspector travel savings of about $223,000, after the first year of implementation. FSIS, however, projects an annual cost increase for the FSIS IPP upgrade increases from GS-7 to GS-8 and GS-8 to GS-9 that would total about $8.3 million, after the first year of implementation. In addition, FSIS projects a one-time training cost for the FSIS IPP that would total about $4.8 million, and a one-time relocation cost for the FSIS IPP that would total about $3.8 million, in the first year of implementation.

Furthermore, possible IPP health improvement effects are expected to be associated with lower recruitment costs, lower medical and worker compensation costs, and fewer unscheduled leaves.

In summary, budgetary benefits in cost savings will accrue to FSIS from the more effective utilization of its inspection program personnel (IPP) to focus on activities that affect food safety. Based on FSIS projections of its budget cost-savings analysis, the expected benefit to FSIS would be the net savings of about $14.6 million, in the first full year of implementation in FY 2013. Then, in subsequent years, the projected net savings would average about $39.6 million.

Summary of Net Social Benefits

Considering the social benefits and costs discussed, FSIS expects the average net benefits to the public health, the poultry industry and consumers is about $377.7 million annually. The costs outlined in Table 16 below are annualized over 10 years at 7% to $20.3 million. Annual net benefits, therefore are $357.4 million.

Table 16. Expected net social benefits from the proposed rule (millions of dollars) starting with the first full year of implementation.

	Primary Estimate	Minimum Estimate	Maximum Estimate
Benefits			
Annual public health benefits	79.2	27.3	144.2
Annual FSIS net savings	39.6		
Annual cost savings for establishments*	258.9		
Annual total benefits	377.7	325.8	442.7
Unquantified benefits	Additional public health benefits from documentation and testing		
Costs			

Annual cost to establishments	20.3		
Annual net benefits	357.4	305.5	422.4

*note: These cost savings will not all be enjoyed by the establishments. A portion of these savings will be passed on to consumers in the form of lower prices.

Analysis of Considered Alternatives

FSIS considered several alternatives to the proposed rule. Table 17 summarizes these alternatives and presents the annual net benefits associated with each alternative.

A. Taking No Action

FSIS considered maintaining the current inspection system and finished product standards requirements for the 289 establishments that slaughtered young chickens and turkeys, and other poultry in 2010. That is, FSIS considered taking no action. Consequently, poultry establishments slaughtering young chickens and turkeys, and other poultry would not benefit from increased flexibility, productivity, or opportunity for innovation. FSIS would not be able to focus its inspection activities on verification of process controls for product safety and OCPs or on additional offline activities (such as unscheduled sanitary procedures, for example). Under this alternative, establishments would be restricted to the current

regulated eviscerating line speeds that in most cases are operated below the capability of their currently installed eviscerating equipment. This action will have zero net benefits.

Table 17. Comparisons of the Considered Alternatives to the Proposed Poultry Slaughter Rule

Considered Alternatives	BENEFITS	COSTS	NET BENEFITS
A. Take No Action	No change in the existing inspection systems for poultry. FSIS does not need significantly more resources.	Establishments would be restricted to the current regulated eviscerating line speeds that in most cases are operated below the capability of their currently installed eviscerating equipment.	Zero Net Benefits.
B. Intensifying the Present Inspection Systems by Allocating Additional FSIS Resources to Eliminate FSIS Inspection Personnel (IPP) Vacancies	Annual benefits of about $258.9 million from reducing dressing costs.	$32.76 million per year for FSIS to add extra inspectors. FSIS resources are limited for expansion of its workforce and these costs may be prohibitive.	Annual net benefits of $225.0 million.
C. Mandatory Use of Dressing Performance Standards and the New Poultry Inspection System for All Establishments that Slaughter Young Chickens and Turkeys	About $259.2 million from reducing dressing costs added to public health benefits and reduced FSIS costs for total benefits of $378.0 million annually.	Annualized costs of $20.4 million, of which about $0.06 million annually borne by very small establishments under this alternative.	This alternative would have net benefits equal to $357.6 million.
D. The Proposed Rule: the Requirement of a New Inspection System for Young Chickens and Turkeys; a Revised Traditional Inspection System for All Poultry other than Ratites; Requirement of Three Locations for Sampling to monitor process control for enteric pathogens; and other Actions (see Table 8 above).	Public health benefits from reduced illnesses, reduced dressing costs, and FSIS savings add to total benefits of $377.7 million annually. Additional unquantified public health benefits from the mandatory component of the proposed rule.	Annualized costs equal $20.3 million. See Tables 14a and 14b below for explanation of these costs.	Selected Alternative Annual net benefits equal $357.4 million, from $377.7 million in benefits less the costs to industry of $20.3 million.
E. Voluntary component only	$377.7 million in benefits. No additional unquantified benefits, as detailed in section titled “other public health benefits resulting from the mandatory component of the proposed rule.”	Annualized costs of $18.5 million.	$359.2 million annually.

B. Intensifying the Present Inspection Systems by Allocating Additional FSIS Resources to Allow Establishments to Increase the Line Speed and Maintain the Same Level of Food Safety.

FSIS considered intensifying the present inspection system by allocating additional FSIS resources to accommodate the demand of the industry for additional IPP on high-speed evisceration systems that the poultry industry is adopting in order to produce safe poultry products and reduce dressing costs per bird. Annual benefits of this alternative equal approximately $258.9 million from reducing dressing costs by 3 cents per bird for 99.9 percent of 8.64 billion birds slaughtered annually. No additional public health benefits result from this alternative because FSIS staff will not be doing additional offline inspection activities.

