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: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the poultry products inspection regulations to establish a new inspection system for young chicken and all turkey slaughter establishments. Young chicken and turkey slaughter establishments that do not choose to operate under the new poultry inspection system may continue to operate under their current inspection system. The Agency is also making several changes to the regulations that will affect all establishments that slaughter poultry other than ratites. This final rule is a result of the Agency's 2011 regulatory review efforts conducted under Executive Order 13563 on Improving Regulation and Regulatory Review.

DATES:

Effective Date: October 20, 2014.

Notification Date: All young chicken and turkey slaughter establishments will initially have until February 23, 2015, to notify their District Office in writing of their intent to operate under the New Poultry Inspection System (NPIS). Establishments that do not notify their District Office of their intent by February 23, 2015, will be deemed to have chosen the inspection system that they are currently operating under. Young chicken and turkey slaughter establishments that decide that they would like to convert to NPIS after the initial notification date may notify FSIS of their intent at any time after that date. The Agency will implement the NPIS in the additional establishments that intend to convert on a schedule consistent with Agency resources and readiness. The Agency intends to implement the NPIS in all young chicken and turkey establishments that choose to operate under the NPIS, regardless of when the establishment notifies FSIS of its intent to transition to the NPIS. However, the initial implementation wave will only include those establishments that submitted their notifications within the initial notification period.

After October 20, 2014, FSIS will begin selecting from those establishments that have notified FSIS of their intent to switch to the NPIS. The Agency will use a computerized ranking system to determine the schedule of establishments for implementation of the NPIS. This ranking system will take into consideration several factors, such as FSIS staffing needs, past performance of the establishment, the location of the establishment with respect to other federally-inspected establishments, and establishment readiness to transition to the NPIS. FSIS will implement the NPIS in phases by clusters of establishments in close geographic proximity to one another. The initial implementation wave will only include those establishments that notified FSIS of their intent to switch to the NPIS during the initial six-month notification period. FSIS expects that in subsequent years many more establishments will choose to transition to the new system. The Agency's implementation strategy for the NPIS is described in more detail in the preamble to this final rule.

Applicability Dates: The regulations that prescribe procedures for controlling visible fecal contamination in 9 CFR 381.65(f), the regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process in 9 CFR 381.65(g), and the regulations that prescribe recordkeeping requirements in 9 CFR 381.65(h) will be applicable as follows:

- In large establishments, defined as all establishments with 500 or more employees, on November 19, 2014;
- In small establishments, defined as all establishments with 10 or more employees but fewer than 500, on December 19, 2014;
- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million February 17, 2015.

FOR FURTHER INFORMATION CONTACT: 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) 205–0495.

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. As a result of FSIS's regulatory review efforts conducted under E.O. 13563, on January 27, 2012, the Agency published a proposed rule to modernize poultry slaughter inspection (''*Modernization of Poultry Slaughter Inspection,*'' 77 FR 13512). This final rule adopts, with modifications, the provisions in the January 2012 proposal. FSIS is issuing this rule to facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter inspection, make better use of the Agency's resources, and remove unnecessary regulatory obstacles to innovation.

This final rule will establish a New Poultry Inspection System (NPIS) for young chicken and all turkey slaughter establishments. The NPIS will not replace, as was proposed, the current Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), or the New Turkey Inspection System (NTIS). As such, young chicken and turkey slaughter establishments may choose to operate under the NPIS or may continue to operate under their current inspection system, i.e., SIS, NELS, NTIS, or Traditional Inspection, as modified by this final rule. Establishments that slaughter poultry other than young chickens or turkeys are not eligible to operate under the NPIS unless they obtain a waiver under the Salmonella Initiative Program. The Agency is not limiting the number of online inspectors in Traditional Inspection to two, as was proposed. FSIS will continue to staff all establishments that do not choose to operate under the NPIS with their current number of online inspectors.

The NPIS is designed to facilitate pathogen reduction in poultry products by shifting Agency resources to allow FSIS inspectors to perform more offline inspection activities that are more effective in ensuring food safety, while providing for a more efficient and effective online carcass-by-carcass inspection. Data from the Agency's Hazard Analysis and Critical Control Point Systems (HACCP)-Based Inspection Models Project (HIMP) pilot study,[1] which was used to inform the NPIS, show that an inspection system that provides for increased offline inspection activities that are more directly related to food safety results in greater compliance with sanitation and HACCP regulations, carcasses with

[1] See ''Evaluation of HACCP Inspection Models Project (HIMP), August 2011 (available on the FSIS Web site at: *http://www.fsis.usda.gov/wps/wcm/connect/fcd9ca3e-3f08-421f-84a7-936bc410627c/Evaluation_HACCP_HIMP.pdf?MOD=AJPERES*).

lower levels of visible fecal contamination, and carcasses with equivalent or lower levels of *Salmonella* contamination.

Key elements of the NPIS include: (1) Requiring that establishment personnel sort carcasses and remove unacceptable carcasses and parts before the birds are presented to the FSIS carcass inspector; (2) shifting Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which will allow for one offline verification inspector per line per shift and will reduce the number of online inspectors to one; (3) replacing the Finished Product Standards (FPS), which will apply to establishments that continue operating under SIS, NELS, and NTIS, with a requirement that establishments that operate under the NPIS maintain records to document that the products resulting from their slaughter operations meet the definition of ready-to-cook (RTC) poultry; and (4) authorizing young chicken slaughter establishments to operate at a maximum line speed of 140 birds per minute (bpm), provided that they maintain process control.

Under all of the current inspection systems, online inspectors visually inspect every carcass, with its corresponding viscera, at fixed locations on the evisceration line immediately after separation of the viscera from the interior of the carcasses. The online inspectors are responsible for identifying unacceptable carcasses and parts, examining carcasses for visual defects, and directing establishment employees to take appropriate corrective actions if the defects can be corrected through trimming or reprocessing. The maximum line speeds authorized under the existing inspection systems reflect the time it takes for an inspector to effectively perform the online carcass inspection procedures required under these systems.

Under the NPIS, there will be one online carcass inspector (CI) and one offline verification inspector (VI) assigned to each evisceration line. As under the HIMP inspection system, VIs and CIs under the NPIS will have different but complementary roles in ensuring that poultry products leaving the slaughter line are safe and wholesome. Under the NPIS, CIs will conduct a continuous online inspection of each carcass at a fixed location immediately before the chiller to determine whether each carcass is not adulterated. CIs under the NPIS will be able to conduct a more efficient and effective online carcass inspection than online inspectors do under the current inspection systems because the CIs are presented with carcasses that have been sorted, washed, and trimmed by establishment employees, and are thus much more likely to pass inspection.

The VIs under the NPIS will conduct offline food safety-related inspection activities and will monitor and evaluate establishment process controls. The VIs will conduct carcass verification checks on carcass samples collected before the CI station to ensure that the establishment is effectively sorting carcasses and that it is producing products that comply with the Agency's zero visible fecal tolerance and other performance standards. The VI and CI will work with the inspector-in-charge (IIC) to ensure that the carcasses presented to the CI are not affected with food safety defects or other conditions at levels that may impair the CI's ability to effectively inspect each carcass. VIs will also perform offline activities in addition to carcass verification checks, such as verifying compliance with sanitation standard operating procedures (SOPs), sanitation performance standards (SPS), and HACCP regulatory requirements, and ensuring that the establishment is meeting all regulatory requirements and is effectively preventing contamination by enteric pathogens and fecal material throughout the entire slaughter and dressing process.

The fastest maximum line speed authorized under the current inspection systems is 140 bpm under the SIS for young chickens. To determine line speeds for SIS, FSIS conducted field and work measurement studies of online inspectors to determine the time needed for an inspector to perform the SIS inspection procedure. The studies showed that online inspectors can perform the SIS inspection procedure at line speeds of up to 140 bpm if each inspector is presented with up to 35 bpm. Thus, under SIS, establishments with automated evisceration equipment may operate at 140 bpm with four FSIS online inspectors assigned to the line. The maximum line speeds authorized under the other inspection systems are 91 bpm with three online inspectors for NELS, and 51 bpm for light turkeys with two online inspectors and 45 bpm for heavy turkeys with two online inspectors for NTIS. As noted in the proposed rule, Traditional Inspection is typically employed at smaller lower production volume establishments that eviscerate carcasses by hand (77 FR 4410). Thus, the maximum line speeds authorized under Traditional Inspection are slower than those under SIS, NELS, and NTIS. The maximum line speed for young chickens under Traditional Inspection is 64 bpm with four online inspectors. The maximum line speed for turkeys under Traditional Inspection is 39 bpm with three online inspectors.

As discussed in more detail later in this document, since 2007, HIMP young chicken establishments have been authorized to operate at line speeds of up to 175 bpm, depending on their ability to demonstrate consistent process control. Experience from the HIMP pilot shows that HIMP establishments operate with an average line speed of 131 bpm, and, although they are authorized to do so, most of the young chicken HIMP establishments do not operate line speeds at 175 bpm. Establishments determine their line speeds based on their equipment and facilities, bird size and flock conditions, and their ability to maintain process control when operating at a given line speed. In addition, line speeds under HIMP depend on the number of employees that the establishments hire and train to perform sorting activities. Although the maximum line speed under the NPIS is 140 bpm and not 175 bpm as authorized under HIMP, FSIS believes that establishments choosing to operate under the NPIS will determine their line speeds based on the same factors that establishments considered when setting line speeds under HIMP for the past 15 years.

Regardless of line speed, because HIMP and NPIS do not require that establishments configure their evisceration lines to accommodate more than one online carcass inspector, establishments operating under the NPIS will have greater control over their lines and greater flexibility over their production process. For example, as under HIMP, establishments operating under the NPIS will have the flexibility to reconfigure and consolidate lines if they determine that they need more space to conduct other activities in their facilities. In addition, because only one online inspector is required at the end of the line, establishments operating under the NPIS will not need to adjust their production based on the availability of FSIS inspection personnel to be stationed online. Establishment employees will staff the lines to perform the online sorting activities. Establishments that operate under NPIS will also have greater flexibility to increase production to respond to customer demands.

As under HIMP, in addition to having more control over their production process, establishments operating under the NPIS will also have more opportunities for innovation and greater flexibility to develop and implement certain types of new technologies. Currently, if an establishment operating

under the existing inspection systems wants to use new technologies for evisceration or for sorting, the establishment must work directly with the Agency to accommodate FSIS's online slaughter inspection methodologies. Doing so takes time and can become an obstacle to innovation. Under the NPIS, establishments will have direct control of the sorting process within their facilities and therefore will have the flexibility to implement and assess the technologies they think are beneficial to their operations.

In addition to the NPIS for young chickens and turkeys, this final rule includes changes to the regulations that will apply to all establishments that slaughter poultry other than ratites. Under this final rule, all poultry slaughter establishments must develop, implement, and maintain written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller, and they must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs (also referred to collectively as ''the HACCP system'' in this document). This final rule also requires 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, and that they incorporate their procedures into their HACCP systems. At a minimum, these procedures must include sampling and analysis for microbial organisms at the pre- and post-chill points in the process to monitor process control for enteric pathogens, with some exceptions for very small and very low volume establishments. Establishments will be required to maintain daily records sufficient to document the implementation and monitoring of these procedures. These new requirements will ensure that all poultry slaughter establishments implement appropriate measures to prevent contamination of carcasses by enteric pathogens and visible fecal material and that both FSIS and establishments have the documentation they need to verify the effectiveness of these measures on an ongoing basis.

FSIS is also rescinding the regulation that requires that poultry establishments test carcasses for generic *E. coli* to monitor for process control. The generic E. coli regulations will be replaced by the new testing requirements described above. The new testing requirements will allow establishments to develop sampling plans that are more tailored, thus more effective in monitoring their specific process control than the current generic E. coli criteria. The Agency has concluded that the use of generic *E. coli* as an indicator for process control may not be as useful in broiler operations as originally thought. The Agency is taking this action to allow establishments to use other more relevant indicators of process control. The Agency established new performance standards for Salmonella and Campylobacter in 2011 to more effectively manage these pathogens (76 FR 15282). Therefore, FSIS is removing the codified *Salmonella* pathogen reduction performance standards for poultry.

Finally, FSIS is removing the prescriptive time and temperature parameters from the chilling requirements for RTC poultry and instead is requiring that poultry establishments incorporate procedures for chilling poultry into their HACCP systems. The Agency is also amending the regulations 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 will be required to address the use of online or offline reprocessing in their HACCP systems.

TABLE 1—ESTIMATED NET SOCIAL BENEFITS FROM THE RULE (MILLIONS OF DOLLARS), ANNUALIZED OVER 10 YEARS WITH A 7% DISCOUNT RATE, FOR VARYING PERCENT CHANGES THAT SWITCH TO NPIS

[Percentage of Industry that Switches to NPIS]

	0%	10%	25%	50%	75%	90%	100%
NPIS:							
Benefits:							
Public health benefits (10%, 90%)	0.0	1.0 (0.3 to 1.7)	2.4 (0.8 to 4.3)	4.8 (1.6 to 8.7)	7.2 (2.4 to 13.0)	8.6 (2.9 to 15.7)	9.6 (3.3 to 17.4)
FSIS net savings	0.0	2.3	5.7	11.4	17.1	20.5	22.8
Unquantified benefits	Increased flexibility for establishments to design and implement production measures tailored to their operations, in some cases possibly including increased line speed up to 140 chickens or 55 turkeys per minute						
Costs:							
Costs to establishments	0.0	1.6	4.0	8.0	12.0	14.4	16.0
Unquantified costs	Industry cost of responding to new NPIS inspections in a manner that may lead to public health benefits (e.g., discarding contaminated food or cooking it longer)						
Mandatory Component:							
Costs to establishments	9.1	9.1	9.1	9.1	9.1	9.1	9.1
Unquantified benefits	Potential additional public health benefits from documentation and testing						
Unquantified costs	Industry cost of responding to information generated by documentation and testing in a manner that may lead to public health benefits (e.g., discarding contaminated food or cooking it longer)						
Total benefits (10%, 90%)	0.0	3.3 (2.6 to 4.0)	8.1 (6.5 to 10.0)	16.2 (13.0 to 20.1)	24.3 (19.5 to 30.1)	29.1 (23.4 to 36.2)	32.4 (26.0 to 40.2)
Total costs	9.1	10.7	13.1	17.1	21.1	23.5	25.1
Net benefits (10%, 90%)	−9.1	−7.4 (−8.1 to −6.7)	−5 (−6.6 to −3.1)	−0.9 (−4.1 to 3.0)	3.2 (−1.6 to 9.0)	5.6 (−0.1 to 12.7)	7.3 (0.9 to 15.1)

FSIS presents the costs and cost savings that would be generated over a range of assumptions with respect to how much of the industry will choose to adopt NPIS within five years. These estimates are scaled from an illustrative calculation that assumes that all 219 small and large non-Traditional establishments adopt NPIS, which, while used to calculate potential maximum effect, is not necessarily FSIS's assumption of the most likely outcome. Later portions of the regulatory impact analysis section contain discussion of the uncertainty surrounding the net benefits associated with how much of the industry will choose to adopt NPIS.

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I. Background

On January 27, 2012, FSIS published the proposed rule, ''*Modernization of Poultry Slaughter Inspection,*'' to establish a new inspection system for young chickens and turkeys. Under the proposal, the new poultry inspection system (NPIS) would have replaced the current Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), and the New Turkey Inspection System (NTIS). The NPIS that FSIS is adopting in this final rule is consistent with the inspection system that FSIS proposed in January 2012, with modifications, which are described below. However, in this final rule, FSIS is not eliminating SIS, NELS, or the NTIS, as was proposed. This final rule will leave all existing inspection systems in place to give establishments the flexibility to operate under the system that is best suited to their operations.

In the proposed rule, FSIS also proposed changes to the regulations that would apply to all establishments that slaughter poultry other than ratites. FSIS is adopting these proposed changes, with some modifications, which are also described below.

When FSIS issued the proposed rule, it initially gave the public until April 26, 2012, to submit comments. The Agency later extended the comment period until May 29, 2012. The public meeting and the Agency's decision to extend the comment period are discussed below.

Comment Period and Public Meeting

On March 21, 2012, FSIS held a public meeting with its National Advisory Committee on Meat and Poultry Inspection (NACMPI) via Web conference to discuss the January 2012 proposed rule to modernize poultry slaughter inspection. FSIS held the meeting in response to a request from certain members of the committee. At the meeting, FSIS provided an overview of the proposed rule and then held an open discussion with the committee members. A transcript of the public meeting is available on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi.*

When the Agency held the public meeting, the comment period for the proposed rule was scheduled to close on April 26, 2012. At the public meeting, some of the committee members representing consumer advocacy organizations requested that FSIS extend the comment period. A coalition of consumer advocacy organizations also submitted a written request for the Agency to extend the comment period. On April 26, 2012, FSIS announced that it was extending the comment period until May 29, 2012 (77 FR 24873).

In the **Federal Register** document that announced the comment period extension, FSIS explained that during the comment period, the Agency had met with a coalition of consumer advocacy organizations and two trade associations representing the poultry industry to clarify certain aspects of the proposed rule to help inform their comments (77 FR 24873). Because the issues addressed in these meetings may have been relevant to the development of other stakeholders' comments, the **Federal Register** document summarized the issues raised at the meetings and the Agency's responses. In the **Federal Register** document, FSIS also requested additional comments on how it should implement the final rule resulting from the January 2012 proposal. The Agency also requested available data on potential worker safety issues associated with increased line speeds. In addition, the Agency explained that it had

received a request to hold a public technical meeting on the proposed rule, but that the Agency did not believe that such a meeting would be useful.

In developing this final rule, FSIS considered all comments submitted in response to the January 2012 proposed rule, as well as those provided at the NACMPI public meeting held in March 2012. Based on its analysis of the issues and of the information provided by the comments, FSIS made certain changes to, and clarified certain aspects of, the proposed regulations. Those revisions are summarized below and are discussed in detail in the Agency's responses to comments.

II. Summary of Modifications Made to the Proposed Rule

In this document, FSIS is finalizing, with some changes, the provisions in the January 27, 2012, proposed rule ''*Modernization of Poultry Slaughter Inspection''* (77 FR 4408). The Agency is modifying the proposal to:

- Change the maximum line speed permitted under the NPIS to 140 bpm for young chickens, for entities that chose to operate under NPIS. The maximum line speed for turkeys will be 55 bpm, as was proposed;
- Leave all existing poultry inspection systems in place and allow young chicken and turkey slaughter establishments that do not choose to operate under the NPIS to continue to operate under their current inspection system;
- Continue to staff all establishments that do not choose to operate under the NPIS with the number of online inspectors that they currently have;
- Allow young chicken establishments that currently operate under HIMP through a *Salmonella* Initiative Program (SIP) waiver to continue to operate under a waiver to run at a maximum line speed of up to 175 bpm;
- Update the SIP waivers for young chicken establishments currently operating under HIMP to remove aspects of HIMP that are inconsistent with the NPIS;
- Establish a phased approach to implement the NPIS in geographic clusters;
- Establish separate applicability dates for large, small, and very small establishments to comply with the provisions in the rule that prescribe the new recordkeeping and microbiological sampling requirements that will apply to all establishments that slaughter poultry other than ratites. The applicability dates will provide additional time for small and very small establishments to comply with these provisions;
- Revise the facilities requirements for the NPIS to require that the online carcass inspection platform be height adjustable;
- Clarify that the records that establishments operating under the NPIS are required to maintain to document that the products resulting from their slaughter operations meet the definition of RTC poultry are subject to review and evaluation by FSIS personnel;
- Revise the proposed regulation that prescribes maximum line speed rates under the NPIS to emphasize establishments' existing legal obligation to comply with the Occupational Safety and Health Administration's regulations;
- Establish a new subpart in the regulations that requires each establishment that participates in the NPIS to submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers. Current young chicken HIMP establishments that will be operating under the updated SIP waivers described above will be required to submit the annual attestation as a condition of their updated waivers;
- Permit very small and very low volume establishments to conduct sampling for microbial pathogens only at the post-chill point in the slaughter and dressing process to monitor their process control procedures instead of requiring sampling at pre- and post-chill, as was proposed;
- Prescribe a minimum frequency with which all establishments that slaughter poultry other than ratites will need to conduct testing for microbial organisms to monitor the effectiveness of their process control procedures; and
- Revise the definition for ''air chill'' to allow an antimicrobial intervention to be applied with water at the beginning of the chilling process if its use does not result in any net pick-up of water or moisture during the chilling process. The initial antimicrobial intervention may result in some temperature reduction of the product if the majority of temperature removal is accomplished exclusively by chilled air.

In addition, because the proposed pre- and post-chill sampling requirements will not apply to ratite slaughter establishments, FSIS is retaining the generic *E. coli* testing regulations as they apply to ratites only, but is rescinding the provisions in these regulations that apply to all other poultry classes. Poultry establishments other than establishments that slaughter ratites will be required to comply with the new sampling requirements prescribed in this final rule.