This alternative does not change the existing inspection system, no additional training is needed for FSIS or establishment staff. This alternative, however, requires an extra FSIS inspector at each of the 573 high-speed non-HIMP chicken and turkey line shifts at $57,153 year for $32.76 million in annual costs. Resource constraints would not allow for this option. These additional costs (to FSIS) will not be offset by increased safety as the newly hired inspectors will not be performing additional offline tasks. This alternative has net benefits of $225.0 million.

C. Requiring Mandatory Use of Dressing Performance Standards and the New Poultry Inspection System for All Establishments that Slaughter Young Chickens and Turkeys

FSIS considered proposing the mandatory use of dressing performance standards and a New Poultry Inspection System in all federally inspected establishments that slaughter young chickens and turkeys. This alternative is the same as the proposed regulation except that this alternative would be mandatory for the young chicken and turkey industry, while the proposed regulation s a choice between the new inspection system and the revised traditional inspection system. This alternative would result in a replacement of existing choices among other (traditional, SIS, NELS, and NTIS) types of inspection systems within the RTC young chicken and turkey industry. For the projected 270 federally inspected establishments that would slaughter young chickens and turkeys under the new inspection system, this alternative has the costs to the poultry industry of replacing online FSIS IPP with trained establishment personnel for sorting birds. As a result, the poultry industry annual labor costs and labor training costs would be higher due to the extra labor and training necessary to take over the sorting and to maintain personnel proficiency in the sorting of young chickens and turkeys, in the establishments that would not voluntarily choose the new inspection system. These

establishments are the very small establishments that do not have large enough volume to make up for the additional costs imposed by this proposed rule.

This alternative has total annual benefits of 378.0 million. This includes benefits of $259.2 million from reducing costs by 3 cents per bird for 100 percent of the 8.64 billion birds slaughtered annually, and public health benefits of about $79.19 million, and FSIS budget savings, which may exceed the estimate of $39.6 million as establishment personnel replace FSIS inspectors. These benefits are slightly higher than those of the proposed alternative because this alternative covers 100 percent of plants and production. Costs to very small establishments are $0.453 million in initial one-time costs and $0.001 million in annual costs, primarily for underline troughs for one-time costs and additional sorter labor and training for ongoing costs. Annualizing the one-time costs for 10 years at 7 percent brings the annualized cost to $0.061 million. These costs for very small establishments are in addition to the $20.3 million annually calculated for the other establishments, bringing the annual cost of the alternative to $20.4 million. The net benefits of this alternative equal $357.6 million annually.

D. The Proposed Rule: the Requirement of a New Inspection System for Young Chickens and Turkeys; a Revised Traditional Inspection System for All Poultry other than Ratites; Requirement that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing process; Requirement that procedures to prevent contamination include Three Locations for Sampling to monitor process control for enteric pathogens; and other Actions (see Table 8 above).

FSIS's preferred alternative is the proposed rule as discussed above. The Proposed Rule has the requirement of a new inspection system for young chickens and turkeys; a revised traditional inspection system for all poultry other than ratites; requirement that establishments develop, implement, and maintain written procedures to prevent contamination of carcasses with enteric pathogens and fecal material contamination, and that these procedures include, at a minimum, three locations for sampling for microbial organisms to monitor process control for enteric pathogens; and other actions (see Table 8).

The proposed rule gives the individual establishment the choice between the new inspection system and the revised tradition inspected system. An establishment will choose the new inspection system if the benefits, primarily from the expected increased flexibility of operations and lower dressing costs per RTC bird, exceeds the costs of implementation of this proposed new inspection system. While this would probably be true for the HACCP large and HACCP small establishments that slaughtered young chickens and turkeys in 2010, the HACCP very small establishments would find that the initial capital investment in additional facilities and equipment, additional labor for sorting and training sorters costs, and other additional annual costs for maintaining the additional facilities and equipment would not lower their average cost of dressing a RTC bird. FSIS rejected this alternative (alternative C above) in order to minimize the impact on small businesses and to allow them the flexibility to choose the proposed revised traditional inspection system, if they stand to lose from the proposed new slaughter inspection system.

Public health benefits (discussed in detail in the next section) of the proposed rule include a reduction in illnesses attributed to young chicken and turkey. The monetized value of this reduction is $79.19 million annually. Industry cost reductions from the proposed rule are about $258.9 million annually from reducing dressing costs by 3 cents per bird for 99.9 percent of 8.64 billion birds. FSIS savings under the proposed rule are expected to equal $39.58 million annually, bringing total benefits to $377.7 million annually.

Costs of the proposed rule include a one-time expenditure of about $13.6 million and net variable expenditures of $18.5 million annually (see Tables 14a and b). Annualizing the costs at 7 percent for 10 years brings the annual cost total to $20.3 million. Net benefits of the proposed rule are $357.4 million annually.

While Alternative C, mandating uniform standards for all establishments, provides net benefits greater in value to the net benefits of the proposed rule, in the interest of regulatory flexibility requirements for small businesses, FSIS proposes in the preferred alternative to make compliance with the proposed new system voluntary. Not adopting the system under the proposed rule will not disadvantage very small establishments

that have niche markets and local markets because the expected market price reduction from the proposed rule is 0.6 to 1 cent per bird which, for an average bird weight of 3.94 lbs., means a price reduction of around 0.15 to 0.25 cents per pound. Evidence of a willingness of consumers to pay a premium for the local food products exists,[29] suggesting that this reduction in price for the output of the firms that adopt the proposed new rule is not expected to disadvantage these establishments that slaughter for local, niche markets.

E. Requiring only the Voluntary Component of the Proposed Rule.

The benefits from this alternative include, as under the proposed rule, the budgetary savings to FSIS from reallocation of personnel and the lower costs per bird from the increased line speeds and public health benefits of $79.19 million annually from reduced illnesses.