III. Comments and Responses

FSIS received over 250,000 comment letters in response to the January 2012 proposed rule. Most comments were submitted as part of organized write-in campaigns. The Agency also received a petition that included approximately 150,000 signatures and form letters before the comment period closed. The Agency received two petitions in November 2012, after the comment period had closed. One of these petitions included approximately 180,000 signatures and 13,000 comments, and the other included over 3,500 signatures. FSIS received an additional petition in September 2013 with approximately 43,000 signatures. All of the petitions requested that the Agency withdraw the proposed rule. The issues raised in the petitions and comments submitted in November 2012 and September 2013 are similar to the issues raised by the petition and comments submitted during the comment period. Therefore, the Agency will address the issues raised in all of the petitions and associated comments in this document.

Most of the individual comments were submitted as part of various write-in campaigns initiated by consumer advocacy organizations, labor unions, animal welfare organizations, and worker and human rights advocacy organizations. FSIS also received individual comments from private citizens, inspection personnel, and members of labor unions.

In addition to the individual comments, form letters, and petitions, the Agency also received approximately 120 separate comment letters from trade associations representing the poultry industry, companies that conduct poultry slaughter operations, consumer advocacy organizations, public health organizations, labor unions, animal welfare advocacy organizations, members of academia, a State Department of Agriculture, and worker/immigrant/human rights advocacy organizations. Following is a summary of the comments and FSIS's responses.

A. NACMPI Meeting and Public Process

Comments: Several consumer advocacy organizations expressed their concern that FSIS published the proposed rule in the **Federal Register** before it consulted with the NACMPI. According to the comments, the Agency

is required to consult with members of the NACMPI before proposing changes to its meat and poultry inspection program, and that the Agency should have consulted with the NACMPI before publishing the proposed rule to modernize poultry slaughter inspection.

Response: FSIS held the March 21, 2012, NACMPI public meeting in response to a request from certain committee members representing consumer advocacy organizations that the Agency convene the committee to discuss the proposed rule. At the meeting, FSIS made clear that it was interested in the committee's comments and suggestions, but that the Agency was not seeking consensus from the committee.

FSIS disagrees that the Agency was required to consult with the NACMPI before proposing changes to its poultry inspection program. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), the Secretary is authorized to ''appoint advisory committees consisting of such representatives of appropriate State agencies . . . to consult with him concerning State and Federal programs with respect to [meat and poultry] inspection and other matters within the scope of this chapter . . .'' (21 U.S.C. 661(a)(4) and 21 U.S.C. 454(a)(4)). The Secretary of Agriculture established the NACMPI to provide advice concerning State and Federal programs with respect to meat and poultry inspection, food safety, and other matters that fall within the scope of the FMIA and PPIA. Under the NACMPI Charter, FSIS consults with the committee in carrying out its specific responsibilities under 21 U.S.C. 607(c), 624, 645, 661(a)(3), and 661(c) of the FMIA and 21 U.S.C. 454(a)(3), 454(a)(4), 454(c), 457(b), and 460(e) of the PPIA. These sections address: Type styles and sizes of labeling; definitions and standards of identity or composition; standards of fill of container; consistency of Federal and Federal-State standards; storage and handling regulations; exemption of establishments subject to non-Federal jurisdiction; Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority; scope of cooperation; and State meat inspection requirements. Thus, the NACMPI charter does not require that FSIS consult with the NACMPI before proposing changes to its poultry inspection program, although the Agency conducted a public meeting after the proposed rule was issued to seek feedback on the proposal.

Comment: Some consumer advocacy organizations noted that FSIS decided not to hold a technical public meeting as requested by a coalition of consumer advocacy organizations.

Response: As stated in the **Federal Register** comment period extension document, FSIS decided not to hold a public technical meeting on the proposed rule because the Agency did not believe that such a meeting would be useful (77 FR 24873). In April 2012, in response to a request from a group of consumer advocacy organizations, FSIS extended the comment period for the proposed rule. In the **Federal Register** document that announced the comment period extension, FSIS summarized issues that were raised in separate meetings with consumer and industry stakeholders and clarified certain aspects of the proposed rule to help inform stakeholder comments. In that document, the Agency also provided additional information on worker safety issues and its tentative strategy to implement the NPIS, and it solicited comments and data on both issues. As such, FSIS provided the public with all of the information it might have during a technical meeting, but through the public comment process. Thus, the process for developing this final rule was open and transparent and provided several opportunities for stakeholder input.

Comment: One public health association said that FSIS failed to comply with E.O. 12866 and E.O. 13563 requirements with respect to public participation. The comment said E.O. 13563 requires that agencies make all of the documents they rely on to justify rules available to the public, and FSIS did not do so. According to the comment, as of May 19, 2012, more than 80 days after the proposal was published, there were only two documents in the public record posted by USDA at Regulations.gov, the January 27, 2012, and April 26, 2012, **Federal Register** document. The comment said that only 12 records are posted on the FSIS Web site. According to the comment, the public is unable to provide informed comments when the underlying records used to develop the proposed rule are not available for review.

A labor union criticized the Agency for publishing a complex statistical analysis while providing little raw data in the supporting documents. The comment also questioned whether the comment period for the proposed rule provided sufficient time for stakeholders to adequately consider the supporting data.

Response: The Agency plans to post supporting documentation for this final rule and future Agency rulemakings on Regulations.gov. Although FSIS acknowledges that the underlying records used to develop the proposed rule were not posted on Regulations.gov, the proposed rule and all related documents, including supporting materials, were posted on the FSIS Web site when the proposed rule published in the **Federal Register**. The supporting materials included the Evaluation of the HACCP-Based Inspection Models Project; the draft 2011 FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection; the Agency's response to Peer Review Comments on its draft 2008 Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection; and the On-Line and Off-Line Reprocessing In-Plant Trial Analysis. The supporting data for the analyses in the Evaluation of the HACCP-Based Inspection Models Project are presented in tables in the report and in the appendices. The data and modeling methods used in the 2011 FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection are also fully described in the Appendix to that document.

The proposed rule and the **Federal Register** document extending the comment period for the proposed rule were posted on both the FSIS Web site and Regulations.gov when those documents published in the **Federal Register**. The preamble to the proposed rule includes the FSIS Web site link to the related materials and supporting documents, and it explains that these documents are also available in the FSIS docket room. These materials have been available on the Agency's Web site during the entire comment period and remain available at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules/proposed-rules-2012/!ut/p/a1/jZDBCoJAEIafpQeQnVURPdqCpaUikdleYsHVFsxdVuvQ06d0UpKcOf3w_XzMIIoKRFv2EjXrhWxZM2bq3CADB3sEojTwAwgTK8jdZIfBxgNwnQAeHoE8Sw-EgJtYK_sL48O_frRCYOqYxDWiivV3Q7SVREXFS65ZY2hei67nGhVKSyU7Xhr62fBung0TsIkuiE51gIcddCd7HyUWpPYc-PGPL7B8sHqci_dx64XC33wAFla5ew!!/?1dmy&current=true&urile=wcm%3apath%3a%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fregulatory-compliance%2Fhaccp%2Fhaccp-based-inspection-models-project%2Fhimp-study-plans-resources%2Fpoultry-slaughter-inspection.*

With respect to the comment that said that FSIS did not provide sufficient time for public comment, E.O. 12866, as supplemented by E.O. 13563, states that agencies are to ''afford the public . . .

with a comment period that should generally consist of not less than 60 days.'' FSIS provided a 90-day comment period for the proposed rule and then extended it for an additional 30 days. The Agency believes that the public had ample time to consider the issues raised in the proposed rule and supporting documentation in order to develop their comments.

Comment: A consumer advocacy organization criticized the Agency for including the anticipated cost savings from the proposal in the Agency's 2013 proposed budget to Congress before the public comment period for the proposal closed.

Response: The Agency concluded that an open, transparent, and effective budgetary process requires that the Agency report on the rule and the associated estimated budget. In addition, the Appropriations Committee Report that accompanied the FY 2013 appropriations bill directs the Agency to notify the Committee of the status of the rule not later than September 15, 2012.[2]

B. The HIMP Report

In the proposed rule, FSIS explained that it was proposing to establish a new system of inspection for young chickens and turkeys based on its experience under the HACCP-based Inspection Models Project (HIMP) pilot study (77 FR 4421). As discussed in the proposal, FSIS initiated the HIMP pilot study in 20 young chicken and 5 turkey slaughter establishments on a waiver basis after the Agency implemented the 1996 HACCP regulations. Similar to the NPIS, under HIMP, establishment personnel are responsible for sorting carcasses, disposing of carcasses affected with conditions that would require that they be condemned, and conducting any trim and reprocessing that they believe necessary to correct removable defects.

In the HIMP inspection system, a single FSIS online carcass inspector (CI) visually inspects every carcass at a fixed point on the evisceration line immediately before the chiller. Under HIMP, an offline verification inspector (VI) is responsible for conducting system verification activities that the Agency has concluded will be more effective in ensuring food safety, such as conducting offline carcass verification checks for septicemia/toxemia and visible fecal contamination, collecting samples for pathogen testing, and verifying the effectiveness of an establishment's HACCP system by, among other activities, reviewing the establishment's HACCP plan and HACCP monitoring records, observing establishment employees performing tasks specified in the HACCP plan, reviewing and determining the adequacy of the corrective actions taken by the establishment when a deviation occurs, and conducting measurements of critical control points (CCPs). The Agency analyzed the data collected from the HIMP study and prepared a written report that presents an evaluation of the model tested (see the ''HIMP Report,'' available on the Agency's Web site at: *http://www.fsis.usda.gov/wps/wcm/connect/fcd9ca3e-3f08-421f-84a7-936bc410627c/Evaluation_HACCP_HIMP.pdf?MOD=AJPERES*).

The HIMP Report assesses FSIS inspection findings across four interrelated inspection activities:

1. Inspection of each carcass by the CI to determine whether the carcass is not adulterated and thus eligible to bear the mark of inspection.

2. Verification by VIs of the establishment's execution of its HIMP process control plan, under which establishment employees sort acceptable and unacceptable carcasses and parts.

3. Verification of the establishment executing its sanitation SOPs and HACCP system.

4. Verification of the outcomes of the establishment's HIMP process control plan, both organoleptic and microbiological.

Inspection of each carcass by the CI to determine whether the carcass is not adulterated. Based on an analysis of data collected from April 1, 2009, through March 31, 2011, the HIMP Report found that fewer than 0.0008 percent of the carcasses presented to the CI were affected with septicemia/toxemia, and fewer than 0.08 percent had visible fecal contamination. Despite these low rates, the CIs in HIMP establishments detected carcasses affected with septicemia/toxemia at a rate of 0.000004 percent or 4 per 100 million carcasses slaughtered and carcasses with visible fecal contamination at a rate of 0.0009 percent or 9 per 1 million carcasses slaughtered.

Verification by VIs of the establishment's execution of its HIMP process control plan. The HIMP Report compares the ratio of all offline inspection procedures conducted in HIMP and non-HIMP establishments in calendar year (CY) 2010. FSIS inspectors in HIMP establishments perform offline inspection procedures to verify that the establishments are properly executing their HIMP process control plans. This comparison shows that overall in CY 2010, FSIS offline inspection personnel performed 1.6 times more offline inspection procedures in HIMP establishments than in non-HIMP establishments.

Verification of the establishment executing its sanitation SOPs and HACCP system. The sanitation SOP and HACCP regulations are among the regulations most strongly related to public health. The HIMP Report's comparison of the ratio of offline inspection procedures performed in HIMP and non-HIMP establishments in CY 2010 shows that FSIS offline inspectors in HIMP establishments performed about 3.0 times more sanitation SOP and HACCP inspection procedures than offline inspectors performed in non-HIMP establishments. It also shows that offline inspectors in HIMP establishments performed 3.4 more HACCP procedures that include random verification of all HACCP requirements than inspectors in non-HIMP establishments.

The HIMP Report also compares health-related non-compliances in HIMP and non-HIMP establishments from CY 2006 through CY 2010. These data show that health-related non-compliance record (NR) rates at HIMP establishments are not statistically different from or are statistically lower for all inspection procedures considered. The HIMP Report also found that the rate of health-related non-compliances for visible fecal contamination from CY 2006 through CY 2010 is about 1.6 times lower in HIMP establishments than in non-HIMP establishments.

Verification of the outcomes of the establishment's HIMP process control plan, both organoleptic and microbiological. To assess the outcomes of establishment's process control plans in addressing visible food safety defects and defects related to the wholesomeness or quality of the product, referred to as ''other consumer protection'' (OCP) defects, FSIS developed performances standards for these defects based on the performance of non-HIMP establishments. The performance standards allow the Agency to compare the performance of establishments operating under HIMP and non-HIMP inspection systems in controlling visible food safety and OCP defects.

A comparison of the findings of the offline VIs in HIMP establishments for the two-year period April 1, 2009, to March 31, 2011, with the HIMP food safety defect performance standards show that the rate of septicemia/toxemia in carcasses processed in HIMP establishments (8 per 1 million or 0.0008 percent) is 125 times lower than

[2] House Appropriations Committee report, p. 23 (*http://appropriations.house.gov/uploadedfiles/hrpt-112-ap-fy13-agriculture.pdf*).

the HIMP performance standard (0.1 percent). The HIMP Report also found that the rate of visible fecal material on carcasses processed in HIMP establishments (fewer than 0.8 per thousand or 0.08 percent) is 19 times lower than the HIMP performance standards (1.5 percent). A comparison of the findings of the offline VIs in HIMP establishments for the two-year period January 1, 2009 through December 31, 2010, with the HIMP OCP performance standards show that OCP defects identified on carcasses processed in HIMP establishments averaged about half the corresponding OCP HIMP performance standard.

To assess the microbiological outcomes of HIMP establishments' process control plans, the HIMP Report analyzed data from FSIS's *Salmonella* verification testing program collected from CY 2006 through CY 2010. The HIMP Report compares the *Salmonella* percent positive rates in 20 HIMP broiler establishments, 64 non-HIMP comparison establishments, and all 176 non-HIMP broiler establishments. The analysis shows that *Salmonella* positive rates in HIMP establishments average about 80 percent of those in non-HIMP establishments.

In the preamble to the proposed rule, FSIS explained that the Agency had concluded, based on analysis of the two-year data sets of food safety and OCP defects, 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 defects and OCP defects that may affect the wholesomeness or quality of the product (77 FR 4419). Data on health-related NRs collected from CY 2006 through CY 2010 show that non-compliances for fecal contamination are lower in HIMP than in non-HIMP establishments and that HIMP establishments have a higher compliance with sanitation SOP and HACCP regulations. HIMP establishments also had equivalent or lower *Salmonella* positive rates than non-HIMP establishments. The Agency explained that it was proposing to establish a new poultry inspection system informed by HIMP that would replace the SIS, NELS, and NTIS inspection systems for young chickens and turkeys (77 FR 4421).

FSIS received several comments on the HIMP Report and the Agency's analysis of the data collected under the HIMP study. Comments from the poultry industry and trade associations representing the poultry industry generally agreed with the findings of the HIMP Report and supported the Agency's decision to establish a new poultry inspection system. Comments from private citizens, consumer advocacy organizations, labor unions, and members of academia raised issues and concerns regarding the data collected under HIMP and the Agency's conclusions based on the HIMP study results.

1. Data and Methods Used in the HIMP Report

Comment: Several comments from consumer advocacy organizations and private citizens questioned whether data collected under that HIMP study should be used to inform the NPIS. The comments said that the HIMP pilot has never been independently evaluated to determine whether the establishments operating under the HIMP inspection system are producing food that is as safe as product produced in establishments operating under non-HIMP inspection systems.

Response: FSIS disagrees with the comment. In 2002, after the Government Accountability Office (GAO) issued its December 17, 2001, report on HIMP [3] (referred to as the ''2001 GAO report''), FSIS contracted with a technical review team selected by the National Alliance for Food Safety to review and evaluate the data collected from young chicken establishments operating under HIMP. The review team focused on the validity of the HIMP study design and methodology to determine whether FSIS could use the organoleptic and microbial data collected under HIMP to compare the performance of establishments operating under HIMP and non-HIMP inspection systems. Overall, the review team found that the HIMP study design and methodology were valid and provided a useful and legitimate comparison of the HIMP and non-HIMP inspection systems. The review team's findings are described in the report: ''*Review of the HACCP-Based Inspection Models Project by the National Alliance for Food Safety Technical Team*'' [4] (also referred to as ''The Hargis Report'').

As stated in the report, ''[t]he review team noted some issues related to optimal design and interpretation, but finds that overall the data collected were both meaningful and useful and that the study was designed and conducted under real-world conditions and limitations.'' The review team also concluded that ''the overall design and methodology . . . were perhaps the best available options to allow for comparison of organoleptic data between the traditional and HIMP systems.''

Comment: One consumer advocacy organization noted that the HIMP Report said that the Agency's evaluations of microbiological and inspection findings are based on data for calendar years (CY) 2006 through 2010, with certain exceptions where only more recent data are available. According to the comment, the HIMP Report does not explain why certain data are missing or why time periods for comparisons are not uniform. The comment noted that the Agency only analyzed data from CY 2010 when comparing the ratio of offline inspection procedures performed in HIMP and non-HIMP establishments.

Response: The time periods for the data that were analyzed for the HIMP Report vary because not all data were available as computerized data sets. Data on the number of carcasses affected with food safety and OCP defects were not available as computerized data sets. FSIS field personnel manually collected these data and recorded the results on paper forms. To reduce the burden on its field personnel, FSIS decided that an analysis of two years' worth of these non-computerized data sets would be sufficient. The HIMP report data for the number of carcasses affected with food safety defects is from April 1, 2009, through March 31, 2011, and data for carcasses affected with OCP defects is from January 1, 2009, through December 31, 2010.

In the body of the HIMP Report, the Agency used computerized data collected from CY 2010 to compare the ratio of offline inspection procedures performed in HIMP and non-HIMP establishments. The Agency used data from 2010 for this analysis because it was the most recent data available. Tables C–2 and C–3 in the Appendix of the HIMP Report contain summary information on non-compliances with sanitation SOP and HACCP regulations and on the number of inspection procedures in HIMP and non-HIMP establishments from CY 2006 through 2010. The data for these years are similar to the data from CY 2010.

Comment: One comment noted that in the preamble to the proposed rule, the Agency compares findings (1) by VIs of OCP defects between January 1, 2009 and December 31, 2010; (2) by VIs of food safety defects between April 1, 2009 and March 31, 2011; and (3) by CIs of food safety defects between April 1, 2009 and March 31, 2011. The comment

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

[4] The Hargis Report is available for viewing by the public in the FSIS docket room and on the FSIS Web site at: *http://www.fsis.usda.gov/OPPDE/nacmpi/Nov2002/Papers/NAFS97.pdf.*

said that while these time periods are not very different, it is possible that the slight shifts were made to conceal results that would be less supportive, or that would even contradict Agency claims.

Response: The two-year period January 1, 2009 to December 31, 2010 was used to evaluate OCP defects, while the two-year period April 1, 2009, to March 31, 2011 was used to evaluate compliance with the HIMP food safety standards. Both of these comparisons used the most recent data available at the time. This is the reason for the different time periods.

2. HIMP as the Basis for the NPIS

Comment: A trade association representing the poultry industry stated that the HIMP pilot program has been successfully carried out for the last 13 years. The comment said that during that time, food safety records in establishments operating under the HIMP inspection system have been as good as those in non-HIMP establishments. The comment stated that the equivalent or lower pathogen rates in HIMP establishments compared to non-HIMP establishments, as documented in the HIMP Report, are evidence that the program has been successful. The comment noted that this success is especially significant given that the review team selected by the National Alliance for Food Safety determined that food safety performance standards provide a scientifically valid measure by which performance of HIMP establishments can be evaluated (Hargis et al. 2002). The comment stated that, based on the data, the trade association agreed with the Agency's conclusion that the NPIS is a positive step toward enhancing food safety.

On the other hand, several consumer advocacy organizations questioned whether it is appropriate for FSIS to use the HIMP study results to predict how establishments will perform when operating under the NPIS. The comments noted that the 2001 GAO report criticized FSIS for not randomly selecting establishments for the HIMP pilot study and questioned whether the data generated by the pilot could be used to predict how all of the young chicken establishments would perform if FSIS were to adopt the HIMP inspection system nationwide.

Several comments stated that because participation in the HIMP study was voluntary and required that poultry establishments meet additional food safety and OCP performance standards, participating establishments could be viewed as high performers with respect to food safety. The comments asserted that for this reason, data from the HIMP pilot may not represent what FSIS is likely to see when the majority of young chicken and turkey slaughter establishments begin to operate under the NPIS.

Response: The trade association comments support the agency proposal. With regard to concerns raised by the consumer advocacy organizations, FSIS addressed these issues in its comments on and response to the 2001 GAO Report. In that document, FSIS stated that although not randomly selected, there is evidence that volunteer establishments participating in the HIMP study are typical of the industry. The volunteer establishments represent diversity in geography, corporate structure, management styles, number of evisceration lines, product distribution patterns, inspection system in use prior to the pilot, and other variables. In addition, the Hargis Report, discussed above, noted that the establishments selected for the HIMP pilot represent the States supplying the majority of domestic chicken production and the size range of establishments included in the study are representative of almost 90 percent of chickens slaughtered in federally-inspected facilities in the United States. The Hargis Report noted that establishment design, equipment, and procedures within poultry establishments are relatively uniform. The report concluded that ''[i]t is very difficult to hypothesize a geographic or plant-selection bias in this study.''