As shown in Table 14a, the costs to firms that adopt the proposed new rule are $9.7 million in one-time costs and $17.2 million in annual costs. These costs annualize to $18.5 million over 10 years at 7%.

[29] "Martinez, Steve et al., *Local Food Systems: Concepts, Impacts, and Issues*, ERR 97, U.S. Department of Agriculture, Economic Research Service, May 2010, discusses consumers' willingness to pay a price premium (p.29) for such characteristics as traceability (p.26, p.70) offered by local producers."

This alternative eliminates the mandatory costs to all firms, whether they adopt the proposed new inspection system or not, under the proposed rule. Under the proposed rule, all firms, including the very small firms that FSIS expects will not adopt the proposed rule, must adopt some measures, as listed in Table 14b. These costs are from plan development, recordkeeping, and testing. The benefits[30] of these activities include the conduct of business in a manner more accountable to the public; the support and document of production safety decision-making; and the facilitation of oversight and transparency activities like audits and inspections. The proposed recordkeeping requirements are designed to help operators of facilities and the Agency to identify potential sources of contamination and contain and mitigate the adverse health effects of contaminated food. While many of these benefits are social and not captured by the firms, the lower probability of recall, the lower costs of indentifying contaminated product if a recall occurs, and enhanced product reputation when a product is not subject to recall, all benefit the implementing firms. Table 14c lists the mandatory costs that

[30] Please see the FDA's preliminary regulatory impact analysis of the Preventive Controls rule for a similar discussion of recordkeeping benefits.

FSIS expects for the 51 very small establishments that FSIS projects will not adopt the proposed new inspection system.

With annual benefits estimated at $377.7 million and costs at $18.5 million, the annual net benefits of this alternative are $359.2 million. FSIS did not select this alternative even though it has higher quantified net benefits (compared to the proposed rule) because the net benefits of the proposed rule are expected to be higher due to additional benefits (disc used in section titled “Other public health benefits resulting from the mandatory component of the proposed rule”).
from the voluntary component of the proposed rule.

VI. Initial Regulatory Flexibility Analysis

In accordance with the Regulatory Flexibility Act, FSIS reviewed the proposed rule for its effects on small businesses. The Administrator has determined that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-612); this proposed rule would not have a significant economic impact on a substantial number of small companies or small entities.

FSIS considered proposing the mandatory use of dressing performance standards and the New Poultry Inspection System in all federally inspected establishments that slaughter young chickens and turkeys. (See Table 17 for a list of all

alternatives considered.) This alternative is the same as the proposed rule except that this alternative would make the new inspection system mandatory for the young chicken and turkey industry, while the proposed rule is a choice between the new inspection system and the revised traditional inspection system.

This alternative would result in a replacement of existing choices among other (traditional, SIS, NELS, and NTIS) types of inspection systems within the RTC young chicken and turkey industry. The poultry industry would not have a choice between the proposed new inspection system and the revised traditional inspection system for establishments that slaughter the young chickens and turkeys.

The preferred alternative (the proposed rule) has the choice that is given to the individual establishment to determine if it is beneficial for the establishment to choose the new inspection system (if the expected increased flexibility of operations and lower dressing costs per RTC bird results in benefits that would exceed the costs of implementation of this inspection system).

While this would probably be true for the HACCP large and HACCP small establishments that slaughtered young chickens and turkeys in 2010, and the HACCP very small establishments could find that the initial capital investment in additional

facilities and equipment, additional labor for sorting and training sorters costs, and other additional annual costs for maintaining the additional facilities and equipment a burdensome change. FSIS expects dressing costs to decrease by about $2.6 million for very small establishments with the proposed new inspection system while expenditures would increase by an annualized amount of $0.28 million for 10 years at 7% to comply with the system. These costs are already in addition to those outlined in Table 14c, which annualize to $0.13 million at 7% over 10 years.

This alternative of mandatory adoption by all establishments was not selected because of its expected economic burden on small businesses and to allow small producers the flexibility to choose the proposed revised traditional inspection system, if they stand to lose from the proposed new slaughter inspection system.

Expected Effects on Small Entities or Small Companies

There are economies of size and scale with the evisceration and dressing of young chickens and turkeys[31]. A possible result of these economies of size and scale is that there are only about 54 HACCP very small establishments owned by 54 small

[31] Ollinger, M., J. MacDonald & M. Madison, Structural Change in U.S. Chicken and Turkey Slaughter. USDA Economic Research Service, Agricultural Economics Report 787. 2000.

companies under Federal Inspection that slaughter poultry. These very small companies slaughtered only about one-tenth of one percent of the young chickens, turkeys, and other poultry slaughtered, in 2010 (ADRS, 2010). Further, about 34, or about 63 percent, of these 54 very small companies slaughtered other livestock such as cattle, calves, swine, sheep, and goats, in 2010, according to FSIS's ADRS. These 34 companies often operate seasonally for slaughtering poultry, yet slaughter livestock during the entire year.

The proposed rule is expected to result in a cost reduction of about 3 cents per bird and a reduction of the price of poultry of about 0.6 to 1 cent per bird (or about 0.15 to 0.25 cents per pound) for those establishments that choose to operate under the new poultry inspections system. All of the very small establishments that slaughter poultry are expected to choose to operate under the revised traditional inspection system rather than the New Poultry Inspection System. However, the reduction in price per bird for establishments operating under the proposed new rule is not expected to impose a burden on very small establishments because they generally slaughter birds that are sold in local, niche markets, where consumers have shown a willingness to pay more for a food product that is of local

origin.[32] An ability to charge a higher price for product differentiation based on origin enables the very small establishments to compete in the market even with the cost advantage that other producers will have with the proposed new rule.

Under the proposed rule, the mandatory costs on very small establishments (shown in Table 14c) annualize at 7% over 10 years to $0.130 million, or about $2,500 per establishment. With the assumption that very small establishments account for one-tenth of one percent of the total number of the nearly 9 billion birds slaughtered annually, the annualized costs of the mandatory portion of the proposed rule amount to less than 1.5 cents per bird or less than 0.4 cents per pound.

There are about 109 small companies that slaughter small quantities of federally inspected poultry. FSIS expects that none of the very small companies would choose to participate in the new inspection system for the slaughter of young chickens and turkeys because of the one-time set-up costs associated with the new system, but would slaughter young chickens, turkeys, and

[32] Please see Martinez, Steve et al., *Local Food Systems: Concepts, Impacts, and Issues*, ERR 97, U.S. Department of Agriculture, Economic Research Service, May 2010 for a discussion of consumers' willingness to pay a price premium (p. 29) for such characteristics as traceability (p. 26, p. 70) offered by local producers.

other poultry under the revised traditional inspection system. The revised traditional inspection system is designed to minimize costs on these small entities while preserving the social benefits from testing and recordkeeping. Using the estimated cost per very small establishment from the Table 14c figures, the annual burden to small entities that do not adopt the rule because the additional fixed costs required by the rule is $1,500. With an estimated cost of establishment labor of $13.95 per hours, this represents about 100 staff hours annually. The return for this expenditure is the benefits from better testing and recordkeeping, such as greater ability to fulfill mandatory oversight requirements, which cost an unspecified number of staff-hours under the current inspection system, and lower insurance premiums. FSIS believes that a Regulatory Flexibility analysis would not be necessary to evaluate the effects of the proposal on small companies. In making this determination, the Agency considered alternatives (see table 17) to the proposed rule, including one alternative rejected for its small business impact: taking no action, intensifying the current system, mandatory standards for all firms that slaughter young chickens and turkeys, and the voluntary component only. Taking no action would prevent the increased utilization of capacity by firms that FSIS expects to

voluntarily choose the proposed new system. For this reason, FSIS rejected this alternative. The second alternative was to intensify the present system but this would require more FSIS resources and was therefore not feasible. FSIS rejected the third option of mandatory requirements for all firms that slaughter young chickens and turkeys because of the burden that this alternative would place on small establishments. The last option of the voluntary component of the proposed new rule only (as shown in Table 14a) would eliminate the public health benefits of the mandatory requirements.

Public health safeguards are a cost of entering commerce and FSIS believes that product differentiation, based on the growing preference for local produce, will enable very small establishments to effectively compete for market share against the larger firms that will enjoy the cost reduction from the proposed new rule.

FSIS assumes that some of the small companies may choose the new inspection system under the proposed rule. With this choice, these small businesses will incur the costs associated with the rule, including the documentation requirements for HACCP systems and sanitation SOPs. These documentation requirements represent fixed costs that small establishments

will allocate to fewer sales units when compared to the number of sales units available for the same purpose for large establishments. With the choice of the revised traditional system, however, FSIS believes that small firms that adopt the new system under the proposed rule will do so only when estimates of the benefits exceed the costs, meaning that small companies that adopt the new system will expect net benefits.

The proposed PSR limits the number of on-line inspectors for the revised traditions inspection system to two. However, plants that are currently operating with more than two on-line inspectors per line will be permitted to continue to do so after the rule goes into effect. Thus, small and very small plants that currently operate with more than two inspectors will not need to modify their operations based on a reduction in inspectors.

Table 18 shows the capacity comparisons for SBA small and large companies. FSIS shows in this table that SBA small companies have a relatively small share of the capacity, 4.7 percent, to slaughter poultry.

Table 18. Capacity Comparisons for Small and Large Companies

Company Size (SBA Definition)	Number of Companies	Number of Facilities	Share of Facilities
Small	109	110	38.10%
Large	49	179	61.90%
TOTAL	158	289	100.00%

Source: ADRS

Table 19 shows the capacity comparisons for HACCP very small, small, and large establishments.

Table 19. Capacity Comparisons for Very Small, Small, and Large Establishments

Establishment Size (HACCP Definition)	Number of Facilities	Share of Facilities
Very Small	54	18.70%
Small	84	29.00%
Large	151	52.30%
TOTAL	289	100.00%

Source: ADRS

Table 20. Accounting Summary for Proposed Rule

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized benefits	$377.7 million	$325.8 million	$442.7 million	RA, PRIA
Unquantified benefits	Public health benefits from documentation and revised testing.			
COSTS				
Annualized monetized costs	$20.3 million			PRIA

VII. E-GOVERNMENT ACT

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other

things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

VIII. EXECUTIVE ORDER 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

IX. USDA NONDISCRIMINATION STATEMENT

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print,

audiotape, etc.) should contact USDA's Target Center at 202–720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

X. Environmental Impact

Summary: Each USDA agency is required to comply with 7 CFR 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)).

Evaluation: Under this proposed rule, young chicken and turkey slaughter establishments that operate under the proposed New Poultry Inspection System will be able to slaughter and

process birds more efficiently because they will be permitted to operate faster line speeds. In the Preliminary Regulatory Impact Analysis (PRIA) of this proposed rule, FSIS predicted that, because of the efficiencies in the proposed new poultry inspections system, the price of chicken products would decrease by two cents per bird. FSIS projected that the predicted price reduction could lead to an increase in sales of poultry products of about a quarter of one percent or less. With the slight increase in sales of poultry products, some establishments may choose to increase the number of birds that they slaughter, which could result in an increase in the number of condemned carcasses and parts that must be disposed of. However, because the predicted increase in sales is very small, FSIS has determined that the increase in the number of birds slaughtered, as well as the number of condemned carcasses and parts that will need to be disposed of, will also be very small and thus will not have a significant individual or cumulative effect on the human environment.