Comment: Two consumer advocacy organizations stated that the NPIS is not an exact replica of the HIMP pilot, which raises further concerns about whether results from the HIMP pilot accurately reflect how establishments will perform under the NPIS.

Response: Although the NPIS is not an exact replica of HIMP, the NPIS was informed by the data collected under HIMP. These data demonstrate that an inspection system that combines the features described in this document, which include carcass sorting by establishment employees, a CI that conducts an inspection of each carcass before the chiller, and, most important, a VI that conducts more offline inspection activities that specifically focus on food safety, does not reduce the effectiveness and may, in fact, lead to better compliance with sanitation and HACCP regulations and in carcasses with lower levels of fecal contamination and equivalent or lower levels of *Salmonella* contamination.

In addition, as discussed in detail below, in the 2014 risk assessment, analysis of historical data shows a statistically significant correlation between specifically targeted unscheduled offline inspection procedures and reductions in *Salmonella* positive samples in young chicken slaughter establishments and *Campylobacter* positive samples in young turkey slaughter establishments. Modeled scenarios involving an increase in targeted inspection activities (specifically unscheduled offline inspection activities, rather than a randomly selected set of activities) suggest that implementing the NPIS would likely result in public health benefits. Assuming that the number of offline inspection procedures performed in all poultry slaughter establishments increase proportionately to the number of such procedures currently performed in HIMP establishments, FSIS's risk model predicts a likely public health benefit. Consistent with the underlying assumptions of the model, it is reasonable to conclude that inspection systems in which Agency resources continue the core online inspection activities while enhancing the frequency and focus of unscheduled offline activities directly related to food safety, such as HIMP and the NPIS, would likely result in a lower prevalence of carcasses contaminated with *Salmonella* and *Campylobacter,* which in turn would likely lead to fewer human illnesses.

Comment: One consumer advocacy organization criticized the Agency's evaluation of HIMP. The comment stated that the HIMP Report compares the current performance of HIMP establishments with performance levels observed from 1998–2000 when FSIS collected baseline data from establishments that later joined the HIMP pilot.

The comment also stated that the Agency failed to explain how the performance level of the bottom four establishments that entered the HIMP pilot is representative of approximately 200 other establishments more than a decade later.

Response: The Hargis Report, described above, concluded that the design of the HIMP pilot ''is generally appropriate for a field study of this nature, and the methodologies employed generally allow for interpretation and comparison of [HIMP versus non-HIMP inspection systems.]'' The Hargis Report also concluded that comparison of HIMP food safety and OCP performance levels with performance standards does provide a scientifically valid measure by which changes in food safety and OCP performance under HIMP can be assessed.

With respect to the comment that suggests that the HIMP OCP performance standards represent the performance level of the bottom four establishments that entered the HIMP pilot, the HIMP OCP performance standards are set at the 75th percentile of what was achieved under the Research Triangle Institute (RTI) baseline study of 16 young chicken establishments under non-HIMP inspection systems before they entered the HIMP study. Thus, the performance standards were set so that 25 percent of the establishments that entered HIMP would have to improve upon their baseline results in order to meet the more stringent standards.

3. Carcass Inspection Under HIMP

In the preamble to the proposed rule, FSIS explained that the Agency 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 (77 FR 4419). With respect to food safety-related defects, the Agency noted that data collected from the HIMP study show that the levels of carcasses affected with septicemic or toxemic conditions (also referred to as ''septicemia/toxemia'') or visible fecal contamination in HIMP establishments is very low (77 FR 4415). The HIMP Report concluded that notwithstanding these very low levels, the data demonstrate that CIs in HIMP establishments effectively identify carcasses affected with septicemia/toxemia and visible fecal contamination. Several consumer advocacy organizations commented on this conclusion.

Comment: Some consumer advocacy organizations stated that the CI detection rate for visible fecal contamination and septicemia/toxemia is based on the assumption that the rates at which VIs detect these food safety-related conditions represents the level at which these conditions occur in the establishment. The comments questioned this assumption. The comments noted that in HIMP establishments, the VI collects eight 10-bird verification samples per line per shift. The comment asserted that there is no evidence to indicate that this sample size is sufficient to represent the true level of food safety defects on carcasses throughout the shift.

Response: FSIS disagrees that the CI detection rate is based on the assumption that the rate at which VIs detect carcasses affected with septicemia/toxemia or visible fecal contamination represents the level at which these conditions occur in the establishment. The CI detection rate is the rate at which CIs in HIMP establishments detected carcasses with these food safety-related conditions before the carcasses entered the chiller. It is not based on the VI detection rate.

FSIS believes that its sampling for food safety defects under HIMP is sufficient to reflect the level of food safety defects on carcasses processed in HIMP establishments. Statistically, given the sample design, the precision of an estimate of an establishment's level of food safety defects depends primarily on the total number of samples for an establishment collected over time.

The food safety performance standards, which are based on thousands of samples collected by a 3rd party contractor and reflect the level of food safety defects on carcasses processed in establishments before they entered the HIMP pilot, vary by defect category. The performance standard for septicemia/toxemia is 0.1 percent, and the performance standard for visible fecal contamination is 1.5 percent. When deciding the number of samples that FSIS should take to reflect an establishment's level of food safety defects over time, FSIS determined that collecting 80 birds per line per shift would provide an estimated defect rate that was close to the true defect rate.

For example, if the true defect rate for visible fecal contamination was 0.1 percent at an establishment that operated one line for two shifts, 300 days per year, taking an 80 bird sample per line per shift would give a total of 48,000 samples a year, per line. This number of samples, assuming a random distribution of defects throughout the year, would give FSIS an estimated defect rate between 0.72 and .128 percent with about 95 percent probability. Thus, FSIS believes that the specified sample size is sufficient to make general comparisons of average defect rates among establishments or lines.

Comment: One consumer advocacy organization stated that another reason that the VI detection rate may not represent the actual level of food safety-related defects in HIMP establishments is that statements it obtained from HIMP inspectors indicate that establishment employees take greater care to prevent and remove visible fecal contamination and to identify and remove septicemic/toxemic carcasses when they know that the VI inspector is getting ready to take a sample.

Response: The comments seem to suggest that establishment employees are able to manipulate the results of the VI's verification checks. FSIS disagrees.

As noted above, VIs in HIMP establishments collect scheduled verification samples that consist of eight 10-bird samples per line per shift. VIs also collect targeted, unscheduled 10-bird samples in response to VI or CI findings of excessive food safety or OCP carcass defects.

VIs in HIMP establishments collect scheduled and unscheduled verification samples for septicemia/toxemia and visible fecal contamination using the same offline verification methodology that offline inspectors in non-HIMP establishments use to collect samples for visible fecal contamination checks. In both HIMP and non-HIMP establishments, offline inspectors do not inform establishment employees when they collect verification samples and, equally important, take care to ensure that the samples represent the operating conditions in the establishment. Thus, there is no reason to believe that employees in HIMP establishments have any significant opportunity, and certainly no additional opportunity, to affect the results of the verification checks.

Comment: Some consumer advocacy organizations said that the data in the HIMP Report do not support the Agency's conclusion that CIs are able to identify carcasses affected with visible fecal contamination and septicemia/toxemia.

With respect to visible fecal contamination, one consumer advocacy organization stated that the data presented in the HIMP Report indicate that CIs did not detect 88 out of 89 birds with fecal contamination going down the line. The comment stated that the inspectors in the VI position who were able to examine both the inside and the outside of the bird detected visible fecal contamination on the carcass at approximately 90 times the rate that the CIs detected it. Another said that based on the data, it is reasonable to calculate that CIs failed to detect over a quarter of a million carcasses with fecal contamination in the 20 HIMP establishments within the two-year period of data collection.

With respect to septicemia/toxemia, one comment said that data presented in the HIMP Report indicate that CIs detect approximately 1 of every 200 carcasses affected by septicemia/toxemia. The comment said that this means that the CI does not detect 199 of every 200 carcasses affected with septicemia/toxemia.

Response: FSIS disagrees with the commenters' conclusions. The commenters' assessments are based on a

comparison of the results of the CI's carcass inspection and the VI's carcass verification checks and do not take into account the difference between the role of the CI and VI under HIMP. Under HIMP, the inspections performed by the VI and CI serve different purposes and are not done in the same way. Thus, the rate at which VIs identify food safety defects when conducting offline verification checks is not an appropriate basis for assessing whether the CI is conducting an effective inspection of each carcass leaving the slaughter line.

Under the HIMP inspection system, the VI and CI have different but complementary roles in ensuring that poultry products leaving the slaughter line are safe and wholesome. CIs are responsible for conducting a continuous online inspection of each carcass to determine whether it is not adulterated. The VI's role is very different. VIs collect carcass samples before the CI inspection station after the establishment has conducted sorting, trimming, and reprocessing activities to monitor and evaluate the establishment's process controls. The samples collected by VIs may be either ''scheduled'' or ''unscheduled.''

On the one hand, VIs collect eight randomly selected 10-bird samples per line per shift. These are referred to as the ''scheduled'' samples because the IIC schedules the collection of the eight sample sets before each shift. On the other hand, VIs also collect targeted, unscheduled 10-bird samples as directed by the IIC in response to VI or CI findings of excessive food safety or OCP carcass defects. These samples are in addition to the 80-bird scheduled samples. Because the VI's unscheduled samples are collected when excessive carcass defects have been identified, the results typically show higher rates of carcass defects than the VI's scheduled sampling results.

The VI detection rates in the HIMP report reflect the combined results of the VI's scheduled and unscheduled sampling and are thus are much higher than the rates that would have resulted had the VI only performed scheduled carcass sampling. Because CIs under HIMP perform an online inspection of each carcass, the CI detection rates are not subject to the same sampling bias introduced by the unscheduled sampling that VIs perform during high defect periods. Significantly, FSIS has not captured what percent of the defects found by VIs were found in scheduled as opposed to unscheduled sampling. Thus, the VI and CI detection rates are not comparable. Therefore, as stated above, the comparisons of the VI and CI detection rates cited by the comments do not provide a valid assessment of the CI's ability to conduct an effective online carcass inspection.

4. Public Health-Related Non-Compliances

In the proposed rule, the Agency noted that the HIMP Report shows that HIMP establishments have public health-related non-compliance record(NR) rates that are not statistically different from or that are statistically lower than the rates for non-HIMP establishments (77 FR 4416–4417). The Agency also noted that HIMP establishments had fewer NRs for visible fecal contamination than non-HIMP establishments. Several consumer advocacy organizations, FSIS inspectors, and a labor union commented on these conclusions.

Comment: Comments from inspectors, labor unions, and consumer advocacy organizations stated that the location of the establishment's critical control point (''CCP'') for food safety defects may prevent a CI from issuing an NR even if the CI detects such a defect. The comments noted that at the start of the HIMP pilot, the CCPs for visible fecal contamination and septicemia/toxemia were located before the FSIS carcass inspection station. The comments stated that before FSIS began collecting data to support the proposed rule, the Agency allowed the HIMP establishments to move their CCPs for fecal contamination and septicemia/toxemia to points after the CI. One comment said that the timing for allowing establishments to move CCPs to a point after the CI suggests that the primary purpose was to reduce the number of NRs issued to HIMP establishments for these conditions. Another comment said that the fact that CIs cannot issue an NR if they observe food safety defects before the CCP, affects the HIMP Report's CI detection rate statistics.

Response: FSIS disagrees with the suggestion that the location of the CCP with respect to the CI affects the comparison of NR rates between HIMP and non-HIMP establishments. The HIMP Report's analysis of NRs for visible fecal contamination in HIMP and non-HIMP establishments is based on a comparison of visible fecal NRs detected through offline verification activities, not on the CI detection rate, as suggested by one of the comments.

As noted above, the VI under HIMP collects carcass samples after establishment employees have sorted and trimmed the carcasses, but before the carcasses are presented to the CI. If the VI detects visible fecal contamination offline, the VI issues an NR because the establishment violated the Agency's zero tolerance for visible fecal contamination. If a CI observes a carcass with visible fecal contamination the CI stops the line to prevent the carcass from entering the chiller. The location of the establishment's CCP for food safety defects does not affect the CI's or VI's duties under HIMP. Thus, because the NR rate for visible fecal contamination under HIMP is based on the VI detection rate, the location of the CCP with respect to the CI inspection station does not affect the HIMP Report's analysis of visible fecal NRs.

With respect to the comment that suggested that the location of the CCP affects the CI detection rate statistics, the CI detection rate reflects the rate at which CIs stop the line to prevent carcasses with food safety defects from entering the chiller. Thus, contrary to the commenter's suggestion, the location of the CCP after the CI inspection station does not affect the CI detection rate.

Comment: One comment stated that the Agency provided no information to demonstrate that documentation policies and opportunities for documenting public health-related NRs were the same in HIMP and non-HIMP establishments. The comment stated that the 2001 GAO report on HIMP noted that after the switch to HIMP, a substantial number of establishments saw increased fecal NR rates. The comment said that the GAO report cited increased line speeds under HIMP as a potential factor for the increased rate of fecal NRs. The comment said that these findings suggest that the transition to HIMP may result in increased rates of fecal contamination.

Response: As noted in the Agency's comments on the 2001 GAO report, under HIMP, the Agency performs verification checks on approximately 80 carcasses per line per shift as opposed to verification on approximately 20 carcasses per line for fecal contamination under non-HIMP broiler inspection. In addition, VIs under HIMP perform more offline inspection activities that FSIS has concluded are more effective in ensuring food safety than inspectors perform in non-HIMP establishments. Thus, FSIS inspectors in HIMP establishments have more opportunities for detecting non-compliances with regulatory requirements that are directly related to public health than inspectors do in non-HIMP establishments. The procedures for documenting public-health related NRs are the same for both HIMP and non-HIMP establishments.

Although the GAO report cited increased line speeds in HIMP establishments as a potential factor for

the increased rate of fecal NRs, the Agency is not aware of any data to support this hypothesis. The increased rates of fecal NRs that occurred at the beginning of the HIMP pilot could just as easily be the result of increased monitoring under the HIMP inspection system rather than an increase in fecal contamination. Further, the final rule includes a maximum line speed of 140 bpm under the NPIS rather than the 175 bpm allowed in the HIMP pilot.

Comment: A consumer advocacy organization stated that it had recently acquired records of NRs written for visible fecal contamination within the last year from two HIMP establishments and two non-HIMP establishments. The comment stated that to the best of the commenter's knowledge, all of the establishments are large establishments with two production lines and two production shifts. The comment said that the non-HIMP establishments had 19 and 23 NRs for visible fecal contamination, respectively, and the HIMP establishments had 93 and 173 visible fecal NRs, respectively. The comment stated that these comparisons add to the concerns that the lower NR rates for HIMP establishments described in the HIMP Report may not be good indicators of the actual level of food safety defects on carcasses.

Response: Because the consumer advocacy organization did not indicate where it obtained the data or which establishments the data are from, FSIS is unable to respond to the comment in detail.

The HIMP Report's comparison of visible fecal NRs issued from offline verification checks in HIMP and non-HIMP establishments compares 'rates,' which adjust for the number of samples taken. The report shows that fecal NR rates at HIMP establishments are statistically lower than those in both the control set of 64 non-HIMP establishments and the 176 all non-HIMP comparison set. In addition, the rate of visible fecal material contamination on carcasses in HIMP establishments is about half that in non-HIMP establishments. Thus, when the sample is viewed as a whole and rates are the unit of comparison, the data show that HIMP establishments have both slightly lower visible fecal NR rates and slightly lower rates of visible fecal contamination than non-HIMP establishments.

The comparison included in the comment is based on NR rates from two HIMP establishment and two non-HIMP establishments and does not necessarily reflect the average NR rates for all HIMP establishments.

Comment: Another consumer advocacy organization stated that it had received records for the first shift of production for 11 young chicken and 3 young turkey HIMP establishments from FSIS through a Freedom of Information (FOIA) request. The organization analyzed documents that covered the period of January 2011 through August 2011. According to the comment, the overwhelming number of NRs filed for the 14 establishments was for visible fecal contamination found on the carcasses. The comment stated that out of 229 NRs filed from March to August 2011, 208 (90 percent) were for visible fecal contamination. Other comments referenced this finding.

Response: The analysis conducted by the consumer advocacy organization is not inconsistent with the conclusions in the HIMP Report. While it is true that a large percentage of public health-related NRs in poultry slaughter establishments are for visible fecal contamination, the occurrence of fecal contamination on carcasses in HIMP establishments is fewer than 8 per ten thousand carcasses, which is about 19 times lower than the HIMP performance standards. In addition, the rate of visible fecal material contamination on carcasses in HIMP establishments averages about half that in non-HIMP establishments (Table 3–7 in HIMP Report).

5. OCP Standards Under HIMP

In the preamble to the proposed rule, FSIS noted that data from the HIMP Report show that OCP defects identified on carcasses processed in HIMP establishments averaged about half the corresponding OCP HIMP performance standards (77 FR 4418). Based on the HIMP data, the Agency concluded that establishments operating under the HIMP inspection system performed better than establishments operating under non-HIMP inspection systems with respect to OCP defects. Several consumer advocacy organizations and some private citizens commented on this conclusion.

Comment: Some consumer advocacy organizations asserted that the OCP standards under HIMP were not stringent. The comments said that even with these less than rigorous OCP defect levels, HIMP establishments were still just meeting the standards.

Response: While there is likely to be some variation in performance among establishments, for the two year period from CY 2009 through 2010, FSIS verification data show that OCP defect levels in HIMP establishments averaged about half the corresponding OCP performance standards.

In addition, the HIMP OCP performance standards are set at the 75th percentile of what was achieved under the RTI's baseline study of the performance of 16 establishments before they entered the HIMP study. Thus, 25 percent of the establishments that entered HIMP have had to improve upon their baseline results to meet the more stringent standards.

Comment: One comment noted that the HIMP study's statistics on compliance with OCP performance standards are based on a sampling of up to 80 carcasses per slaughter line per shift of production. The comment asserted that when each slaughter line is processing upwards of 100,000 chickens per eight hour shift, this sample size is likely to be too small to accurately reflect the level of OCP defects on RTC carcasses produced by the establishment.

Response: FSIS disagrees with the comment. FSIS believes that its sampling for OCP defects under HIMP is sufficient to reflect an establishment's level of OCP defects. Statistically, given the sample design, the precision of an estimate of an establishment's level of OCP defects depends primarily on the total number of samples for an establishment collected over time.

The OCP performance standards, which are based on a tightening of the FPS for removable animal diseases and trim and dressing defects for establishments before they entered the HIMP pilot, vary by OCP defect category. For example the performance standard for OCP–1, Condition-Animal Diseases, is 1.7 percent, and the performance standard for OCP–3, Digestive Content (Ingesta), is 18.6 percent. When deciding the number of samples that FSIS should take to reflect an establishment's level of OCP defects over time, FSIS determined that collecting at most 80 birds per line per shift would provide an estimated defect rate that was close to the true defect rate. For example, if the true defect rate for OCP–1 defects was 1 percent at an establishment that operated one line for two shifts, 300 days per year, taking an 80 bird sample per line per shift would give a total of 48,000 samples a year, per line. Eighty samples are not always collected; but in general, close to this number were collected daily. It is reasonable to assume that the total number of samples would not be less than 90 percent, or 43,200 samples. This number of samples, assuming a random distribution of defects throughout the year, would give FSIS an estimated defect rate between 0.905–1.095 percent with about 95 percent probability. Thus, FSIS believes that the specified sample

size is sufficient to make general comparisons of average defect rates among establishments or lines.

6. Salmonella Positive Rates in HIMP Establishments

The HIMP Report compares *Salmonella* positive rates for HIMP young chicken slaughter establishments with a control set of 64 non-HIMP establishments and all 176 non-HIMP broiler establishments (77 FR 4418–4419). The data show that *Salmonella* positive rates are equivalent or lower in HIMP establishments than they are in non-HIMP establishments. The Agency concluded that the increase in offline inspection activities provided for under HIMP resulted in the initial lower levels of *Salmonella* contamination in HIMP establishments. Several consumer advocacy organizations and private citizens commented on the HIMP Report's analysis of *Salmonella* positive rates in HIMP and non-HIMP establishments and on the Agency's conclusions with respect to this analysis.

Comment: A consumer advocacy organization stated that the HIMP Report's analysis of the *Salmonella* positive rates for HIMP establishments may not reflect the rates for all establishments operating under HIMP. The comment noted that data from the Agency's *Salmonella* testing program show that the Agency collected data on *Salmonella* positive rates from only 14 HIMP establishments in 2006, 17 HIMP establishments in 2007, and 15 HIMP establishments in 2008. The comment noted that the Agency collected *Salmonella* data from only 10 of the 20 HIMP broiler establishments in 2010. The comment also said that the Agency provided no comparison on *Salmonella* results in the turkey establishments. One member of academia said that the Agency's microbial sampling and analysis under the HIMP pilot were not performed with adequate frequency or power to detect sporadic low-level contamination of carcasses.

Response: FSIS uses the same methodology to schedule and conduct verification sampling for *Salmonella* in both HIMP and non-HIMP establishments. Under the FSIS risk-based methodology for scheduling *Salmonella* verification sample sets, not all establishments are sampled every year. FSIS schedules up to 75 new sample sets each month. The establishments and products selected for sample sets are chosen according to a risk-based algorithm that involves sorting the list of eligible establishments and their respective products by certain criteria and selecting the top 75 from this list. Depending on the frequency of production, product type, and availability of resources, the time to complete a sample set ranges from less than two months to over a year. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time. However, since the same method is used in both HIMP and non-HIMP establishments, *Salmonella* positive levels represent a valid means of comparing the performance of HIMP and non-HIMP establishments.