Expected sales of poultry products will determine the number of birds that poultry establishments slaughter. Allowing establishments to operate at faster lines speeds will allow them to slaughter the birds more efficiently. It will also allow them to reduce their hours of operation while

maintaining production at a rate necessary to meet market demands. Thus, by allowing establishments to reduce their hours of operations, the faster line speeds permitted under this proposed rule will result in a small, if any, increase in water use or runoff by establishments that operate under the New Poultry Inspection System. In addition, poultry slaughter establishments are required to meet all local, State, and Federal environmental requirements. Thus, FSIS has determined that allowing establishments to operate under faster line speeds provided in the proposed PSR will not have a not have a significant individual or cumulative effect on the human environment.

FSIS also considered the potential environmental effects of the provision in the proposed rule that would permit poultry slaughter establishments to use approved online reprocessing (OLR) antimicrobial systems. One antimicrobial agent used in OLR systems, trisodium phosphate (TSP), can result in high levels of phosphorus as a byproduct, which, if untreated, could overcome local municipal water systems. FSIS estimates that approximately 5-7 of the 144 establishments operating under regulatory waivers for OLR are using TSP as an antimicrobial agent. As noted above, regardless of the substance that an

establishment chooses to use for its OLR system, it is required to meet all local, State, and Federal environmental requirements. The waste water from the few poultry establishments that use TSP is handled routinely by existing water treatment systems or recycled as by-products without entering the plant's systems, municipal water systems, or the ground water. Thus, FSIS has determined that allowing establishment to use approved OLR antimicrobial systems will not have a significant individual or cumulative effect on the human environment.

Conclusion: For the reasons discussed above, FSIS has determined that the proposed PSR will not have individual or cumulative effect on the human health environment. Therefore, this regulatory action is appropriately subject to the categorical exclusion from the preparation of an EA or EIS provided under 7 CFR 1b.4(b)(6) of the USDA regulations.

XI. PAPERWORK REDUCTION ACT

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB).

Title: Poultry Slaughter Inspection

Type of Collection: New

Abstract: Under this proposed rule, each official poultry slaughter establishment would need to maintain as part of its HACCP plan, or sanitation SOP, or other prerequisite program, written procedures addressing (1)the prevention, throughout the entire slaughter and dressing operation, of contamination of carcasses and parts by enteric pathogens (e.g. Salmonella and Campylobacter) and by fecal material, and (2) the prevention of carcasses and parts contaminated by visible fecal material from entering the chiller. Each establishment operating under the proposed new inspection system would also have to maintain written procedures to prevent caracasses affected with septicemia and toxemia from entering the chiller. The procedures addressing prevention of contamination by enteric pathogens would need to include, at a minimum, microbial testing at pre-chill and at post-chill. In addition, each establishment operating under the proposed inspection system would need to maintain records that document that the products resulting from its slaughter operations meet the definition of ready-to-cook poultry.

The proposed regulations that would require poultry slaughter establishments to have written procedures in their HACCP plans, or sanitation SOPs, or prerequisite programs is already covered under an approved information collection, Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (OMB control number 0583-0103).

The proposal that poultry slaughter establishments monitor their systems through microbial testing and recordkeeping creates a new information collection burden. FSIS estimates that large establishments will test and record microbial results at the 2 prescribed locations (pre-chill and post-chill) 15 times a day, small establishments 7 times a day, and very small establishments 3 times a day.

Estimate of Burden: FSIS estimates that it will take 5 minutes per response.

Respondents: Poultry Slaughter Establishments.

Estimated Number of Respondents: 289.

Estimated Number of Responses per Respondent: Large establishments 15,300; small establishments 7,140; very small establishments 1,800.

Estimated Total Annual Burden on Respondents: 250,160.

hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Room 6083, South Building, Washington, DC 20250.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington,

DC 20253. To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

XII. ADDITIONAL PUBLIC NOTIFICATION

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this proposed rule, FSIS will announce it on-line through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp. FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/ news_&_events/email_subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

XIII. PROPOSED REGULATORY AMENDMENTS

List of Subjects

9 CFR Part 381

Poultry inspection, Poultry products, Recordkeeping requirements

9 CFR Part 500

Administrative practice and procedure, Meat inspection, Poultry and poultry products

For the reasons stated in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.7, 2.18, 2.53.

2. Section 381.36 is amended as follows:

a. Paragraph (c) is revised.

b. Paragraphs (d) and (e) are removed.

The revisions read as follows:

§ 381.36 Facilities required.

* * * * *

(c) *Facilities for post-mortem inspection under the New Poultry Inspection System.* The following facilities requirements apply to establishments operating under the New Poultry Inspection System and are in addition to the requirements for obtaining a grant of inspection.

(1) The following provisions apply to the online carcass inspection station:

(i) On each production line, at a point before the chiller and after the establishment has completed all sorting, trimming,

and reprocessing activities necessary to comply with § 381.76(d)(2) of this part, at least 4 feet of floor space along the conveyor line must be provided for one online carcass inspection station.

(ii) The conveyor line must be level for the entire length of the online carcass inspection station. The vertical distance from the bottom of the shackles to the top of the platform (paragraph (c)(1)(iii) of this section) must not be less than 60 inches.

(iii) Each online carcass inspection station must have a platform that is slip-resistant and can be safely accessed by the inspector. The platform must be a minimum length of 4 feet and have a minimum width of 2 feet. The platform must be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(iv) Conveyor line stop/start switches must be located within easy reach of the online carcass inspector.

(v) A minimum of 200-foot candles of shadow-free lighting with a minimum color rendering index value of 85 must be provided where the birds are inspected to facilitate online carcass inspection.

(vi) Hand rinsing facilities must be provided for use by and within easy reach of the online carcass inspector. The hand rinsing facilities must have a continuous flow of water or be capable of being immediately activated and deactivated in a hands-free manner, must minimize any splash affect, and must otherwise operate in a sanitary manner that prevents contamination of carcasses and inspector clothing. The hand rinsing facilities must provide water at a temperature between 65 and 120 degrees Fahrenheit.

(vii) A separate clipboard holder for holding recording sheets must be provided for and within easy reach of the online carcass inspector.

(viii) Receptacles for condemned carcasses and parts that comply with the performance standards in §416.3(c) of this chapter must be provided at each online carcass inspection station.

(ix) Hangback racks designed to hold at least 10 carcasses must be provided and positioned within easy reach of the online carcass inspector.

(x) A buzzer switch shall be located within easy reach of the online carcass inspector to be used by the carcass inspector to alert the inspector-in-charge, offline inspectors, or establishment management of conditions that require their attention.

(2) The following provisions apply to pre-chill and post-chill offline verification inspection stations:

(i) One or more offline verification inspection stations must be located at the end of the line or lines prior to the chiller; one or more offline verification inspection stations must also be located after the chiller or chillers. The Agency will determine the number of stations needed in establishments having more than one processing line or more than one chiller.

(ii) Floor space for all offline verification inspection stations must consist of a minimum of 3 feet along each conveyor line and after each chiller, as applicable, to allow carcasses to be removed for evaluation by the verification inspector. The

space must be level and protected from all traffic and overhead obstructions.

(iii) At the pre-chill location, the vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iv) At each offline verification inspection station, a table designed to be readily cleanable and drainable must be provided for offline verification inspectors to conduct offline verification activities. At turkey slaughter establishments, the table must be at least 3 feet wide, 2 feet deep, and 3 feet high. At all other poultry slaughter establishments, the table must be at least 2 feet wide, 2 feet deep, and 3 feet high

(v) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85 on the table surface must be provided.

(vi) The establishment must provide a separate clipboard holder for holding recording sheets; or alternatively, the establishment may provide electronic means for the offline verification inspector to record inspection results.

(vii) Hangback racks designed to hold at least 10 carcasses must be provided and positioned within easy reach of the offline verification inspector.

(viii) Hand washing facilities must be provided within easy access of all offline verification inspection stations.

(3) Each establishment operating under the New Poultry Inspection System must provide a location at a point along the production line after the carcasses are eviscerated at which an inspector may safely and properly inspect for leukosis the first 300 carcasses of each flock together with associated viscera either uniformly trailing or leading, or otherwise identified with the corresponding carcass. The leukosis inspection area must provide a minimum of 200-footcandles of shadow-free lighting on the surface where the viscera are inspected.

(4) A trough or other similar drainage facility must extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splashing.

3. Section 381.65 is amended as follows:

a. Paragraphs (e) and (f) are redesignated as paragraphs (f) and (e) respectively.

b. Newly redesignated as paragraph (f) is revised .

c. A new paragraph (g) is added.

d. A new paragraph (h) is added.

The revisions and additions read as follows:

§ 381.65 Operations and procedures, generally.

* * * * *

(f) Procedures for controlling visible fecal contamination. Official poultry slaughter establishments must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chilling tank. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

(g) Procedures for controlling contamination throughout the slaughter and dressing process. Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by

enteric pathogens (e.g., Salmonella and Campylobacter) and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must include sampling and analysis for microbial organisms at the pre-chill and post-chill points in the process. The sampling frequency must be adequate to monitor the establishment's ability to maintain process control for enteric pathogens. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (h) of this section.

(h) Recordkeeping requirements. Official poultry slaughter establishment must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data. Records require by this section must be maintained for at least one year and must be accessible to FSIS.

4. Section 381.66 is amended as follows:

a. Paragraph (b) is revised.

b. Paragraphs (c)(3) and (c)(4) are removed.

c. Paragraph (e) is revised.

The revisions read as follows:

§ 381.66 Temperatures and chilling and freezing procedures.

* * * * *

(b) Chilling performance standards, except for ratites.

(1)(i) Each official poultry slaughter establishment must ensure that all poultry carcasses, parts, and giblets are chilled immediately after slaughter operations so that there is no outgrowth of pathogens, unless such poultry is to be frozen or cooked immediately at the official establishment.

(ii) Previously chilled poultry carcasses and major portions must be kept chilled so that there is no outgrowth of the pathogens, unless such poultry is to be packed and frozen immediately at the official establishment.

(2) After product has been chilled, the establishment must prevent the outgrowth of pathogens on the product as long as the product remains at the establishment.

(3) The establishment must develop, implement, and maintain written procedures for chilling that address, at a minimum, the potential for pathogen outgrowth, the conditions affecting

carcass chilling, and when its chilling process is completed. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program.

* * * * *

(e) Air chilling. Air chilling is the method of chilling raw poultry carcasses and parts exclusively with air. No water, including mists or sprays, may be used to help chill the product. However, an anti-microbial intervention that is applied with water may be used for a short duration if its use does not result in any pick-up of water or moisture and if it does not assist the chilling process by lowering the product temperature.

* * * * *

5. Section 381.67 is amended as follows:

a. The section heading is revised.

b. The first sentence of the introductory text is amended by removing the words “young chicken and squab” and adding in their place the word “poultry.”

c. The second to the last sentence of the introductory text is removed.

d. The last sentence of the introductory text is revised.

e. The table is revised.

f. A new table is added after the first table.

The revisions read as follows:

§ 381.67 Poultry slaughter inspection rate maximums under traditional inspection procedure.

* * * Section 381.76(b) specifies when the traditional inspection procedure can or must be used.