With respect to the comment that said that the Agency's microbial sampling and analysis under the HIMP pilot were not performed with adequate frequency or power to detect sporadic low-level contamination of carcasses, the sampling and analysis for *Salmonella* under the HIMP pilot was used to compare performance of both HIMP and non-HIMP establishments, not to detect sporadic, low-levels of contamination in HIMP establishments.

Comment: One consumer advocacy organization said that the Agency's conclusion that HIMP establishments have lower *Salmonella* positive rates than non-HIMP establishments is misleading because the HIMP Report compared *Salmonella* positive rates for HIMP establishments with all establishments operating under non-HIMP inspection systems. According to the comment, the Agency should have compared rates for HIMP establishments with the rates for comparably sized non-HIMP establishments.

Response: The HIMP Report compared *Salmonella* positive rates in HIMP establishments with both comparable non-HIMP establishments and all young chicken slaughter 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 chicken in all 5 years considered in the study. The analysis shows that with respect to *Salmonella* positive rates, the HIMP establishments performed better than or as well as both the comparison set of 64 non-HIMP establishments and the set of all 176 non-HIMP establishments from CY 2006 through 2010.

Comment: A consumer advocacy organization asserted that the *Salmonella* positive rates in HIMP establishments do not support the Agency's claim that HIMP establishments have consistently performed better under HIMP than they did under non-HIMP inspection systems. The comment stated that the Agency's own *Salmonella* data from 1998–2007 demonstrate that 14 of the 20 HIMP establishments had lower *Salmonella* positive rates under the non-HIMP inspection systems than they did under the HIMP, and that the average *Salmonella* positive rate for all 20 of the HIMP establishments was better when the establishments were operating under non-HIMP inspection systems. The organization conducted its own analysis of the Agency's *Salmonella* data from January 1, 2006 through September 20, 2007 and said that its analysis shows that the HIMP establishments had an average *Salmonella* positive rate of 8.9 percent, while the non-HIMP establishments had an average rate of 6.5 percent.

Response: In CY 2006 through 2008, the *Salmonella* positive rate in HIMP establishments was statistically significantly lower than in the 64 non-HIMP comparison set, and there was no statistically significant difference in CY 2009 and CY 2010. A comparison of HIMP establishments with all non-HIMP broiler establishments shows that the *Salmonella* positive rate in HIMP establishments was statistically significantly lower in CY 2006 through 2009 and not statistically significantly different in CY 2010. This analysis demonstrates that with respect to *Salmonella* positives rates, HIMP establishments are performing at least as well as current non-HIMP establishments.

With respect to *Salmonella* data from January 1, 2006, through September 20, 2007, referenced by the comment, FSIS has analyzed the most recent data from that time period and found *Salmonella* positive rates of 7.55 percent and 9.61 percent for HIMP and non-HIMP establishments, respectively.

Comment: A consumer advocacy organization stated that in CY 2009 and CY 2010, HIMP establishments had higher *Salmonella* positive rates than the 64 non-HIMP comparison establishments. The comment noted that the HIMP Report shows that the rates for the HIMP establishment were 4.9 percent and 4.7 percent in CY 2009 and CY 2010, respectively, and the rates for the non-HIMP establishments for these years were 4.3 percent and 4.0 percent, respectively. The comment suggested that before moving forward with the NPIS, FSIS should first try to understand why this happened.

Response: FSIS disagrees with the comment's suggestion that HIMP establishments had higher *Salmonella* rates than non-HIMP establishment in CY 2009 and CY 2010. The differences

in *Salmonella* positive rates in CY 2009 and CY 2010 noted by the comment are not statistically significant. On the other hand, in CY 2006 through 2008, the *Salmonella* positive rate in HIMP establishments was statistically significantly lower than in the 64 non-HIMP comparison set.

Comment: Some consumer advocacy organizations stated that reductions in *Salmonella* positive rates may be the result of factors other than increased offline inspection procedures performed under the HIMP inspection system. The comments noted that from CY 2006 through 2008, *Salmonella* positive carcass rates in HIMP establishments were statistically significantly lower than in the non-HIMP comparison establishments, but that in CY 2009 and CY 2010, there was no statistically significant difference. The comments also noted that both HIMP and non-HIMP establishments lowered their *Salmonella* positive rates considerably between CY 2006 and CY 2010.

The comments asserted that because the Agency did not report any changes to the HIMP or non-HIMP inspection systems during that time, it is reasonable to assume that factors other than increased offline inspection activities in HIMP establishments may have caused such a significant decrease in *Salmonella* positive rates. One comment noted that in 2008 FSIS began publishing the names of establishments in Categories 2 and 3 under the Agency's new *Salmonella* performance standards. The comment stated that the data for CY 2009 and CY 2010 may indicate that the industry as a whole reduced its *Salmonella* positive rates as a result of this initiative. Another comment stated that the decline in *Salmonella* positive rates may have been caused by an increase in the use of online reprocessing technology throughout the industry.

Response: In the preamble to the proposed rule, the Agency explained that results in CY 2010 most likely reflect the effects of the *Salmonella* initiatives that FSIS began implementing in 2006 to reverse the multi-year trend of persistently higher percent positive rates for *Salmonella* detected through the Agency's HACCP verification testing each year (77 FR 4419). As a result of these initiatives, the industry reduced the incidence of positive *Salmonella* results, particularly those establishments with the highest *Salmonella* positive rates. Nonetheless, before these initiatives were fully implemented, the HIMP report shows that HIMP establishments performed better than non-HIMP establishments with respect to *Salmonella* positive rates. The reduction in *Salmonella* positive rates in both HIMP and non-HIMP establishments reflects the effectiveness of FSIS's initiatives to reduce *Salmonella* industry-wide.

Comment: One member of academia said that the Agency needs to conduct more frequent sampling for a broader range of pathogens to assess the impact of the HIMP inspection system.

Response: Salmonella is a key pathogen of concern in poultry products. FSIS conducts *Salmonella* verification sampling in both HIMP and non-HIMP establishments. Thus, *Salmonella* positive rates are a valid means of comparing the performance of both HIMP and non-HIMP establishments.

C. The Risk Assessment

The preamble to the proposed rule explained that in June 2011, FSIS completed a quantitative risk assessment to model 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* (77 FR 4420). FSIS updated the 2011 Risk Assessment in response to public comments received on the January 2012 proposed rule; that version of the risk assessment was subsequently posted to the FSIS Web site in August 2012 (referred to as the August 2012 version). In addition, the 2011 risk assessment was subjected to independent external peer review; the risk assessment was further updated in response to the peer review comments. It has also benefited from editing consistent with the Office and Management memorandum, *Final Guidance on Implementing the Plain Writing Act of 2010* (M–11–15), striving to make the risk assessment report language ''clear, concise, well-organized. The most recent version of the risk assessment, which reflects the revisions made in response to public and peer review comments, is referred to as the July 2014 version. Both the August 2012 version and the July 2014 versions have been posted to the FSIS Risk Assessment Web page at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments.*

The HIMP Report explained that FSIS inspectors performed more offline inspections to verify compliance with sanitation SOP and HACCP regulations in HIMP establishment than they do in non-HIMP establishments. The regression analysis of historical data that was included in the risk assessment showed a statistically significant correlation between unscheduled offline inspection procedures and reduction in the prevalence of *Salmonella* and *Campylobacter* positive samples. Based on these results, FSIS thinks it is reasonable to conclude that the redeployment of Agency resources to unscheduled offline activities is likely to contribute to improved food safety resulting from a lower prevalence of carcasses contaminated with *Salmonella* and *Campylobacter,* which in turn we expect to lead to fewer human illnesses.

Comment: Several comments requested that the Agency clarify the status of the 2011 risk assessment's peer review. The comments noted that the Agency had prepared a risk assessment in 2005 that was peer reviewed. The comments said as a result of the peer review, the Agency prepared a revised risk assessment in 2008 but, according to the comments, the docket for the proposed rule contains neither the 2008 risk assessment nor a peer review of that risk assessment.

Response: The FSIS ''Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection'' has been available to the public on the FSIS Risk Assessment Web site since 2008 at: *http://www.fsis.usda.gov/wps/wcm/connect/07c57a64-932f-4ebb-977b-2b10e45a1830/Poultry_Slaughter_Risk_Assess_Jan2008.pdf?MOD=AJPERES.* The analysis was originally peer reviewed in 2006 by an independent group of mathematical modeling specialists. The risk assessment was modified and improved based on the initial peer review. Because the model and analysis has continued to evolve, the 2011 version of both the model and analysis have undergone a peer review. The 2011 risk assessment has been updated based on the peer review comments. The 2011 risk assessment, the peer review comments, FSIS's response to those comments, and the current version of the risk assessment are available on the FSIS Web site at: *http://www.fsis.usda.gov/wps/wcm/connect/8f374626-ee06-49d3-9d41-6eb65ad32cbb/Poultry_Slaughter_Risk_Assess_Aug2012.pdf?MOD=AJPERES.*

Comment: A consumer advocacy organization said that the risk assessment provides little raw data, little explanation of how it was analyzed, and is largely silent on the assumptions upon which it was based. A comment from a labor union was also critical of the FSIS risk assessment.

Response: FSIS generally disagrees with the comments. The risk assessment uses all relevant data taken from FSIS's inspection database paired with *Salmonella* and *Campylobacter* regulatory and baseline sampling data for young chickens and turkeys. Overall,

substantial amounts of empirical data were used in this risk assessment. It uses the Young Chicken Baseline and PR/HACCP *Salmonella* verification data from July 2007–September 2010 and the Young Chicken Baseline *Campylobacter* data from July 2008–September 2009. It also uses the Young Turkey Baseline and PR/HACCP *Salmonella* verification data from July 2007–September 2010 and the Young Turkey Baseline *Campylobacter* data from August 2008–July 2009. There are about 40,900 raw data samples collected on 94 inspection procedures taken from the computerized Performance-Based Inspection System (PBIS).

Although FSIS thinks that the 2011 version of the risk assessment is fully documented, the July 2014 version has benefited from the addition of language that more clearly describes how the model works and articulates more it clearly the underlying assumptions. As noted above, this version also was updated in response to peer review comments. As discussed above, the 2011 version of the risk assessment, the peer review comments on that version, FSIS's response to the peer review comments, and the updated 2014 version of the risk assessment are posted on the FSIS Web site.

Comment: A commenter said that one of the major assumptions in the risk assessment is that if performing more unscheduled offline inspection procedures ''either reduces (or does not change) the occurrence of foodborne pathogens such as *Salmonella* and *Campylobacter* on finished poultry products, then a net public health benefit may result.'' The comment questioned how there could be a ''net public health benefit'' if there is no change to the incidence of pathogens on poultry carcasses. The comment said that FSIS should not predicate a significant restructuring of the poultry slaughter inspection program based on a finding that there will be no change to the incidence of contamination of poultry products. According to the comment, any substantial change to meat or poultry inspection should result in significant improvements to public health.

Response: The Agency agrees that the statement in the risk assessment may not fully articulate how a net public health benefit may result if performing more unscheduled offline inspection procedures reduces (or does not change) the occurrence of foodborne pathogens. To clarify, the risk assessment estimates that if more unscheduled offline inspection procedures reduces the occurrence of a specific foodborne pathogen, such as *Salmonella,* but does not change the occurrence of a different pathogen, such as *Campylobacter,* there will be an overall reduction in pathogens on finished poultry products. This aggregate reduction of pathogens and the subsequent reduction in human illnesses is what was hypothesized to result in a net public health benefit.

The risk assessment characterizes a negative correlation between the frequency of unscheduled offline inspection activities and the prevalence of both *Salmonella* and *Campylobacter* positive samples. Based on these modeling results, FSIS thinks it is reasonable to conclude that redeployment of Agency resources from online inspection activities to targeted unscheduled offline activities is likely to produce an improvement in the food safety system resulting from a lower prevalence of carcasses contaminated with *Salmonella* and *Campylobacter,* which could in turn result in a net reduction in the number of human illnesses.

Comment: Several comments noted that the Agency conceded that ''substantial uncertainty about forecasted changes in illness rates'' results from uncertainty about the change in future inspection activities and the rates of human illnesses attributable to poultry.

Response: The risk assessment analyzed data on specific types of inspection activities and the prevalence of *Salmonella* and *Campylobacter* in young chicken and turkey slaughter establishments. The results suggest that, because inspection personnel assigned to the NPIS will conduct more of the type of inspection activities that were correlated with lower *Salmonella* and *Campylobacter* prevalence, the NPIS will likely result in fewer human illnesses than would be expected if not implemented. In addition to the expected values, the analysis provides the statistical uncertainty of the estimated number of averted illnesses by reporting the upper and lower 80 percent confidence bounds around the estimates to acknowledge that uncertainty always will exist in such models.

Comment: Several consumer advocacy organizations noted that the 2011 version of the risk assessment predicts that additional unscheduled offline procedures could lead to as many as 986 fewer *Campylobacter*-related illnesses per year. The comment noted that the risk assessment states that ''this analysis suggests ambiguous effects of the proposed rule with respect to *Campylobacter* occurrence on chicken carcasses'' and thus does not show a clear public health benefit.

Some comments noted that the Agency recently established a performance standard for *Campylobacter.* The comment said that the Agency does not have enough experience with the *Campylobacter* performance standards to assess industry efforts to reduce *Campylobacter* in poultry to make any reasonable predicted public health benefits. The comments said that if the Agency's proposed changes to poultry slaughter inspection are truly intended to improve public health, the Agency needs a much better understanding of *Campylobacter* rates in poultry establishments and of how the Agency's proposal will impact those rates.

One comment added that the risk assessment suggests that ''the positive *Salmonella* implications of HIMP'' could be applied to *Campylobacter,* but the Agency provides no justification for this statement. The comment said that several studies point to the difficulty of making correlations between controlling for *Salmonella* and controlling for *Campylobacter.*

The comments asserted that FSIS should postpone implementation of the proposed rule until it has collected additional data on *Campylobacter* and is better able to estimate the impacts of the proposed rule on reducing this pathogen.

Response: The Risk Assessment presented the results of two scenarios—one that was based on only increasing unscheduled offline procedures (referred to as the ''discriminate scenario'') and one that did not specify the particular activities to be increased (referred to as the ''indiscriminate scenario''). The former (discriminate scenario), which was based on the type inspection procedures performed more often in the HIMP establishments, suggested larger improvements to public health than the indiscriminate model. FSIS peer-reviewed risk assessment (July 2014), results suggest that the *discriminate scenario* of increased off-line inspection could decrease the number of positive *Salmonella* and *Campylobacter* samples in young chicken and young turkey establishments with high probability. This is the scenario upon which this rule is based.

As noted by the comments, the Agency recently established performance standards for *Campylobacter* for young chicken and turkey slaughter establishments. Because the Agency has not been collecting and analyzing samples for *Campylobacter* as long as it has been collecting and analyzing samples for *Salmonella,* there are fewer

Campylobacter sampling results available for analysis. Thus, although the trends for the *Salmonella* and *Campylobacter* results are the same, the *Campylobacter* results are less robust because of the smaller sample size. The updated risk assessment estimates that there would be a reduction of 3,980 *Salmonella* illnesses attributable to young chicken and turkey establishments combined. This in itself would be a positive public health outcome. Because an increase in unscheduled offline inspection activities is expected to result in fewer *Salmonella* illnesses, FSIS believes that there is no reason to delay implementation of the rule until the Agency collects and analyzes more samples for *Campylobacter.* Additionally, Agency responses to *Campylobacter* sample set failures will continue to follow procedures for Salmonella set failures, i.e. immediate follow-up testing for both organisms and, in most instances, Food Safety Assessments, regardless of whether an establishment adopts the NPIS or not.

Comment: A consumer advocacy organization said that the risk assessment relies heavily on the data collected through the HIMP pilot and the microbiological verification testing programs. The comment asserted that, because these programs are not representative of all poultry establishments, data collected through these programs cannot be generalized to the entire poultry industry. The comment said that the microbiological verification testing programs were not designed to estimate the incidence of foodborne pathogens in meat and poultry products, nor were they designed to evaluate trends over time. The comment said that despite these limitations, the risk assessment has used these data to evaluate the public health impact of reassigning online inspectors to offline activities and has concluded that there is a public health benefit to doing so. The comment suggested that FSIS conduct a pilot study in a representative sample of poultry establishments to ensure that there is a public health benefit before implementing the proposed rule in all poultry establishments.

Response: The assertion that the risk assessment relies on data that are not representative of all poultry establishments is not accurate. The risk assessment uses a volume-weighted model to account for the fact that the microbiological sampling is not proportional to volume. The risk assessment relies on *Salmonella* data collected from 189 young chicken and 25 turkey slaughter establishments and on *Campylobacter* data collected from 181 young chicken and 65 young turkey slaughter establishments from July 2007 to September 2010. There are 20 young chicken establishments and 5 turkey establishments operating under the HIMP inspection system.

The risk assessment does not use the results of microbiological verification testing programs to estimate the prevalence of foodborne pathogens in poultry products or to evaluate trends over time, as suggested by the comment. The risk assessment uses FSIS microbiological verification testing results to analyze correlations between observed positive samples and offline inspection activities in young chicken and turkey slaughter establishments. These correlations are then used as one input to the model that characterizes changes in attributable human illness. The risk assessment showed that the greatest effect on *Salmonella* and *Campylobacter* prevalence and related illness would occur when inspection activities are concentrated on increased unscheduled offline procedures. Thus, FSIS disagrees with the comment's suggestion that the Agency should not implement the proposed rule until it conducts a pilot study in a representative sample of poultry establishments to ensure that there is a public health benefit. The Agency has ample evidence to support its conclusions that there is a solid basis to allow for the NPIS.

Comment: Comments from a consumer advocacy group and a labor union said that the risk assessment is based on the assumption that the Agency's *Salmonella* verification data accurately reflect the performance of the establishments. The comments questioned whether the Agency's *Salmonella* verification results reflect the typical operating conditions in establishments. According to the comments, establishments know when FSIS is about to collect *Salmonella* verification samples because the test kit is mailed to the establishment right before the inspectors are to collect the samples. According to the comments, on days when inspectors collect samples for *Salmonella* testing, it is not unusual for the establishments to increase the concentration of available chlorine in the chiller. The comments asserted that the results of the risk assessment are not reliable because the predictions are not based on typical operating conditions in establishments. As a result, the comments said that FSIS's claims that the proposed rule may reduce the number of *Salmonella* and *Campylobacter* related illnesses are highly speculative and unlikely to be realized.

Response: FSIS disagrees with the comments. The available data from FSIS's microbiological baseline studies and the Agency's *Salmonella* verification results indicate that FSIS's *Salmonella* verification sampling results do reflect typical operating conditions in the establishment.

The Agency compared its most recent baseline data for *Salmonella* prevalence in young chicken and turkey slaughter establishments collected under its National Microbiological Data Collection Programs completed in 2008 and 2009, respectively, with the results of the *Salmonella* samples that it collected and analyzed under its HACCP *Salmonella* verification program for similar time periods. The estimated *Salmonella* prevalence associated with the two sets of data, when volume weighted and adjusted for other establishment characteristics, were not significantly different. FSIS has documented this conclusion in a series of Agency reports [5] and written material associated with the **Federal Register** notice, ''New Performance Standards for *Salmonella* and *Campylobacter* in Young Chickens and Turkey Slaughter Establishments, Response to Comments and Announcement of Implementation Schedule,'' which announced the new *Salmonella* and *Campylobacter* performance standards (76 FR 15282).

In addition, under both HIMP and non-HIMP inspection systems, the protocol is for inspectors to randomly collect scheduled *Salmonella* verification samples and do not inform establishments when they collect the samples. FSIS uses the best available data and has taken steps to enhance data quality going forward. For example, FSIS authorizes its inspectors to request that the Agency schedule additional *Salmonella* verification sampling if they have evidence to demonstrate that an establishment altered its food safety system to coincide with the FSIS *Salmonella* verification sample set.[6] Since FSIS implemented this policy, there have been 10 requests, from which 3 were found to be process changes during *Salmonella* sampling that justified an additional verification set. As of July 21, 2014, there have been no requests since December 2013. Thus,

[5] *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices/notices-2011*; *Salmonella* and *Campylobacter* Notice and comparisons of HACCP and baseline report.

[6] See FSIS Notice 66–12, which reissued the policy in former FSIS Notice 42–11 at: *http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/66-12.pdf.*

FSIS has no basis to think that establishments are regularly making changes to their processes that would substantially affect the Agency's *Salmonella* verification results or, in turn, affect the conclusions of the risk assessment or the HIMP report.

Comment: A consumer advocacy organization said that the risk assessment's assumptions regarding unscheduled inspection procedures were based on procedures assigned under the PBIS. The comment said that now that FSIS has implemented the Public Health Inspection System (PHIS), the number of pre-operational sanitation procedures that inspectors conduct on a monthly basis was reduced to accommodate other inspection procedures under PHIS. According to the comment, the risk assessment is flawed in that it is not based on the inspection tasks that FSIS inspectors will actually be performing under PHIS.

Response: The risk assessment is based on the data that were available at the time that FSIS conducted the analysis. At that time, the available data on offline inspection procedures reflected the number of such procedures scheduled under PBIS. The analysis of historical data that is presented in the risk assessment showed a relationship between lower *Salmonella* in young chicken and *Campylobacter* in turkey prevalence and the type of inspection activities that will be conducted more frequently under the NPIS. FSIS inspectors will continue to conduct both unscheduled and scheduled offline inspection activities under PHIS. Thus, the Agency thinks that the risk assessment's results are valid under PHIS.

Comment: Two consumer advocacy organizations said that while the risk assessment details the uncertainty about the change in human illness rates when offline inspection activities are intensified, there is no comparable examination of the human illness changes from reducing online Federal inspection activities. One of the comments asserted that the risk assessment also did not fully consider the other changes to the inspection system that the Agency was proposing. This comment specifically noted that the risk assessment did not consider the increase in line speeds that had been proposed under the NPIS. Both comments asserted that the Agency should withdraw the rule until an analysis of all of the modifications and variables provides certainty that the inspection changes will not increase the risk to human health.

Response: FSIS disagrees with the suggestion that the Agency withdraw the rule until it conducts an additional analysis. The modifications noted by the comments were addressed in the HIMP pilot study. FSIS thinks that the performance of establishments under HIMP, as documented in the HIMP report, represents what would be achieved under the NPIS. These results support moving forward with this final rule.

As under HIMP, under the NPIS, establishment employees will be responsible for conducting online sorting activities that are currently conducted by FSIS online inspectors. Based on the results of the HIMP pilot, FSIS thinks that establishment employees can perform these activities as effectively as FSIS inspectors do. To ensure that they do, FSIS inspectors in establishments operating under the NPIS will verify that establishment employees are effectively sorting carcasses on an ongoing basis. As they do under HIMP, VIs under the NPIS will collect samples and conduct verification checks and CIs will perform a visual inspection of each carcass at the end of the line before the chiller. If inspection personnel find food safety-related defects or the presence of persistent, unattended trim and dressing defects or removable animal diseases on carcasses and parts, FSIS will require that the establishment take appropriate action to ensure that establishment employees are effectively sorting carcasses and that the establishment is operating under conditions needed to produce safe, wholesome, and unadulterated product. Therefore, the Agency believes that establishment employees operating under FSIS inspection can effectively perform the sorting activities that they will be responsible for under the NPIS.

FSIS also disagrees with the comment that suggested that the Agency conduct an additional risk assessment to estimate the effects of line speeds on food safety and public health. The focus of the risk assessment is to determine how performing a greater number of sanitation, sampling, and other offline activities in young chicken and turkey slaughter establishments might affect the number of human illnesses from *Salmonella* and *Campylobacter.* Although the regression analysis used in the risk assessment did include a categorical variable representing line speed as a structural (fixed effect) variable in the regression model that predicts prevalence, the results do not reflect measures that establishments typically implement in response to a given line speed in order to maintain process control.[7] The Agency believes that the performance of establishments under HIMP, as documented in the HIMP report, represent what would be achieved under the NPIS at similar line speeds.

Comment: One comment said that the risk assessment concludes that more unscheduled offline procedures are the key to lowering *Salmonella* levels. The comment noted that the risk assessment did not consider whether this would be the case if inspectors also did not perform all of the scheduled food safety verifications, which were the only inspection tasks that inspectors performed more in HIMP establishments than in non-HIMP establishments. According to the comment, this is important because there are no scheduled offline food safety checks in the NPIS. The comment questioned the Agency's ''assum[ption] that offline inspection activities after the voluntary implementation of the new inspection system will parallel offline inspection activities in current HIMP establishments.''

Response: Inspection procedures that will be performed in establishments operating under the NPIS will be determined by protocols currently required under PHIS. Under PHIS, inspectors perform both routine (scheduled) procedures and directed (unscheduled) procedures. Thus, inspectors assigned to establishments operating under the NPIS will perform both scheduled and unscheduled offline procedures, just as they currently do in both HIMP and non-HIMP establishments. These offline procedures include, verifying compliance with HACCP and Sanitation SOP requirements, performing carcass verification checks for septicemia/toxemia and visible fecal contamination, verifying sanitary dressing requirements, and collecting samples. The offline inspection activities conducted under the NPIS are intended to be the same rather than parallel the procedures of the existing inspection systems, yielding the same or better public health outcomes.

D. The New Poultry Inspection System (NPIS)

In the preamble to the proposed rule, the Agency explained that, based on its experience under HIMP, it was proposing to establish the NPIS for young chickens and turkeys (77 FR 4421). The proposed rule would have eliminated SIS, NELS, NTIS, and the HIMP pilot and would have required

[7] See Appendix Tables 6–9 in the July 2014 Risk Assessment.

that all young chicken and turkey slaughter establishments operate either under the NPIS or the Traditional Inspection System, as modified in the proposed rule. The proposed rule would also have limited the number of online inspectors under Traditional Inspection to two for each evisceration line, with an exception for existing establishments that slaughter poultry other than young chickens and turkeys that are currently operating with more than two online inspectors.

As discussed below, after considering the comments, FSIS has decided to modify the proposed rule to leave in place all of the existing poultry inspection systems. FSIS has also decided to allow the 20 young chicken establishments that have been granted SIP waivers to operate under HIMP to continue to operate under a SIP waiver to run at line speeds of up to 175 bpm. However, FSIS will update these SIP waivers to remove aspects of HIMP that are inconsistent with the NPIS, such as the OCP performance standards. If an establishment operating under a SIP waiver described above goes out of business or decides to give up its waiver, FSIS will select another establishment to take its place. Thus, as under the current HIMP protocol, FSIS will continue to provide SIP waivers for up to 20 young chicken establishments to operate at 175 bpm. Under this final rule, the maximum line speed under the NPIS for turkeys will be 55 bpm, as was proposed. Thus, there is no need for the five HIMP turkey establishments to continue to operate under an updated SIP waiver because they will be able to achieve the same results by operating under the NPIS. FSIS has also decided that it will not limit the number of online inspectors under Traditional Inspection to two. Under this final rule, FSIS will continue to staff all establishments that do not choose to operate under the NPIS with the number of online inspectors currently assigned to the establishment.

The preamble also explained that FSIS would allow establishments that slaughter classes of poultry other than young chickens and turkeys to operate under the NPIS under a waiver through the Salmonella Initiative Program (SIP). Under the 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.

1. General Comments on the NPIS

Comment: Comments from producers of poultry products and trade associations representing the poultry industry expressed general support for the NPIS. Comments from some FSIS inspection personnel and some private citizens also expressed support for the NPIS. Some comments noted that the existing inspection systems were designed before FSIS implemented HACCP and were developed to identify visual defects that affect the quality of the product. The comments agreed that Agency resources are better spent performing activities that are more effective in ensuring food safety rather than performing functions that establishments can effectively accomplish under FSIS inspection by both VIs and CIs. Another comment said that the NPIS will give establishments the flexibility to investigate and develop new and more efficient technologies. The comment agreed with the Agency's conclusion that the new inspection system will improve the effectiveness of poultry slaughter inspection and overall food safety, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources. Another comment said that the NPIS is the next logical step in protecting public health through modern, science-based food safety technology.

One comment that supported the NPIS proposal stated that it should be considered as part of a comprehensive food safety program that includes the recently implemented PHIS and performance standards for *Salmonella* and *Campylobacter* in broilers and turkeys. The comment said that the proposal should not be considered separate and apart from other regulatory food safety programs.

Response: The Agency agrees with the thrust of these comments and concurs. Certainly the NPIS is part of the initiatives that contribute to the Agency's comprehensive food safety program. As noted by one comment, among these initiatives are the *Salmonella* and *Campylobacter* performance standards, the SIP, PHIS, as well as the NPIS.

Comment: Comments from consumer advocacy organizations, labor unions, FSIS inspectors, public health organizations, animal welfare advocacy organizations, members of academia, human and worker rights advocacy organizations, and some private citizens objected to the NPIS for various reasons. Many of these comments objected to the NPIS because the commenters view the NPIS as a system that ''privatizes'' inspection by replacing USDA online inspectors in part with establishment employees. The petitions submitted in response to the proposed rule express these same views.

Response: The NPIS will not privatize poultry inspection; this system makes Federal inspection of poultry more effective and carcass inspection by FSIS inspectors more efficient.

Under the existing poultry slaughter inspection systems, FSIS inspectors check each carcass for defects and disease and direct establishment employees to take corrective actions. Under the NPIS, a well-trained FSIS CI will conduct a carcass-by-carcass inspection after establishment employees have sorted, trimmed, and conducted any necessary reprocessing. Thus, under the NPIS the CI will be able to conduct a more effective and efficient carcass-by-carcass inspection because carcasses will only be presented for inspection by the CI if they have been sorted by the establishment and are likely to pass inspection.

As discussed earlier in this document, the VIs under the NPIS will conduct offline food safety-related inspection activities and will monitor and evaluate establishment process controls. The VIs will conduct carcass verification checks on carcass samples collected before the CI station to ensure that the establishment is effectively sorting carcasses and that it is producing products that comply with the Agency's zero visible fecal tolerance and other performance standards. VIs will also perform offline activities in addition to carcass verification checks, such as verifying compliance with sanitation SOPs, SPS, and HACCP regulatory requirements, and ensuring that the establishment is meeting all regulatory requirements and is effectively preventing contamination by enteric pathogens and fecal material throughout the entire slaughter and dressing process.

2. Scope of the NPIS

Comment: One comment said that it interprets the proposed rule to limit establishments that slaughter mature fowl to operate under the NPIS only if they participate in the SIP. The comment noted that the only other alternative for establishments that slaughter mature fowl would be to operate under Traditional Inspection. The comment stated that FSIS should expand the scope of the NPIS to include classes of poultry other than young chickens and turkeys without additional qualifications. According to the comment, requiring that establishments that slaughter poultry classes other than young chickens and turkeys operate under a SIP waiver places them at a competitive disadvantage because they must incur costs associated with the

additional testing and data collection required under the SIP.

Response: The NPIS was informed by the Agency's experience under the HIMP pilot, which, for poultry, was limited to young chicken and turkey slaughter establishments. Thus, the Agency would need additional data to support an expansion of the NPIS to classes of poultry other than young chickens and turkeys. As noted by the comment, FSIS would permit establishments that slaughter classes of poultry other than young chickens and turkeys to operate under the NPIS under a waiver through the SIP. At a later time, the Agency would consider the data collected in such poultry slaughter establishments operating under a SIP waiver to determine whether to expand the NPIS to other classes of poultry.

Comment: Comments from two labor unions and a worker rights advocacy organization stated that although the proposed rule allows young chicken and turkey slaughter establishments to choose whether they will operate under the NPIS or under Traditional Inspection, there is no real choice because the Agency proposed to limit the number of online inspectors in establishments operating under Traditional Inspection to two. The comments noted that because most of the establishments that slaughter young chickens and turkeys are large automated operations, it is unlikely that these establishments will choose the traditional method of inspection with slower line speed and two inspectors per line. A comment from an individual questioned why establishments cannot choose to continue to operate under their current inspection systems. The comment stated that FSIS did not require that establishments operate under SIS, NELS, or NTIS when the Agency established those inspection systems. The comment said that allowing establishments to choose to keep their current inspection system gives them a true choice and maintains competition in the marketplace.

A comment from a member of academia said that the proposed rule gives establishments that slaughter young chickens and turkeys the flexibility to decide whether the benefits of switching to the NPIS exceed their estimated costs to operate under such a system. The comment said that many very small establishments are likely to choose to remain under Traditional Inspection because, unlike larger establishments, the benefits of operating under the NPIS may not exceed their costs.

Response: After careful consideration of these comments, FSIS has decided to revise the proposed rule to allow establishments that do not choose to operate under the NPIS to continue to operate under their current inspection system, i.e., SIS, NELS, NTIS, or Traditional Inspection. FSIS has also decided to allow the 20 young chicken establishments that have been granted SIP waivers to operate under HIMP to continue to operate under a SIP waiver to run at line speeds of up to 175 bpm. However, FSIS will update these SIP waivers to remove aspects of HIMP that are inconsistent with the NPIS, such as the OCP performance standards. If an establishment operating under a SIP waiver described above goes out of business or decides to give up its waiver, FSIS will select another establishment to take its place. Thus, as under the current HIMP protocol, FSIS will continue to provide SIP waivers for up to 20 young chicken establishments to operate at 175 bpm. Under this final rule, the maximum line speed under the NPIS for turkeys will be 55 bpm, as was proposed. Thus, there is no need for the five HIMP turkey establishments to continue to operate under an updated SIP waiver.

This final rule will give establishments the flexibility to operate under the system that is best suited to their operations. FSIS has also determined that allowing establishments to continue to operate under their current inspection system instead of converting to the modified Traditional Inspection with two online inspectors will create less disruption to the industry when FSIS begins to implement the NPIS. As noted by the comments, large establishments will likely choose to operate under the NPIS, while very small establishments are likely to choose to operate under the modified Traditional Inspection System. Some establishments may be interested in operating under the NPIS but are not prepared to make the capital investments needed to convert right away. Under this final rule, these establishments will have the option to switch to the NPIS at a later date without having to convert to a modified Traditional Inspection first.

3. Carcass Sorting and Inspection Under the NPIS

a. Carcass Sorting by Establishment Employees

Comment: Several comments from consumer advocacy organizations, FSIS inspectors, labor unions, and private citizens objected to the NPIS's requirement that establishment employees properly sort carcasses before they are presented to the CI for inspection because the comments believe that establishment employees will miss many food safety and OCP defects. Many of the comments referenced the analysis conducted by the consumer advocacy organization that obtained FSIS inspection records from 14 establishments participating in the HIMP pilot presented in an earlier comment. According to the comments, the analysis shows that establishment employees missed food safety and wholesomeness defects at high rates.

Another comment stated that it had secured affidavits from three USDA inspectors who have worked in HIMP establishments who report that because of excessive line speeds and lack of training, company employees routinely miss many food safety and wholesomeness defects. The comments stated that FSIS must more thoroughly evaluate the proposal to allow establishment employees to perform preliminary carcass sorting before it implements the NPIS.

Response: The overall performance of HIMP establishments measured by the findings of offline inspections by VIs was as good as or better than non-HIMP establishments. Results from the VI inspections in HIMP establishments, which are conducted after establishment employees have completed the initial carcass sorting, show that the rates of carcasses with septicemia/toxemia and visible fecal contamination in HIMP establishments were very low, well below the levels set by the HIMP performance standards. These results were discussed in detail above. In addition, as discussed above, OCP defect rates identified on carcasses in HIMP establishments average about half the corresponding OCP HIMP performance standard. Thus, the data from the HIMP pilot show that establishment employees do effectively sort carcasses, dispose of carcasses that must be condemned, and conduct necessary trimming and re-processing activities before the carcasses are presented to the CI for online carcass inspection.

Comment: Several comments from consumer advocacy organizations and private citizens noted that the NPIS does not require that establishment employees performing the sorting function receive training or prove proficiency in performing their duties. The comments noted that the 2001 GAO report on the HIMP pilot program criticized FSIS for not requiring that establishment employees complete training before assuming carcass sorting activities. The comments said that FSIS should accept the GAO recommendation for FSIS to develop a

training and certification program in conjunction with industry.

Response: FSIS is not prescribing specific sorter training or certification. However, the Agency has developed guidance documents to assist establishments in training their sorters. This guidance is available on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.* The guidance that the Agency has developed is based on the training that FSIS provides to online inspection personnel that are responsible for sorting carcasses under the existing inspection systems.

FSIS agrees with the comment that training of sorters is important to ensure that they are able to properly perform their duties. Proper training is necessary if sorters are to make accurate decisions on how to address animal disease conditions and trim and dressing defects. Under the NPIS, if sorters do not make these decisions correctly, FSIS inspection personnel will take appropriate action such as stopping the production line, issuing NRs, and directing the establishment to reduce the line speed to ensure that the establishment is able to maintain process control, that establishment sorters are able to successfully perform their duties, and that FSIS CIs are able to conduct a proper inspection.

Comment: A comment from an animal welfare advocacy organization said that by requiring establishment employees to sort out damaged carcasses before FSIS conducts online inspection, employees remove the evidence, i.e., the carcasses themselves, that birds may have died from causes other than slaughter. The comment asserted that this eliminates one means by which FSIS can verify that establishments are employing good commercial practices.

Response: Inspectors in both HIMP and non-HIMP establishments verify that poultry is being slaughtered in accordance with good commercial practices. Compliance with these requirements ensures that poultry are handled humanely prior to FSIS online inspection. On a daily basis, FSIS offline inspectors observe operations in the receiving, hanging, stunning, bleeding, and pre-scalding areas in both HIMP and non-HIMP establishments. Compliance and enforcement actions are taken as warranted and necessary.

b. Online Carcass Inspection

Comment: Several consumer advocacy organizations expressed concern that online inspectors will only look at the back of the bird under the NPIS. The petitions submitted in response to proposed rule also raised this issue. The comments stated that it is necessary to inspect the front and inside of the carcass in order to detect food safety defects. According the comments, under the NPIS, most inspectors will only look at the back of the bird as it quickly moves down the line and are therefore less likely to identify food safety defects in each carcass.

Response: FSIS disagrees with the comments. The CI carcass presentation under the NPIS allows the CIs to focus their inspection on the same condemnable diseases and conditions that online inspectors focus on under the current inspection systems. Therefore, the Agency believes that the CI carcass presentation under the NPIS will allow the CI to conduct an effective online inspection to detect food safety defects.

Under all four existing inspection systems, i.e., SIS, NELS, NTIS, and Traditional Inspection, FSIS online inspectors focus their inspection on identifying and condemning carcasses with septicemic and toxemic animal diseases and other condemnable conditions that cannot be corrected through trimming or reprocessing. Unlike septemia/toxemia, visible fecal material on the surfaces of a carcass is a food safety defect that can be corrected through reprocessing. Therefore, all poultry slaughter establishments have an online or offline reprocessing system for carcasses accidentally contaminated with fecal material.

Under the current inspection systems, FSIS online inspectors do not issue NRs or condemn carcasses if they observe visible fecal contamination on the interior or exterior carcass surfaces. The Agency ensures that the establishment reprocesses the carcasses after online inspection to remove any fecal contamination before the carcasses enter the chiller. Unlike the NPIS, after such reprocessing, none of the current inspection systems provide for an additional online carcass inspection before the reprocessed birds enter the chiller.

FSIS online CIs under the NPIS will continue to focus on identifying and condemning carcasses with septicemic and toxemic animal diseases and other condemnable conditions that cannot be corrected through trimming or reprocessing. In addition, while the Agency will continue to ensure that the establishments operating under the NPIS reprocess carcasses to remove any visible fecal contamination before the carcasses enter the chiller, the FSIS online CI will also inspect all of the carcasses after they have been sorted, washed, trimmed, and reprocessed, before the carcasses enter the chiller. If there is evidence of fecal material on a carcass, or that the carcass is affected with septicemia or toxemia, the CI will stop the line to prevent the affected carcass from entering the chiller. In addition, the CI will issue an NR because the establishment's procedures for preventing visible fecal contamination and for addressing carcasses with septicemia/toxemia were not effective.

Poultry diseases and conditions, except for avian visceral leukosis, are readily identified by observing the carcass alone; pathogens require testing. Inspection of the outside of the carcass for signs of septicemia/toxemia is sufficient to determine whether the carcass and corresponding viscera must be condemned. Carcasses affected with systemic septicemic or toxemic conditions are darker in color due to dehydration or hemorrhaging and may be smaller or have less body fat due to inappetence or increased metabolic rate. Accordingly, inspection of the exterior of the carcass in accordance with the presentation required under the NPIS is sufficient for CIs to effectively identify and condemn carcasses affected with septicemia/toxemia, along with their corresponding viscera. As discussed elsewhere in this document, an FSIS offline inspector will determine the leukosis status of each flock slaughtered. Viscera in leukosis positive flocks will be inspected by FSIS inspectors.

Thus, online inspection under the NPIS is at least as good, if not better, than online inspection under the current inspection systems. CIs under the NPIS will focus their inspection not only on detecting septicemic and toxemic animal diseases, but on detecting visible fecal contamination as well. In addition, as discussed throughout this document, the VI under the NPIS will conduct carcass verification checks on carcass samples collected before the CI station to ensure that the establishment is effectively sorting carcasses and that it is producing products that comply with the Agency's zero visible fecal tolerance and other performance standards. The VI and CI will work with the IIC to ensure that food safety defects or other conditions do not impair the CI's ability to effectively inspect each carcass.

Comment: Several labor unions and consumer advocacy organizations expressed concern that the NPIS does not require that an inspector examine the viscera of each bird or be able to identify each bird's viscera for inspection. These comments asserted

that an examination of the viscera is important in determining whether or not a bird is diseased, contaminated, or otherwise adulterated.

Response: All poultry diseases and conditions, except for avian visceral leukosis, are readily identified by observing the carcass alone. If the CI identifies a carcass with a condemnable condition, the viscera associated with that carcass must also be condemned. When a carcass is condemned, establishments that have maintained the identity of the corresponding viscera must dispose of that viscera as inedible or, where the identity has not been maintained, must dispose of all viscera harvested within the time period related to the condemned carcass. In either case, the CI's visual examination of each carcass also determines the disposition of the corresponding viscera. The CI's online carcass inspection serves as an inspection of the viscera.