MAXIMUM PRODUCTION LINE RATES—POULTRY OTHER THAN TURKEYS AND RATITES—TRADITIONAL INSPECTION PROCEDURES

Line configuration[1]	Number of in-spection stations	Birds per in-spector per minute
6-1	1	25
12-1	2	23
12-2	2	21

[1]Birds are suspended on the slaughter line at 6-inch intervals. The first number indicates the interval in inches between the birds that each inspector examines, i.e., 6 or 12 inches. The second number indicates how many of the birds presented, the inspector is to inspect, i.e., “1” means inspect every bird and “2” means inspect every second bird.

MAXIMUM PRODUCTION LINE RATES—TURKEYS—TRADITIONAL INSPECTION PROCEDURES

Line configuration[1]	Number of inspection stations	Birds per inspector per minute for light birds (<16 lbs)	Birds per inspector per minute for heavy (>16 lbs)
12-1	1	20	16
24-2	2	34	26

[1]Birds are suspended on the slaughter line at 12-inch intervals. The first number indicates the interval in inches between the birds that each inspector examines, i.e., 12 or 24 inches. The second number indicates how many of the birds presented, the inspector is to inspect, i.e., “1” means inspect every bird and “2” means inspect every second bird.

6. Section 381.68 is revised to read as follows:

§ 381.68 Maximum line speed rates under the New Poultry Inspection System

(a) The maximum line speed for young chicken slaughter establishments that operate under the New Poultry Inspection System is 175 birds per minute.

(b) The maximum line speed for turkey slaughter establishments that operate under the New Poultry Inspection System is 55 birds per minute.

(c) Notwithstanding paragraphs (a) and (b) of this Section, establishments that operate under the New Poultry Inspection System must reduce their line speed as directed by inspectors-in-charge. Inspectors-in-charge are authorized to direct establishments to operate at a reduced line speed when in his or her judgment a carcass-by-carcass inspection cannot be adequately performed within the time available due to the manner in which the birds are presented to the online carcass inspector, the health conditions of a particular flock, or factors that may indicate a loss of process control.

7. Section 381.76 is revised to read as follows:

§ 381.76 Post-mortem inspection under Traditional Inspection, the New Poultry Inspection System, and Ratite Inspection

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in every official establishment. Each carcass, or all parts comprising such carcass, must be examined by an inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned. Each carcass eviscerated shall be prepared as ready-to-cook poultry.

(b) There are three systems of post-mortem inspection: New Poultry Inspection System, which may be used for young chickens and turkeys; Traditional Inspection, which may be used for all poultry, except for ratites; and ratite inspection. Traditional Inspection must be used for young chickens and turkeys if the New Poultry Inspection System is not used.

(c) Official establishments that operate under traditional inspection must meet the following requirements:

(1) No viscera or any part thereof may be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless its identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made;

(2) Each carcass to be eviscerated must be opened so as to expose the organs and the body cavity for proper examination by the inspector.

(3) If a carcass is frozen, it must be thoroughly thawed before being opened for examination by an inspector.

(d) The New Poultry Inspection System may be used for young chickens and turkeys if the official establishment requests to use it and meets or agrees to meet the requirements of this

paragraph (d) and the Administrator approves the establishment's request. The Administrator may permit establishments that slaughter classes of poultry other then young chickens and turkeys to operate under the New Poultry Inspection System under a waiver from the provisions of the regulations as provided in § 381.3(b) of this part.

(1) Facilities: The establishment must comply with the facilities requirements in §381.36(c) of this part.

(2) Carcass Sorting and Disposition:

(i) The establishment must conduct carcass with associated viscera sorting activities, dispose of carcasses and parts exhibiting condemnable conditions, and conduct appropriate trimming and reprocessing activities before carcasses are presented to the online carcass inspector.

(ii) Any carcasses removed from the line for reprocessing activities or salvage must be returned to the line before the online carcass inspection station. The establishment must include in its written HACCP plan, or sanitation standard operating procedure, or other prerequisite program a process by which parts, other than parts identified as "major portions" as

defined in 9 CFR 381.170(b)(22), are available for inspection offline after reprocessing or salvage.

(iii) The establishment must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chilling tank. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. These procedures must cover, at a minimum, establishment sorting activities required under paragraph (d)(2)(i) of this section.

(iv) The establishment must maintain records to document that the products resulting from their slaughter operations meet the definition of ready-to-cook poultry in § 381.1 of this part.

(v) If there is evidence that a flock may be affected by avian visceral leukosis, the inspector-in-charge is authorized to adjust inspection procedures as needed to ensure adequate inspection of each carcass and viscera for that condition. The inspector-in-charge is also authorized to require the establishment to adjust its processing operations as needed to accommodate the adjusted inspection procedures.

(3) Presentation for Online Carcass Inspection: To ensure the online carcass inspector may properly inspect every carcass, the establishment must present carcasses as follows:

(i) Each carcass, except carcasses and parts identified as “major portions” under 9 CFR 381.179(b)(22), must be held by a single shackle;

(ii) Both hocks of each carcass must be held by the shackle;

(iii) The back side of the carcass must be faced toward the inspector;

(iv) There must be minimal carcass swinging motion; and

(v) Establishments that slaughter young chickens must notify the inspector-in-charge prior to the slaughter of each new flock to allow the inspection of viscera as provided in § 381.36(c)(3) of this part. The establishment must ensure that it can sufficiently identify viscera and parts corresponding with each carcass inspected by the online carcass inspector so that if the carcass inspector condemns a carcass all corresponding viscera and parts are also condemned.

8. Section 381.91 is amended by revising paragraph (b) to read as follows:

§ 381.91 Contamination.