Additionally, FSIS inspectors conduct verification checks on all harvested giblets and necks and will apply the RTC standards under the NPIS. These inspection activities ensure that carcasses and parts, including viscera, have been inspected and are determined by FSIS inspectors to be not adulterated. Inspection procedures for avian visceral leukosis are discussed below.

Comment: A few labor unions expressed concern that under the Traditional Inspection System retained by the proposed changes to part 381, there is no guarantee that an inspector will be able to inspect a carcass along with its viscera. The unions stated that under the current inspection regulations, the carcass and its viscera are inspected together, as the viscera is required to be ''uniformly trailing or leading.'' One union was of the view that while proposed 9 CFR 381.76(c) requires that the identity of each bird's viscera be ''maintained in a manner satisfactory to the inspector until such inspection is made,'' this seems to depart from the current requirements in 9 CFR 381.76 because the ''new'' Traditional Inspection System does not ensure that the viscera and the corresponding carcasses can be inspected by a government inspector.

Response: As discussed above, under this final rule, the regulations that prescribe requirements for the existing inspection systems will remain in place, with some modifications. Thus, the regulations for all inspection systems except the NPIS and HIMP will continue to require that carcasses and viscera be inspected together.

c. Inspection for Avian Visceral Leukosis

As discussed in the preamble to the proposed rule, avian visceral leukosis is a rare manifestation of the viral disease leukosis that is not transmissible to humans (77 FR 4421–2). Avian visceral leukosis can only be detected by observing the viscera. Avian leukosis does not present a human health concern, but it may render poultry unwholesome or otherwise unfit for human food.

As explained in the preamble to the proposed rule, it is common commercial practice to vaccinate each chicken flock for viral leukosis. On rare occasions, the vaccine is not effective. If it is not, visceral leukosis is present on a flock basis. Thus, under the NPIS, an offline inspector will observe the viscera of the first 300 birds slaughtered from each young chicken flock to determine whether the disease is present in the flock. FSIS has followed this practice in young chicken HIMP establishments, and it has been effective. In the HIMP report, FSIS explained that ''[i]t is FSIS's experience that when a flock has avian visceral leukosis, 10 to 15 percent of the birds in the flock have detectable leukosis lesions. For a flock in which 10% of the birds have detectable avian leukosis, a 300 bird sample provides a greater than 95% probability of detecting 22 or greater more birds with visible leukosis lesions'' (HIMP Report, p. 26). From these calculations, the Agency concluded that a 300-bird sample is adequate to detect avian leukosis in a flock.

FSIS received several comments on the proposed avian visceral leukosis inspection procedures.

Comment: A trade association and a poultry producer argued that FSIS should eliminate the proposed avian visceral leukosis check. According to the trade association, the check serves no meaningful public health purpose, is not scientifically sound, and is an outdated inspection approach. The trade association stated that when avian leukosis inspection procedures were originally designed, scientists did not know that the condition is caused by Marek's Disease and the Avian Leukosis Complex. According to the trade association, modern treatment and flock handling practices have effectively eliminated these diseases in commercial poultry operations. The comment stated that comprehensive literature reviews of these conditions, including a statement by the National Institutes of Health, have concluded that neither disease presents an apparent risk to public health. Additionally, the trade association stated that as early as 1984, Agency data has shown that avian visceral leukosis was present in only .017 percent of young chickens slaughtered, and that number is lower today.

Response: As noted by the comment, avian visceral 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. Thus, carcasses affected with the condition need to be condemned. Because avian visceral leukosis, if present, will be present throughout an entire flock, inspecting the first 300 birds of each flock is an appropriate and effective procedure for identifying the disease.

Under the NPIS, an establishment must ensure that it can identify viscera and parts corresponding with each carcass. This final rule also requires that establishments operating under the NPIS provide a location along the production line at which an inspector can inspect for avian leukosis ''the first 300 carcasses of each flock together with associated viscera either uniformly trailing or leading, or otherwise identified with the corresponding carcass.''

Comment: One labor union stated that FSIS is going to require that establishments notify the IIC when they intend to slaughter a new flock so that FSIS may inspect the viscera, but ''flock'' is not defined anywhere in the regulations. The union stated that FSIS's clarification of flock, ''In general, a flock constitutes birds raised under similar circumstances on the same premises'' in the preamble to the proposed rule is imprecise and the clarification is not included in the PPIA or Federal regulations. The union asserted that this lack of a definition of ''flock'' makes the process for detecting avian leukosis problematic.

Response: Establishments are able to identify which birds belong to the same flock because birds from the same flock, i.e., birds that have been raised under similar circumstances on the same premises, arrive at slaughter together. Establishments operating under the NPIS will identify when a new flock arrives and are required to notify the IIC when they intend to slaughter a new flock.

d. Verification Inspection

Comment: A consumer advocacy organization and a trade association requested that FSIS clarify the role of the VI under the NPIS. The consumer advocacy organization requested that FSIS explain how the NPIS will enable

inspectors to conduct more food safety checks; whether more VIs will be assigned to each slaughter line; whether VIs will have to cover more than one slaughter line in an establishment; and whether VIs will have more than one establishment to cover on a given shift, similar to processing assignments.

Response: There will be one CI and one VI assigned to each evisceration line per shift in establishments that chose to operate under the NPIS. As stated throughout this document, because the establishment's employees will be responsible for sorting carcasses, disposing of carcasses that must be condemned, and conducting any trimming or reprocessing activities before carcasses are presented to the online CI, the CI will be better able to focus on detecting carcasses with visible defects that impact food safety, such as visible fecal contamination and septicemia/toxemia.

In addition to online inspection performed by CIs, VIs under the NPIS will conduct offline food safety-related inspection activities and will monitor and evaluate establishment process controls. The VIs will conduct carcass verification checks on carcass samples collected before the CI station to ensure that the establishment is effectively sorting carcasses and that it is producing products that comply with the Agency's zero visible fecal tolerance and other performance standards. As in HIMP, VIs under the NPIS will also conduct an array of other inspection activities that are important to ensure food safety, such as performing ante-mortem inspection; collecting samples for pathogen testing; verifying the effectiveness of the establishment's HACCP system; and verifying that the establishment is meeting sanitary dressing requirements. As noted throughout this document, the VI and CI will work with the IIC to ensure that food safety defects or other conditions do not impair the CI's ability to effectively inspect each carcass.

Comment: A consumer advocacy organization argued that the NPIS decreases the protections that are part of the HIMP pilot program. The comment stated that under HIMP, VIs collect and examine 10-bird samples for food safety defects every hour, and examine at least two of the 10-bird samples for wholesomeness defects. Because of the decreased role of online FSIS inspectors, the consumer advocacy organization stated that these 10 bird samples are the only hands-on verification of poultry carcasses under HIMP. This comment expressed concern that the NPIS does not provide for scheduled verification checks, i.e., food safety or wholesomeness checks, and the Agency has been unwilling to commit to any specific number of scheduled checks.

Response: FSIS agrees with the consumer advocacy organization's assertion that the verification checks that VIs conduct for food safety defects under HIMP are necessary to ensure that establishment employees are effectively sorting carcasses and disposing of carcasses that must be condemned before the carcasses are presented to the CI. Effective carcass sorting by establishment employees is essential for the CI to conduct an efficient and effective online carcass-by-carcass inspection. Therefore, under the NPIS, VIs will continue to conduct carcass verification checks for food safety defects at a point in the slaughter process before the CI's online fixed position. VIs will also verify that establishments are effectively addressing OCP defects through review of establishment records documenting that the establishment is producing RTC poultry and through observation of carcasses when conducting verification checks.

Because HIMP was a pilot study, the activities for offline VIs needed to be more controlled and prescriptive to ensure that the data collected from each establishment participating in the study were consistent. Under the NPIS, the carcass verification checks will be more risk-based to reflect the performance of the establishment. Thus, for some establishments, VIs may conduct more carcasses verification checks under the NPIS than they do under HIMP.

Under the NPIS, the Agency will follow the same procedure used under HIMP to schedule VI carcass checks for food safety defects to ensure that VIs collect an appropriate number of verification samples to assess each establishment's performance under the NPIS. The Agency will monitor and analyze the ongoing results of its verification activities to assess the effectiveness of the establishment's carcass sorting and other process control procedures. The Agency will modify carcass verification checks and other verification activities as needed to respond to findings through the same data-driven process that FSIS uses for all in-plant verification.

The inspection results recorded in PHIS provide FSIS with the information it needs to ensure that verification activities are targeted at identified public health risks. Under PHIS, FSIS is able to modify verification activities to respond to specific situations in individual establishments, to findings in a particular type of establishment, or across the entire regulated industry. In-plant inspection personnel use PHIS to initiate additional verification tasks if their inspection findings raise concerns about an establishment's compliance with regulatory requirements. FSIS managers use PHIS to initiate additional verification and sampling tasks in individual establishments in response to certain criteria, such as not meeting the *Salmonella* performance standard. They are also able to adjust the frequencies and priorities of verification tasks on a national level to quickly shift inspectors' focus to verify requirements where findings indicate problems may be occurring.

Comment: One trade association requested that the Agency clarify where in the process a finding of fecal contamination would result in a regulatory noncompliance.

Response: Similar to HIMP, under the NPIS, the VI will issue an NR for visible fecal contamination if the VI detects such contamination when performing carcass verification checks.

In addition, this final rule requires that all poultry slaughter establishments develop, implement, and maintain written procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and to incorporate these procedures into their HACCP systems. It also requires that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent fecal contamination and contamination by enteric pathogens throughout the entire slaughter and dressing process and to incorporate these procedures into their HACCP systems. These requirements are intended to ensure that establishments are taking the necessary steps to prevent contamination throughout the process and not just cleaning up the birds at the end of the process.

Accordingly, if the CI in an establishment operating under the NPIS observes a carcass with visible fecal contamination, in addition to stopping the line to prevent the carcass from entering the chiller, the CI will also issue an NR because the establishment's procedures for preventing visible fecal contamination were not effective. Because establishments are required to prevent visible fecal contamination throughout the entire process, the CI will issue the NR regardless of where the establishment's CCP for visible fecal contamination is located.

In addition, under this final rule, FSIS inspectors under all poultry inspection systems will not just be inspecting at the end of the line to verify that the establishment's procedures for preventing visible fecal contamination

are effective. Inspection personnel will be conducting verification activities throughout the entire process to ensure that the establishment's procedures for preventing contamination by enteric pathogens and visible fecal material are effective.

e. RTC Poultry Definition Under the NPIS

As noted in the preamble to the proposed rule, removing the SIS, NELS, and NTIS would have included removing the FPS prescribed under these inspection systems (77 FR 4422). As discussed above, FSIS has modified the proposed rule to leave all existing inspection systems in place. Therefore, under this final rule, establishments that continue to operate under SIS, NELS, and NTIS will continue to be subject to the FPS.

However, as was proposed, under the NPIS, the FPS will be replaced with a requirement that establishments document that the products resulting from their slaughter operations meet the definition of ready-to-cook (RTC) poultry. As explained in the preamble to the proposed rule, establishments operating under the NPIS would (like HIMP establishments) have the flexibility to design and implement measures to address OCP defects that are suited to their operations (77 FR 4423). FSIS received several comments from trade associations, consumer advocacy organizations, and industry members on the RTC poultry standard. Comments from members of the poultry industry and a trade association expressed support for the RTC poultry standard and agreed that establishments should have the flexibility to design and implement measures to address OCP defects that will be most effective in their operations. Other comments raised various issues that are discussed below.

Comment: Comments from consumer advocacy organizations suggested that the RTC standard is not stringent enough and that the lack of enforceable OCP goals will make it difficult for FSIS to enforce the RTC standard. The comments said that in contrast to the HIMP inspection system, the Agency is not committing to any specific level of scheduled VI verifications for OCP defects under the NPIS. One comment said that the Agency should have a robust sampling scheme to deal with OCP defects. Another comment maintained that without specific standards for ensuring that OCP defects are promptly identified and addressed, it will be difficult to compare establishments across the industry and trace the causes of systematic defects.

Response: FSIS disagrees with the comments that said that the RTC standards are not stringent. The Agency believes that it can effectively address OCP defects by requiring that establishments operating under the NPIS maintain records to document that the products resulting from their slaughter operations meet the RTC definition. However, to address concerns expressed by the consumer advocacy organizations, the Agency is making clear in this final rule that these records are subject to review and evaluation by FSIS inspectors.

As noted above, the HIMP Report found that for the two-year period from CY 2009 through 2010, HIMP establishments maintained OCP defect levels that average about half the OCP performance standards derived from the performance of non-HIMP establishments. Because the data show that establishments operating under the HIMP inspection system performed well in controlling OCP defects, FSIS tentatively concluded that it was not necessary to adopt prescriptive OCP requirements under the NPIS (77 FR 4423). Instead the Agency proposed to require that establishments operating under the NPIS document that the products resulting from their slaughter operations meet the definition of RTC poultry. Although the NPIS will give establishments the flexibility to design and implement effective measures for addressing OCP defects, establishments will still be responsible for ensuring that the poultry products resulting from their slaughter operations meet the RTC definition.

As was proposed, under this final rule, FSIS will verify that an establishment operating under the NPIS is producing RTC poultry by reviewing the establishment's records and observing carcasses as part of their inspection activities. This approach is consistent with the Agency's view that the verification activities performed by FSIS inspectors should be predominantly focused on activities that are more important in ensuring food safety, but that it is also necessary to verify compliance with requirements that provide non-food safety protections to consumers.[8]

For their record reviews, FSIS inspectors will verify that establishments operating under the NPIS have written criteria for determining whether carcasses meet the RTC definition and that they are documenting that the poultry products resulting from their slaughter operations meet these criteria before packaging or further processing that will conceal the defect. FSIS expects that the establishment will maintain records that, at a minimum, include the following information:

- The records system that the establishment uses to document that it is producing RTC poultry. For example, an establishment may use statistical process control charts, HACCP records, or other documentation.
- The points in the operation where the establishment monitors carcasses to determine whether they meet the RTC definition and records the results of its monitoring activities. For example, an establishment may conduct monitoring and recording the results at a pre-chill and a post-chill station.
- The frequency with which the establishment conducts monitoring activities. The records should specify how often the establishment monitors carcasses per line per shift. For example, an establishment may conduct and document its monitoring activities at least every two hours per line per shift at the pre-chill location and at least twice per shift per line for post-chill location.
- The definitions of the OCP non-conformances or processing and trim defects that for which the establishment is monitoring. For example, the establishment may be monitoring carcasses for processing and trim non-conformances as specified in the current FPS regulations, for trim and processing OCP defects specified under the HIMP OCP performance standards, or defects as defined in a published study or a study that the establishment conducted itself. If the establishment references a study, it should give a brief description of the study and have the supporting information on file.
- The criteria that the establishment uses to determine that the products resulting from its slaughter operation meet the RTC definition. For example, an establishment may follow the subgroup limits for non-conformances and defects in the current FPS regulations, the trim and processing defect levels for the HIMP OCP performance standards, or it may determine the upper limits for non-conformances using a statistical process control program.
- The corrective actions that the establishment will take if the levels of defects and non-conformances exceed its evaluation criteria for RTC poultry.

As noted in the preamble to the proposed rule, poultry carcasses that

[8] See FSIS Directive 7000.1, ''Verification of Non-Food Safety Consumer Protection Regulatory Requirements,'' December 11, 2006 (*http://www.fsis.usda.gov/wps/wcm/connect/aa15d83f-cd09-4553-a705-2e3a0eb94e5d/7000.1.pdf?MOD=AJPERES*).

meet the FPS under SIS and NELS, or that meet the OCP performance standards under HIMP, are ''suitable for cooking without the need for further processing,'' and as such, meet the RTC poultry definition. Therefore, establishments operating under the NPIS that adopt the FPS or the OCP HIMP performance standards as their criteria for determining whether they are producing RTC poultry will meet the regulatory requirements if: (1) They can document that the products resulting from their slaughter operations consistently meet these standards and (2) FSIS inspectors do not observe persistent, unattended defects on the products resulting from the establishment's slaughter operations. Establishments that adopt criteria other than the FPS or the HIMP OCP standards must have documentation to demonstrate how they will use these criteria to demonstrate that the products resulting from their slaughter operations meet the RTC poultry definition.

In addition to record reviews, FSIS inspectors will verify that establishments operating under the NPIS are producing RTC poultry by visually observing carcasses as part of their inspection activities. The presence of persistent, unattended trim and dressing defects on carcasses at the end of the process would indicate that the establishment is not producing RTC poultry. It may also indicate a general lack of control in an establishment's overall slaughter and dressing process. Thus, if inspectors observe persistent, unattended defects, FSIS will require that the establishment take appropriate actions to ensure that its process is under control and that it is operating under conditions necessary to produce safe, wholesome, and unadulterated RTC products. If inspection personnel through their record review or direct observation of carcasses find evidence that an establishment is producing poultry that does not meets the RTC definition, the IIC will be authorized to take appropriate action to ensure that the establishment remedies the defects, including requiring that the establishment slow the line speed.

Comment: Some consumer advocacy organizations said that if FSIS does not establish specific OCP standards for the NPIS, consumers will have no assurances that poultry establishments operating under the NPIS are producing poultry in a uniform manner and adequately removing carcasses defects. One comment noted that there is an increasing market for chicken parts and processed chicken, which enables companies to profit from unwholesome product because consumers have no way to determine that the product has defects. As an example, the comment noted that consumers cannot recognize unwholesome tissue in breaded, battered, or marinated products.

Response: Under the NPIS, establishments will be required to document that the products resulting from their slaughter operations meet the RTC poultry definition. Thus, because the RTC standard applies to carcasses and parts at the end of the slaughter process, establishments will be required to ensure and document that all carcasses and parts meet the RTC definition before the establishment conducts any additional processing to produce battered, marinated, or other processed products.

Comment: Some consumer advocacy organizations noted that the 2001 GAO report on HIMP recommended that FSIS require establishments to implement statistical process controls (SPC), and that FSIS should monitor the efficacy of these systems. The comments noted that while FSIS encourages establishments to implement SPC, the proposed rule does not require it.

Response: FSIS agrees that SPC systems are effective tools for establishments to use to manage and control their production. Some HIMP establishments currently use SPC systems to monitor their compliance with the HIMP OCP performance standards. The Agency believes that most establishments operating under the NPIS will choose to use SPC systems to allow them to document that their poultry products meet the RTC definition. However, instead of mandating the use of SPC, the Agency has decided to allow establishments operating under the NPIS to implement the process controls that they have determined will best produce RTC poultry that is wholesome and not adulterated. The Agency believes that it will be more effective and more consistent with HACCP requirements to provide each establishment operating under the NPIS the flexibility to determine how best to meet the RTC requirement within the context of its production environment while holding the establishment to the *Salmonella* and *Campylobacter* performance standards.

Comment: Comments from poultry producers and trade associations recommended that the Agency allow establishments to apply the RTC standard at any appropriate location at or before the point of packaging or clarify that the Agency intended this flexibility if that is the case. One comment from a trade association said that because an establishment may apply processes targeting RTC criteria and other quality issues at various locations after the chiller, it is not appropriate for the CI to inspect for RTC criteria before the chiller. The comment noted that the RTC standard addresses quality not food safety issues, so there is no food safety concern associated with birds that may not yet meet the RTC standard entering the chiller. The comment said that a bird with bruising, for example, will not ''contaminate'' other birds in the chiller. The comment said that the CI should not be distracted from inspecting for food safety issues with the additional task of checking for RTC criteria.

Response: This final rule maintains the current requirements that all poultry slaughter establishments prepare all eviscerated carcasses as RTC poultry.[9] This final rule also requires that establishments operating under the NPIS maintain records to document that the products resulting from their slaughter operations meet the definition of RTC poultry. Thus, like the FPS, the RTC definition applies to the products at the end of the slaughter process. However, if the CI or the VI observe the presence of persistent unattended defects before the chiller when performing online inspection or conducting offline verification checks, FSIS will address the effectiveness of an establishment's sorting process and its ability to maintain process control. The Agency will require that the establishment operating under the NPIS take appropriate actions to ensure that it is producing safe, wholesome products that meet the definition of RTC poultry.

Comment: One consumer advocacy organization agreed that requiring that establishments operating under the NPIS maintain documentation to demonstrate that they are meeting the RTC standard is beneficial but stated that it did not have enough information on the difference between the FPS and the RTC standard to make a specific comment. Another comment requested that FSIS retain the existing FPS as a safe-harbor for establishments that choose to continue assessing compliance with the RTC standard prior to chilling.

Response: RTC 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

[9] See 9 CFR 381.76(a) under the current regulation and this final rule.

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 RTC 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 do not meet the RTC poultry definition.

As discussed above, establishments operating under the NPIS will have the flexibility to design and implement measures to address OCP defects that are best suited to their operations, and certainly establishments may adopt procedures to address OCP defects based on the existing FPS in order to meet the RTC poultry standard.

4. Facilities Requirements and Staffing for the NPIS

a. Facilities Requirements

Comment: One industry member suggested that establishments operating under that NPIS be permitted to place the carcass inspection station at any location before the chiller. The comment stated that establishments have many reasons for placing carcass inspection stations at locations other than immediately before the chiller. The industry member believed that a facility-specific approach would be more successful in ensuring food safety.

An industry member expressed concern that because of space or line-layout constraints, establishments may not be able to place a carcass inspection station meeting FSIS requirements immediately before the chiller. According to this industry member, some equipment cannot be moved, or if it can be moved, it will result in higher costs and will be less effective elsewhere on the line.

Response: The CI inspection station needs to be located at the end of the processing line immediately before the chiller to allow the CI to ensure that carcasses affected with food safety defects do not enter the chiller and to ensure that the establishment's procedures for preventing visible fecal contamination are effective. Thus, FSIS disagrees and concludes that a prescribed location for the CI station best ensures effective inspection and food safety.

Comment: Two comments from inspectors recommended that FSIS modify the proposed rule to require that the online CI's platform be height-adjustable. The comments stated that, while handling of every carcass is not required under the NPIS, online inspectors will still be required to visually inspect each carcass and that the ideal platform height for one inspector may not be ideal for another significantly taller or shorter inspector. One comment believed that an adjustable platform will benefit inspectors that wear corrective lenses.

Response: FSIS has considered the comments and agrees that the CI inspection platform should be height-adjustable to ensure that CIs are able to conduct an effective visual inspection of each carcass. The Agency is amending the proposed facilities requirements to require that the CI inspection platform under the NPIS be height-adjustable. Most establishments that choose to operate under the NPIS will likely move their present adjustable inspector platform to the new CI location when they convert to the NPIS. Other establishments may consolidate lines and therefore will have extra adjustable inspector platforms when they convert to the NPIS.

Comment: One trade association stated, to be consistent with HACCP, FSIS should remove the requirement in proposed 9 CFR 381.36(c)(4) for a ''trough or other similar drainage facility'' extending beneath the conveyor at all places where processing occurs. According to the trade association, drainage issues are covered by the general requirement for establishments' to maintain sanitary conditions.

Response: FSIS believes that requiring that establishments provide a trough or other drainage and collection facility beneath the conveyor at all places is necessary to maintain sanitary conditions in the establishment. The existing regulations that prescribe facilities requirements for the SIS, NELS and NTIS provide for a trough or other drainage facility under the conveyor.

b. Staffing

Comment: A consumer advocacy organization expressed concern that there will be fewer FSIS inspectors in establishments operating under the NPIS than there are in establishments operating under the HIMP pilot because, according to the comment, FSIS has refused to commit to maintaining similar, specific levels of food safety activities under the NPIS. The comment asserted that the Agency has already allowed staffing levels to decrease in some HIMP establishments.

Another consumer advocacy organization stated that the proposed rule should include language regarding the number of full-time VIs and CIs needed in establishments operating under the NPIS. The comment said that FSIS should use production volume, along with other risk factors to determine the number of inspectors needed at each facility, and that the number of inspectors assigned to a facility be reviewed routinely based on the establishment's performance.

Response: The staffing for each evisceration line under the NPIS will remain the same as the staffing for each line under HIMP. As in HIMP, each establishment operating under the NPIS will have one VI and one CI per line per shift, as well as an IIC. While the verification activities of the VI under the NPIS may not necessarily be identical to those under HIMP, a VI will continue to be assigned to each line so there will be no net reduction in the level of verification inspection. FSIS District Managers and staff conduct periodic reviews of in-plant staffing requirements to ensure appropriate coverage of frontline inspection activities. This is already a standard practice and will not change under the NPIS.

5. Line Speeds Under the NPIS

Based on FSIS's experience under HIMP, the Agency proposed that the maximum line speeds for young chicken establishments operating under the NPIS be 175 bpm and that maximum line speeds for turkey slaughter establishments be 55 bpm (77 FR 4423). However, the Agency's experience from the HIMP pilot has shown that HIMP establishments operate with an average line speed of 131 bpm, and that, although they are authorized to do so, most of the young chicken HIMP establishments do not operate line speeds at 175 bpm. As noted above, the maximum line speed permitted under the current poultry inspection systems is 140 bpm under the SIS for young chickens, and there are many young chicken establishments that do not operate at the maximum line speeds authorized under the current inspection systems. Establishments determine their line speeds based on their equipment and facilities, bird size and flock conditions, and their ability to maintain process control when operating at a given line speed.

Regardless of line speed, HIMP and NPIS do not require that establishments configure their evisceration lines to accommodate more than one online carcass inspector. Establishments operating under the NPIS will have greater control over their lines and greater flexibility over their production process. For example, consistent with HIMP, establishments operating under the NPIS will have the flexibility to reconfigure and consolidate lines if they determine that they need more space to

conduct other activities in their facilities. In addition, because only one online inspector is required at the end of the line, establishments operating under the NPIS will not need to adjust their production based on the availability of FSIS inspection personnel to be stationed online. Establishment employees will staff the lines to perform the online sorting activities. These establishments will also have greater flexibility to vary their line speeds within the limits established by this rule or increase production to respond to customer demands.

In addition to having more control over their production process, establishments operating under the NPIS will also have more opportunities for innovation and greater flexibility to develop and implement new technologies. Currently, if an establishment operating under the existing inspection systems wants to use new technologies for evisceration or for sorting, the establishment must work directly with the Agency to accommodate FSIS's online slaughter inspection methodologies. Doing so takes time and can become an obstacle to innovation. Under the NPIS, establishments will have direct control of the sorting process within their facilities and therefore will have the flexibility to implement and assess the technologies they think are beneficial to their operations and food safety.

As will be mentioned in the section on ''*Implementation of the NPIS,*'' some comments from consumer advocacy organizations suggested that instead of allowing establishments to adopt all of the changes in the proposed NPIS at once, FSIS should implement the NPIS in phases to ensure that establishments maintain process control as each change is adopted. However, because establishments operating under the NPIS will have greater flexibility to adopt new technologies, it would be difficult to develop an implementation strategy to assess each change that establishments make to convert to the NPIS that could be applied consistently across the industry.

After considering the comments, FSIS agrees that it is important to assess establishments' ability to maintain process control as they implement changes to operate under the NPIS. Data from the HIMP pilot demonstrate that establishments operating under HIMP are able to maintain process control at line speeds of up to 175 bpm. However, as noted above, although they are authorized to do so, most HIMP establishments do not operate at 175 bpm. The average line speed under HIMP is 131 bpm. It is also the case that non-HIMP establishments have been operating successfully at line speeds of 140 bpm or less.

Therefore, under this final rule, the maximum line speed for young chickens will be 140 bpm for establishments operating under the NPIS instead of 175 bpm, as was proposed. Limiting the maximum line speed for young chickens under the NPIS to 140 bpm also addresses the concern raised in some of the industry comments that establishments permitted to implement the NPIS first during a staggered implementation will be able to increase their line speeds while other establishments will be economically harmed as they wait for their implementation date.

After the NPIS has been fully implemented on a wide scale, and the Agency has gained at least a year of experience under the new system, FSIS intends to assess the impact of changes adopted by establishments operating under the NPIS by evaluating the results of the Agency's *Salmonella* and *Campylobacter* verification sampling, reviewing documentation on establishments' OCP performance, and other relevant factors. FSIS will consider these results in assessing whether establishments operating under the NPIS have implemented measures that are effective in maintaining process control.

The maximum line speed for turkey establishments will remain at 55 bpm, as was proposed, because this is similar to the current maximum line speed of 51 bpm authorized under the NTIS. The comments on line speeds under the NPIS were also directed at the proposed 175 bpm line speeds for young chickens.

FSIS has decided to allow the 20 young chicken establishments that have been granted a SIP waiver to operate under HIMP to continue to operate line speeds at a maximum of 175 bpm. As discussed above, FSIS will update these SIP waivers to remove aspects of HIMP that are inconsistent with the NPIS, such as the OCP performance standards. Data from the HIMP pilot demonstrate that HIMP establishments operating at the line speeds authorized under HIMP were capable of consistently producing safe, wholesome, and unadulterated product, and that they consistently met pathogen reduction and other performance standards. Additionally, once the NPIS is fully implemented at most establishments, data from these establishments can be used to compare against data from the young chicken establishments operating under the updated SIP waivers.

The comments on the NPIS maximum line speeds that would have been permitted under the proposed rule raised a number of issues. The issue that FSIS received the most comments on was the potential effects that increased line speeds may have on the health and safety of workers in poultry slaughter establishments. Because the issues raised by these comments do not involve the technical aspects of the NPIS, FSIS will address them in a separate section of this document.

a. Line Speed and Process Control

Comment: Comments from members of the poultry industry and trade associations representing members of the poultry industry supported faster line speeds under the NPIS. One comment stated that the industry has made technological advancements and has produced scientific data to demonstrate that establishments can operate at faster line speeds and still maintain food safety. According to the comment, since HIMP's inception, establishments operating under HIMP have demonstrated that safe product could be produced at faster line speeds, as evidenced by pathogen testing data for these establishments.

Some trade associations went further and suggested that the Agency remove the maximum line speed limits and allow establishments to determine their line speeds based on their ability to maintain process control while ensuring inspection of each carcass. The comments said that this would provide options for future changes as both Agency and industry technology evolve and food safety challenges change. According to one comment, limits on maximum line speeds could limit an establishment's future investment decisions and affect hiring practices.

Response: As discussed above, under this final rule the maximum line speed for young chickens will be 140 bpm instead of 175 bpm, as was proposed. FSIS has determined that maintaining a maximum line speed of 140 bpm under the NPIS will allow the Agency to assess the impact of the various changes and new technologies adopted by establishments operating under the NPIS. As noted above, establishments operating under the HIMP pilot may continue to operate under the line speeds authorized under HIMP.

b. Line Speeds and Online Carcass Inspection

Comment: Several labor unions, consumer advocacy organizations, and members of academia stated the maximum allowable line speeds that had been proposed under the NPIS

would be too fast to allow the CI to conduct an adequate online inspection. The petitions submitted in response to the proposed rule also raised this issue.

Comments from a labor union, members of academia, and a private citizen stated that while the most significant food safety concern is microbiological contamination that is not visible to the naked eye, the visual inspection of birds for signs of disease, remaining feathers, and fecal matter remains critical to ensure that product is safe and wholesome. The comments stated that the faster line speeds that would have been permitted under the proposed NPIS would make it difficult for the CI to perform this task.

Response: FSIS disagrees with the comments. Although the maximum line speeds allowed under the NPIS will be 140 bpm for young chickens, the Agency's experience under HIMP shows that CIs in HIMP establishments are able to conduct an effective online inspection of each carcass when operating under the line speeds authorized under HIMP, i.e., up to 175 bpm for young chickens and 55 bpm for turkeys.

Since 2007, HIMP young chicken establishments have been authorized to operate at line speeds of up to 175 bpm depending on their ability to demonstrate consistent process control. Experience during the HIMP pilot has shown that HIMP establishments operate with an average line speed of 131 bpm, and, although they are authorized to do so, most of the young chicken HIMP establishments do not operate line speeds at 175 bpm. As stated throughout this document, establishments determine their line speeds based on their equipment and facilities, bird size and flock conditions, and their ability to maintain process control when operating at a given line speed. In addition, similar to HIMP, line speeds under the NPIS will depend on the number of employees that the establishments hire and train to perform sorting activities. Although the maximum line speed for young chickens under the NPIS will be 140 bpm instead of 175, as was proposed, FSIS believes that establishments choosing to operate under the NPIS will determine their line speeds based on the same factors that establishments considered when setting line speeds under HIMP for the past 15 years.

Furthermore, as noted throughout this document, under the NPIS, the VI and the CI will work with the IIC to ensure that the food safety defects or other conditions do not impair the CI's ability to conduct an inspection of each carcass. The VI and CI will notify the IIC whenever circumstances indicate a loss of process control, e.g., if the VI observes the presence of persistent unattended defects or has evidence to indicate that the establishment is having difficulty maintaining sanitary conditions, or if the CI finds multiple carcasses with defects. The IIC will take appropriate remedial actions and will be authorized to and may require that the establishment slow the line speed. Under all of the poultry inspection systems, the IIC is authorized to direct establishments to operate at a reduced line speed when in his or her judgment the online inspector cannot perform an adequate carcass-by-carcass inspection because of the health conditions of a particular flock, or because of factors that may indicate a loss of process control.[10]

Comment: A comment from members of academia said that between routine cleanings of equipment, pathogens introduced by infected and colonized birds can spread throughout a processing facility, contaminating surfaces, equipment and workers' personal protective equipment. The comment noted that studies have shown that *Salmonella* species, along with other human pathogens, may survive the various process controls and decontamination methods used in U.S. processing facilities. The comment stated that because of the faster line speeds that FSIS had proposed for the NPIS, more carcasses would be processed in each facility per shift. According to the comment, this may increase the likelihood that human pathogens will be introduced into the processing environment and that a greater number of carcasses will become cross-contaminated following the introduction of an infected and colonized bird. The comment did not submit studies or other evidence to support this view.

Response: As explained above, the maximum line speed for the NPIS established in this final rule will be 140 bpm, which is also the maximum line speeds permitted under the current SIS inspection system. Thus, the comment that faster line speeds under the NPIS may contribute to the introduction and spread of pathogens in the processing environment is no longer applicable to this final rule.

[10] See FSIS Notice 64–13, ''Inspection Responsibilities and Authorities for Reducing Slaughter or Evisceration Line Speed'' at: *http://www.fsis.usda.gov/wps/wcm/connect/8612aba6-8f99-47c0-b024-1e33b3627a84/64-13.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=8612aba6-8f99-47c0-b024-1e33b3627a84.*

Regardless of line speed, as discussed in more detail under the section of this document on ''*Changes that Affect All Establishments that Slaughter Poultry Other than Ratites,''* in addition to proposing the NPIS for young chickens and turkeys, FSIS also proposed to require that all poultry slaughter establishments develop, implement, and maintain, as part of their HACCP systems, written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing process. At a minimum, these procedures must include sampling and analysis for microbial organisms pre- and post-chill to monitor process control for enteric pathogens. FSIS also proposed to require that establishments maintain daily records sufficient to document the implementation and monitoring of their process control procedures.

The records that will be required under this rule, including the records of the establishment's testing results, will provide establishments and FSIS with ongoing information on the effectiveness of the establishment's process controls. These records will also enable establishments to identify situations associated with an increase in microbial levels so that they can take the necessary corrective actions to prevent further potential contamination. Additionally, the new testing requirements will ensure that establishments are able 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.

E. Implementation of the NPIS

1. Background

In the **Federal Register** document that extended the comment period for the proposed rule, the Agency provided additional information on proposed implementation of the NPIS to solicit more focused comments on the issue (77 FR 24876). In that document, FSIS explained that it proposed to provide a time period in which all young chicken and turkey slaughter establishments would have an opportunity to contact the Agency to indicate whether they were interested in operating under the NPIS. The Agency explained that those establishments that choose to operate under the NPIS would inform the Agency when they would wish to begin implementing the NPIS in their establishment. When it issued the document, FSIS had tentatively decided that establishments would have six

months to decide whether they would operate under the NPIS and up to three years to switch to the new system.

FSIS received comments on its proposed implementation plan from members of the poultry slaughter industry, trade associations representing the industry, and consumer advocacy organizations. The Agency considered these comments in developing the implementation strategy discussed below.

2. Implementation Strategy

Under FSIS's final implementation strategy for the NPIS, all young chicken and turkey slaughter establishments will initially have six months from the date of publication of this final rule to notify their District Office in writing if they intend to operate under the NPIS. If an establishment does not give its District Office written notification of its intent before the end of the initial 6-month period, the establishment will be deemed to have selected to continue to operate under its current inspection system for purposes of the initial implementation. FSIS encourages establishments to notify their District Office as soon as possible after publication of this final rule of whether they intend transition to the NPIS during the initial implementation period and, if so, when they will be ready to transition to the NPIS. Implementation will not take place at all eligible establishments at the same time. It will be phased in over time to ensure proper FSIS inspection force readiness to successfully implement the NPIS.

As soon as this final rule publishes in the **Federal Register**, and establishments have started to notify FSIS of their intent regarding the NPIS, FSIS will begin selecting establishments to switch to the NPIS. FSIS is using a computerized ranking system to determine the schedule of establishments for NPIS implementation. This ranking system is based on a number of factors, such as FSIS staffing needs, past performance of the establishment, and the location of the establishment in relation to other FSIS-regulated establishments. Scores for each establishment will be tabulated, and the establishments will be ordered from highest score to lowest. The highest scoring establishments will be placed first in the transition schedule. Many establishments will likely receive the same score so a random number will be added to their scores to separate these establishments and order them. A description of the ranking algorithm and the rational for the ranking process is available on the FSIS Web page at: *http://www.fsis.usda.gov/wps/portal/fsis/home.*

Once the ordered list of establishments is created, it will be divided into blocks based on the expected number of establishments that can be transitioned each month (expected to be approximately 12). A computer program then examines the list by looking at the corporate ownership (Dunn and Bradstreet corporate parent) of each establishment. If a disproportionate number of one corporation's establishments appears in the transition schedule for any month, another random number will be added to the establishments' scores to separate them.

Because switching to the NPIS is voluntary, the implementation schedule will also need to be adjusted based on establishment readiness. Establishments that want to transition to the NPIS must notify FSIS and provide a date at which they can be ready to transition. Some establishments that are placed near the beginning of the transition schedule based on the computerized ranking system may need to be moved to a later month in the schedule because they are not ready. In addition, FSIS is aware that several large parent corporations are establishing roving teams to prepare their establishments for the transition. The work of these teams may also cause some establishments not to be ready to transition at the earliest opportunity and require rescheduling them into later months.

FSIS will be implementing the NPIS by clusters of establishments in close geographic proximity to one another. Once the NPIS is fully implemented at all of the establishments in a cluster, FSIS will then begin implementing the NPIS in the next selected cluster. Young chicken and turkey slaughter establishments that decide that they would like to convert to NPIS after the initial notification date may notify FSIS of their intent at any time after that date. The Agency will implement the NPIS in the additional establishments that intend to convert to the NPIS on a schedule consistent with Agency resources and readiness. The Agency intends to implement the NPIS in all young chicken and turkey establishment that choose to operate under the NPIS, regardless of when the establishment notifies FSIS of its intent to transition to the NPIS. However, the initial implementation wave will only include those establishments that submitted their notification within the initial notification period.

3. Comments on Proposed Implementation Plan

Comment: A few trade associations and a poultry producer stated that the implementation process needs to be structured in a way that is fair and ensures that FSIS is not allowing one company a competitive advantage over another. One poultry producer was concerned that the establishments permitted to implement the NPIS first will be able to increase their line speeds, efficiency, and slaughter capacity, while other establishments will be economically harmed as they wait for their implementation date. Industry members and trade associations did not agree on what they believed to be the best implementation strategy.

Response: The system that FSIS will be using to determine the schedule of establishments for implementation of the NPIS does take into consideration corporate ownership of the establishments.

As discussed above, FSIS is using a computerized ranking scoring system based on various factors, such as FSIS staffing needs, establishment performance, and establishment location, to generate an ordered list of establishments for NPIS implementation. After the Agency establishes the initial establishment list, the list will be divided into blocks based on the expected number of establishments that can be transitioned each month. A computer program then examines the list by looking at the corporate ownership of each establishment. If a disproportionate number of one corporation's establishments appear in the transition schedule for any month, another random number will be added to the establishments' scores to separate them. FSIS believes that this process will provide for a fair and objective NPIS implementation schedule.

With respect to the comment that expressed concern that the establishments permitted to implement the NPIS first will be able to increase their line speeds while other establishments wait for their implementation date, as discussed above, the maximum line speed for young chickens under the NPIS will be 140 bpm. Thus, although establishments that convert to the NPIS will have greater control over their line and production process, the maximum line speeds for all young chicken establishments will be 140 bpm regardless of when they convert to the NPIS.

Comment: A State Department of Agriculture and a trade association supported the idea of staggered implementation. One trade association stated that establishments should be given a greater amount of time to determine whether they want to convert to a new inspection system or operate under Traditional Inspection, as was proposed. Another trade association expressed concern that a turkey establishment may not know by the end of the 6-month period, as proposed by FSIS, if it will want to convert to the NPIS because of the long grow-out cycle for turkeys compared to chickens (18–22 weeks for toms, broilers can be as short as 5 weeks). This trade association also stated that there needs to be a process for those establishments that want to adopt the NPIS at a date beyond the proposed 3-year implementation period.

Response: FSIS agrees that staggered implementation is the best approach. The 6-month time period also works well for Agency planning and staffing needs. The Agency has concluded that an initial 6-month notification period is a reasonable amount of time. Therefore, all young chicken and turkey slaughter establishments will have 6 months to determine whether they want to convert to the NPIS during the initial transition period or continue to operate under their current inspection system. Additionally, there will be a process for those establishments that want to adopt the NPIS at a date beyond the initial implementation period. Those establishments may notify FSIS of their intent to operate under the NPIS at any time after the initial 6-month notification period. FSIS will implement the NPIS in the additional establishments as Agency resources and readiness allow.