* * * * *

(b) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents need not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut must be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone or may be re-processed as provided in subparagraph (b)(1) or (b)(2) of this section.

(1) Online reprocessing. Poultry carcasses accidentally contaminated with digestive tract contents may be cleaned by applying an online reprocessing antimicrobial intervention to all carcasses after evisceration and before the carcasses enter the chiller if the parameters for use of the antimicrobial intervention system have been approved by the Administrator. Establishments must incorporate procedures for the use of any online reprocessing antimicrobial intervention system into their HACCP plans, Sanitation Standard Operating Procedures, or other prerequisite programs.

(2) Offline reprocessing. Contaminated inner surfaces that are not cut may be cleaned at an approved reprocessing station

away from the main processing line by any method that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. All visible specks of contamination must be removed, and if the inner surfaces are reprocessed other than solely by trimming, all surfaces of the carcass must be treated with chlorinated water containing 20 ppm to 50 ppm available chlorine or another approved antimicrobial substance in accordance with the parameters approved by Administrator . Establishments must incorporate procedures for the use of any offline reprocessing into their HACCP plans, Sanitation Standard Operating Procedures, or other prerequisite programs.

9. Section 381.94 is removed.

10. Section 381.129 is amended by adding a new paragraph (b)(6)(v) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(6) * * *

(v) Ready-to-cook chicken may bear the claim “air chilled” or “air chilling” on its label only if the product was chilled

under a process that meets the definition of air chilling in §381.66(e) of this part.

* * * * *

PART 500—RULES OF PRACTICE

11. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53

12. Section 500.6 is amended to remove and reserve paragraph (f).

Done in Washington, DC: January 20, 2012

Alfred V. Almanza,

Administrator.

Note: The following Appendix will not appear in the Code of Federal Regulations.

APPENDIX A - HIMP PERFORMANCE STANDARDS

Establishments operating under HIMP are required to meet performance standards for food safety and non-food-safety related defects and to maintain process control plans to meet those performance standards. The following is a description of the HIMP performance standards.

FSIS has a zero tolerance for visible fecal contamination and septicemic and toxemic animal diseases (see 9 CFR 381.83 and 381.65(e)). Notwithstanding this zero tolerance policy, there are two categories of food safety related performance standards under HIMP for these conditions: “FS-1” addresses septicemic and toxemic animal diseases and “FS-2” addresses visible fecal material. The Agency developed performance standards for FS-1 and FS-2 conditions to compare the performance of HIMP and non-HIMP establishments in meeting the zero tolerance for septicemic and toxemic animal diseases and visible fecal contamination.

To develop the performance standards, a private contractor, the Research Triangle Institute (RTI), conducted a study of 16 young chicken establishments operating under the

existing poultry inspection systems to establish baseline organoleptic and microbial levels at young chicken slaughter establishments operating under the inspection systems provided for under the current regulations. The baseline studies were conducted between 1998 and 2000, prior to young chicken slaughter establishments beginning to operate under HIMP. The performance standards for the FS-1 and FS-2 conditions were set at the 75th percentile of what was achieved under the RTI baseline study. The young chicken performance standards for each food safety defect category are presented in Table 1.

TABLE A-1: Food Safety Performance Standards for Young Chicken Slaughter Establishments*

Defect Categories	Performance Standards Based on Existing Inspection Systems (% of carcasses)
Food Safety 1 Condition-Infectious (e.g., Septicemia, toxemia)	0.1%*
Food Safety 2 Contamination-Digestive Content (e.g., fecal	

material)	1.5% *

*FSIS has a zero tolerance for Food Safety 1 and 2 defects

As noted above, the FS-1 and FS-2 HIMP performance standards were developed for purposes of comparison. Therefore, FSIS inspection personnel in HIMP establishments are responsible for enforcing the zero tolerance for visible fecal contamination and septicemic and toxemic animal diseases. If the online carcass inspector in a HIMP establishment identifies a carcass with FS-1 or FS-2 conditions, he or she stops the evisceration line and notifies the establishment to hang the affected carcass back for condemnation or reprocessing. The carcass inspector

does not restart the line until the contaminated carcass is removed.

Non-food-safety related performance standards are referred to as “Other Consumer Protection” standards, or “OCPs,” under HIMP. There are five categories of OCPs various types of trim and dressing defects that mainly affect the quality of products. Examples include removable non-septicemic and non-toxemic animal diseases, breast blisters, bruises, fractures, and feathers. Together, the five OCP categories account for 29 specific defects addressed under the current regulations by the FPS, codified at 9 CFR 381.76. The OCP categories are logically grouped and simpler to apply than the FPS. Under the FPS, defects are weighted and a complex numerical system is applied to each sample group of carcasses. In contrast, to determine compliance with the OCP categories, an individually sampled carcass with any defect in one of the five categories is counted as “defective.” A carcass with more than one category of defects is counted in both (or more) categories. The performance standard for each category is expressed as the maximum percentage of sampled carcasses that may contain one or more defects from that category. The young chicken performance standards for each OCP category are presented in Table A-2.

TABLE A-2: OCP Performance Standards for Young Chicken Slaughter Establishments

Nonconformance Category	Performance Standard (% carcasses)
OCP-1 Condition – Animal Diseases – non-septicemic or non-toxemic (e.g., airsacculitis, arthritis, ascites, skin leukosis, avian tuberculosis, cadaver, enteritis, erysipelas, inflammatory process, nephritis, osteomyelitis, other tumors—carcinoma, sarcoma, etc., pericarditis, pneumonia, reportable disease, salpingitis, tenosynovitis	1.7%
OCP-2 Condition – Miscellaneous (e.g., breast blister, bruises, external mutilation, fractures, overscald, sores, scabs, and localized inflammatory process)	52.5%

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