Comment: A consumer advocacy organization recommended that FSIS implement one new provision in the rule at a time and assess the potential food safety impact of each change before implementing the next provision. The comment said that the Agency must ensure that microbial contamination rates on carcasses continue to improve as incremental changes are implemented. For example, before implementing other changes for the NPIS, this consumer advocacy organization suggested that FSIS implement the proposed new mandatory testing provisions that would apply to all poultry slaughter establishments. According to the comment, all poultry establishments should be required to operate under the new testing program for at least 90 days to generate a baseline that FSIS could use to assess the effects that the additional proposed measures may have on contamination rates. This comment stated that after establishments have generated the necessary baseline data, FSIS could implement additional program changes while assessing the effects on microbial contamination rates against the existing baseline data to ensure that individual changes do not negatively impact process controls. The comment said that if establishments demonstrate that they are maintaining process control as each change is implemented, FSIS could consider additional individual changes.

Response: As discussed above, because establishments operating under the NPIS will have more control over their lines and greater flexibility to implement new technologies, it is difficult to predict how establishments will implement the NPIS when this rule becomes effective. Thus, it would be difficult to develop an NPIS implementation strategy to assess individual changes adopted by each establishment that could be applied consistently across the industry.

However, as discussed earlier in this document, after considering the comments, FSIS agrees that it is important to assess establishments' ability to maintain process control as they implement changes to operate under the NPIS. Therefore, to allow the Agency to assess the impact of the various changes implemented by establishments to operate under the NPIS, the maximum line speed under the NPIS will be 140 bpm for young chickens. This is the maximum line speed permitted under the existing poultry inspection systems under SIS.

After the NPIS has been fully implemented on a wide scale, and the Agency has gained at least a year of experience under the new system, FSIS intends to assess the impact of changes adopted by establishments operating under the NPIS by evaluating the results of the Agency's *Salmonella* and *Campylobacter* verification sampling, reviewing documentation on establishments' OCP performance, and considering other relevant factors. FSIS will consider this information in assessing whether establishments operating under the NPIS have implemented measures that are effective in maintaining process control.

Furthermore, under this final rule, large establishments, small establishments, and very small establishments will be required to implement the new microbiological sampling requirements 90 days, 120 days, and 180 days, respectively, after the publication of this final rule. Therefore, depending on when each establishment converts to NPIS, they will likely have already implemented the new sampling requirements when they transition to NPIS. When establishments transition to the NPIS, they will be expected to maintain records, including records of their test results, to demonstrate that they are maintaining process control. Therefore, FSIS has concluded that it is not necessary to require that establishments generate a baseline for at least 90 days before implementing the NPIS.

Comment: A State Department of Agriculture stated that the smallest volume establishments should have the longest time to comply because they will find it difficult to implement certain sections of the proposed rule because of limitations in personnel, budget, time, and expertise in microbiology. As an example, the comment said that very small establishments may need additional time to implement their revised sampling programs.

Response: FSIS agrees that small businesses should have more time to implement the new sampling requirements. Small establishments will have 120 days and very small establishments will have 180 days to implement the regulations that prescribe procedures for controlling visible fecal contamination in 9 CFR 381.65(f), the regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process in 9 CFR 381.65(g), and the recordkeeping requirements in 9 CFR 381.65(h).

Comment: A poultry producer and a trade association stated that FSIS should consider allowing industry the option of staggering implementation by line and shift as coordinated between establishment management and the District Office. This poultry producer argued that this will allow the industry to conduct on-the-job training with staff and help the Agency reallocate inspection resources over a period of time instead of having to reassign an entire establishment of inspection program personnel all at once.

Response: FSIS has decided not to give establishments the option to stagger implementation by line and shift. It would be too difficult for FSIS to perform its inspection activities at establishments that are operating different lines or shifts under the NPIS and one of the other inspection systems at the same time. For Agency planning and resource purposes, if an establishment wants to convert to the NPIS, all of the establishment's lines and shifts will be required to switch to the NPIS during the transition.

Comment: A few trade associations stated that implementation plans should be establishment specific. One trade association stated that these establishment specific plans should be based on the systems, methods of processing, and supply considerations of that establishment. Another trade association argued that establishments should be allowed to develop individualized implementation plans in coordination with their District Offices to facilitate Agency planning and resource allocation.

One trade association stated that there should be a significant transition period where establishments may continue to operate under their current inspection system while developing their implementation plans and making them available to the Agency. Under the trade association's plan, the Agency would have a set period of time to comment on the plans, after which establishments would begin making the necessary financial, facility, and personnel changes to implement the NPIS. The trade association also recommended that the Agency publish a list of pre-approved implementation strategies in an FSIS notice and encourage establishments to use strategies from the list to develop their individualized implementation plans.

Response: FSIS expects that establishments will work closely with their District Offices to implement the NPIS. As stated above, all young chicken and turkey slaughter establishments will have 6 months from the date of publication of this final rule to notify their District Office in writing whether they intend to operate under the NPIS during the initial transition period. FSIS will attempt to accommodate establishments' requests to transition to the NPIS at the times stated in their notification to the District Office. However, FSIS will be implementing the NPIS by clusters of establishments in close geographic proximity to one another. The system that FSIS will be using to determine the schedule of establishments for implementation of the NPIS is described above. Once an establishment is selected to convert to the NPIS, the District Office will work with the establishment to successfully transition its operations.

FSIS does not plan to publish a list of pre-approved implementation strategies. However, if an establishment wants to make changes to its operation to prepare for conversion to the NPIS, FSIS will try and accommodate those changes as long as they do not affect FSIS inspection activities or procedures. For example, if an establishment operating under the current system wants to have employees practice sorting by removing carcasses with septicemic or toxemic conditions from the line before inspection and include these condemned birds in the official Lot Tally totals, the FSIS District Office will work with the establishment to try to accommodate such a request. FSIS will consider these requests on a case-by-case basis. FSIS has concluded that allowing this type of flexibility will help establishments successfully transition to the NPIS.

Comment: A consumer advocacy organization stated that before FSIS allows an establishment to transition to the NPIS, the Agency should require that the establishment demonstrate that it is financially capable of meeting the new requirements and assuming its new role under the new inspection system. The comment stated that the theory behind the consideration is that a firm under financial duress might cut corners in its processes that could compromise food safety.

Response: Before an establishment is allowed to transition to the NPIS, the establishment will need to develop a plan to meet the new requirements. FSIS will not be imposing any financial requirements on establishments before they are allowed to transition to the NPIS. Once an establishment transitions to NPIS, it will have to demonstrate that it is maintaining process control.

In addition, as discussed above, rather than eliminate SIS, NELS, and NTIS, as was proposed, this final rule will leave in place all existing inspection systems. Thus, establishments that do not have the resources to convert to the NPIS during the first implementation phase will have the flexibility to operate under the inspection system that is best suited to their operations. These establishments will also have the option to convert to the NPIS at a later date without having to convert to a modified Traditional Inspection first.

Comment: Several industry members and trade associations stated that the proposed rule lacks detail regarding implementation and that implementation plans need to be clearly communicated to industry through listening sessions or roundtables like HACCP or PHIS implementation to help successful transition to the NPIS. One poultry producer believed that FSIS may benefit from hosting a public meeting to receive feedback on how best to implement the NPIS. One trade association stated that the Agency needs to work closely with stakeholders on implementation. One trade association also stated that communication with inspection program personnel needs to happen well before implementation and that communication materials need to be shared with industry in an open and transparent manner.

Response: This final rule provides more detail regarding implementation if an establishment chooses the NPIS. FSIS intends to communicate its plans to industry, inspection program personnel, other stakeholders, and the public through additional means as necessary. Before implementation, FSIS will communicate with its inspection program personnel about the NPIS and provide them with materials regarding the NPIS. FSIS issues instructions to inspection program personnel through FSIS Notices and Directives, which are published on the FSIS Web site and are accessible to the public.

Comment: Several industry members and trade associations stated that FSIS needs to provide clear and consistent guidance to FSIS personnel and industry. One poultry producer argued that FSIS should provide industry with the training tools utilized for inspection program personnel under the existing slaughter systems to facilitate the transition to the NPIS. Additionally, one trade association stated that a compliance guide (e.g., describing training related to quality defects and disease conditions) that is at least equivalent to FSIS's expectations of its inspection program personnel should be created. A State Department of Agriculture and a trade association stated that FSIS needs to provide scale-appropriate guidance and training materials (e.g., guidance on developing anti-contamination procedures and sampling programs) to small and very small establishments to assist in compliance with the rule.

Response: As stated previously, FSIS has converted the current instructions that it provides Agency inspectors into guidance for industry to use to train establishment sorters. This guidance is available on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index*.

FSIS intends to provide guidance to industry on the new sections of this final rule, including the new sampling plans. Guidance and training materials will be scale-appropriate and will focus on guidance that is appropriate for small and very small establishments.

Comment: Several trade associations advocated that the Agency should create an experienced group of experts to coordinate implementation of the NPIS, address key issues that arise during implementation, and focus on facility and inspector concerns. According to one of the trade associations, this approach would minimize cost and

disruption to the industry and inspection, provide mutually beneficial training opportunities, and ensure a consistent approach to implementing the NPIS across the nation. Several trade associations stated that the group of experts should function as an operational hotline (similar to the Agency's Small Plant Hotline) to quickly address questions from establishments and inspectors about the NPIS and how it is supposed to work in specific situations.

Response: The Agency will continue to provide technical support to its workforce and industry through its standard channels. For example, FSIS will continue to encourage referring questions to its Policy Development Staff through askFSIS at *http://askfsis.custhelp.com* or by telephone at 1–800–233–3935. Members of the Policy Development Staff were involved in the development of this final rule and will have the expertise to address issues that arise during implementation of this final rule. FSIS believes that its existing Agency resources are sufficient to address issues that arise with respect to this final rule. Additionally, the Agency will be providing appropriate instructions, guidance, and training to its inspectors on the NPIS. The Agency will also provide guidance to industry that will help establishments with regard to this final rule.

F. Line Speeds and Worker Safety

1. Collaboration With the National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH) is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services. NIOSH's mission is to generate new scientific knowledge and provide practical solutions vital to reducing risks of illness, injury, and death in the field of occupational safety and health, and transfer that knowledge into practice. In the proposed rule, FSIS acknowledged the potential for an increase in inspection line speed to affect establishment employee safety (77 FR 4423–4425). The Agency explained that to obtain preliminary data on the matter, it had asked NIOSH to evaluate the effects of increased inspection line speeds on establishment worker safety by evaluating the inspection lines and workers from establishments that had been granted waivers from line speed restrictions under the SIP. As noted in both the proposed rule and the **Federal Register** document to extend the comment period, NIOSH initiated such an evaluation in one non-HIMP establishment that is operating under a waiver from line speed restrictions under SIP (77 FR 4423 and 77 FR 2487).

The current NIOSH evaluation assessed this establishment prior to any changes allowed under the SIP line speed waiver, and also after changes were implemented. NIOSH completed its evaluation and made its final report available to the public in March 2014 (Evaluation of *Musculoskeletal Disorders and Traumatic Injuries Among Employees at a Poultry Processing Plant;* Report No. 2012–0125–3204, March 2014. Available on the Internet at: *http://www.cdc.gov/niosh/hhe/reports/pdfs/2012-0125-3204.pdf*). The report describes NIOSH's findings and recommendations from an evaluation conducted before and after the establishment combined two evisceration lines into one and increased the evisceration line speed. The NIOSH evaluation provides valuable information to FSIS, the Department of Labor's Occupational Safety and Health Administration (OSHA), and other stakeholders.

FSIS considers the NIOSH evaluation to be an important first step in measuring any impact of evisceration (or inspection) line speeds on workers in poultry slaughter and processing establishments. Without the NIOSH evaluation and access that FSIS was able to ensure, such information likely would not be developed. As stated previously, FSIS will consider the available data on employee effects collected from NIOSH activities when implementing the final rule. FSIS has committed to working with NIOSH and OSHA on disseminating the guidance resulting from the current NIOSH study, and ensuring greater awareness by FSIS and the industry about worker safety and health.

2. Collaboration With OSHA

OSHA is an agency of the United States Department of Labor, and was created to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education, and assistance. OSHA is helping FSIS address the health and safety of FSIS inspectors when they are performing their duties in federally-regulated establishments. FSIS has an Occupational Safety and Health Division, comprised of professional Occupational Safety and Health Specialists, a Certified Professional Ergonomist, Certified Industrial Hygienists, and Certified Safety Professionals dedicated to ensuring a safe and healthful work environment for FSIS employees. FSIS is in the process of establishing a Safety and Health Committee made up of program representatives as well as members of the National Joint Council of Food Inspection Locals to ensure continual improvement of FSIS's safety and health programs. FSIS has recently placed an increased emphasis on occupational safety and health for its employees, and has identified a reduction of the injuries and illnesses for FSIS employees as a key measure in the FSIS Strategic Plan for FY 2011–2016.[11] FSIS Directive 4791.12, ''*Reporting and Correcting Occupational Hazards,*'' and FSIS Directive 4791.13, ''*Workplace Inspections, and Injury, Illness and Motor Vehicle Incident Reporting,*'' provide FSIS inspection personnel with procedures for reporting and correcting workplace safety and health hazards that affect FSIS employees. FSIS AgLearn Course 8500, ''*Recognizing and Reporting Occupational Safety and Health Hazards,*'' is available to improve FSIS employees' ability to recognize and report workplace safety and health hazards in accordance with the FSIS worker safety directives.

FSIS also recognizes the importance of establishment worker safety and will work with OSHA to heighten FSIS employees' awareness of serious occupational safety hazards in FSIS-regulated establishments. FSIS has begun working with OSHA to continually update and improve the training of FSIS inspectors in recognition of serious workplace hazards and will provide a referral system to report such hazards to OSHA. The Agency will issue an FSIS Notice, ''*Procedures for Notifying the Occupational Safety and Health Administration (OSHA).*'' The notice establishes a procedure for FSIS inspection personnel to notify OSHA directly of serious workplace hazards that may affect non-federal establishment personnel in meat and poultry products establishments and in egg product plants. The notice provides inspection personnel with OSHA's confidential 1–800 number to refer an occupational safety or health concern for a plant employee directly to OSHA.

FSIS has also taken action to encourage establishments to comply with OSHA requirements. In May 2011, the Agency published an article on ''*Reporting Work Related Injuries*'' in its ''Small Plant News'' publication.[12] The

[11] *http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/strategic+planning/.*

[12] ''Small Plant News, Vol. 4, No. 2. Available on the Internet at: *http://www.fsis.usda.gov/wps/wcm/*

article discussed the importance of OSHA's requirements for recording and reporting work-related injuries, illnesses and fatalities, and provided guidance to small establishments on how to comply with these requirements. The article encouraged small establishments to contact OSHA with any questions on OSHA's requirements and included contact information for OSHA's regional recordkeeping coordinators.

The Agency published another worker safety article in the December 2012 ''Small Plant News'' titled ''*Know OSHA's Safety and Health Standards.*'' [13] The article provides an overview of the OSHA regulations that affect federally-inspected meat and poultry establishments and processed egg products plants. It also provides an excerpt of the standards described in OSHA's Small Business Handbook and provides a link that allows interested parties to access the document on the Internet.

As part of FSIS's ongoing collaboration with OSHA, FSIS had numerous discussions with OSHA during the development of this final rule on how best to address potential issues related to line speeds and worker safety. As discussed above, to allow FSIS to assess the impacts of changes implemented by establishments that convert to the NPIS, the maximum line speeds under the NPIS established in this final rule will be 140 bpm for young chickens instead of 175 bpm, as was proposed. The highest maximum line speed under the current inspection systems is 140 bpm under SIS. Thus, under this final rule, any increase in line speed that establishments implement under the NPIS will not exceed the maximum line speeds authorized under the existing inspection systems.

OSHA has provided FSIS with a set of recommended actions that poultry establishments can take to address the health and safety of establishment employees. These recommendations are as follows:

- Develop and implement policies to encourage prompt reporting of injuries and illnesses;
- Evaluate existing programs to ensure that they do not discourage employees from reporting injuries and illnesses;
- Implement a training program for employees on job hazards, early symptoms of illnesses and injuries, and how to prevent them. Ensure that training is offered in a manner and language that workers can understand;
- Conduct routine surveillance of injury and illness logs as well as the workplace to identify potential job hazards;
- Establish an employee complaint or suggestion procedure designed to allow employees to raise job hazard issues without fear of reprisal;
- Request employee feedback on workplace modifications; and
- When job hazards are identified, implement mitigating measures.

FSIS and OSHA agree that surveillance for injuries and illnesses is particularly important to identify whether workers are experiencing adverse health or safety effects when performing their duties and to trigger appropriate intervention if they are.

Although FSIS does not have the authority to require that establishments adopt these recommendations, the Agency believes that prudent establishments will consider them carefully. FSIS recommends that establishments develop plans to implement OSHA's recommendations. FSIS expects establishments to adopt the OSHA recommendations discussed in this preamble and any other reasonable measures to minimize the risk of adverse health and safety effects to establishment employees. Establishments are reminded that Federal and State OSHA retain authority over assuring worker safety, and that OSHA will be paying close attention to poultry slaughter establishments, including those that elect to operate under the NPIS. FSIS recommends that establishments review OSHA's recordkeeping regulations at 29 CFR 1904, OSHA's General Industry Standards at 29 CFR 1910, and OSHA's Prevention of Musculoskeletal Injuries in Poultry Processing (*https://www.osha.gov/Publications/OSHA3213.pdf*).

In addition to the recommended actions to enhance surveillance for work-related injuries and illnesses, OSHA also recommended that establishments implement an employee injury and illness prevention program. FSIS and OSHA agree that injury and illness prevention programs may substantially reduce the number and severity of workplace injuries and alleviate the associated financial burdens on U.S. workplaces. Most successful injury and illness prevention programs are based on a common set of key elements, including management leadership, worker participation, hazard identification and assessment, hazard prevention and control, education and training, and program evaluation and improvement.[14] The Agency expects that a prudent establishment would have such a program in place. FSIS recommends that establishments that do not have existing employee illness and injury prevention programs adopt OSHA's recommendation and take the necessary actions to begin to implement such a program.

All poultry establishments are required to comply with applicable laws administered by other agencies, including the occupational safety statutes administered by OSHA. To stress the importance of establishment worker safety, FSIS has modified the proposed regulation that prescribes maximum line speed rates under the NPIS to emphasize establishments' existing legal obligation to comply with OSHA statutes. Thus, 9 CFR 381.69 now includes a new paragraph (d) that states that establishments operating under the line speed limits authorized in this section shall comply with all other applicable requirements of the law, including, but not limited to, 29 U.S.C. 654(a). Although this new paragraph is included in the regulation that prescribes line speeds for establishments operating under the NPIS, establishments operating under any inspection system also must continue to comply with all other applicable requirements of the law.

FSIS supports collaboration among industry, academia, and governmental bodies such as OSHA, NIOSH, and FSIS to identify causal relationships between workplace factors and musculoskeletal disorders (MSDs), and develop mitigation strategies that are technically and economically feasible. The NIOSH evaluation is a strong starting point for this effort, but additional work may be needed.

3. General Comments on Line Speed and Worker Safety

In the **Federal Register** document to extend the comment period on the proposed rule, FSIS requested comments on the effects of increased line speeds and production volume on worker safety (77 FR 24877). FSIS received many comments on this issue from worker and human rights advocacy organizations, poultry establishment employees, consumer advocacy

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[13] ''Small Plant News, Vol. 6, No. 3. Available on the Internet at: *http://www.fsis.usda.gov/wps/wcm/connect/1b75a216-fa3c-43fb-a5eb-7cc27ed942fa/Small_Plant_News_Vol6_No3.pdf?MOD=AJPERES.*

[14] OSHA [2013]. Prevention of Musculoskeletal Injuries in Poultry Processing. U.S. Department of Labor, Occupational Safety and Health Administration, OSHA 3213–09N; available at: *https://www.osha.gov/Publications/OSHA3213.pdf.*

OSHA [2012]. Injury and Illness Prevention Programs—White Paper. U.S. Department of Labor, Occupational Safety and Health Administration; available at: *http://www.osha.gov/dsg/InjuryIllnessPreventionProgramsWhitePaper.html.*

organizations, labor unions, public health associations, members of academia, companies that own poultry slaughter establishments, trade associations that represent the poultry industry, and private citizens. The vast majority of comments that the Agency received in response to the proposed rule were on this issue.

Many of the comments stated that FSIS should consult with NIOSH and OSHA on the final rule. Additionally, many of the comments submitted by workers and human rights advocacy organizations, immigrant advocacy organizations, consumer advocacy organizations, labor unions, public health associations, and members of academia said that FSIS should withdraw the proposed rule because of risks that the proposed increased maximum line speeds could potentially pose to the health and safety of thousands of poultry slaughter and processing workers. These comments said that if FSIS does not withdraw the rule, the Agency should at least withhold implementation until NIOSH completes a comprehensive study of the effect of production line speed on the health and safety of workers, and OSHA considers any implications for potential rulemaking.

Most of these comments referred to governmental reports, or research studies published in the occupational and public health literature. The most commonly cited sources included:

- The 2005 GAO report, which linked production line speed to occupational injury and illness rates in the slaughter industry and called for independent research to better understand this relationship;
- 2010 Bureau of Labor Statistics (BLS) data showing that injury rates were higher among poultry processing workers than the overall private industry average, and that more lost time, job transfers and restricted duty were incurred in the poultry industry than the overall private industry average;
- A study by the Wake Forest School of Medicine Center for Worker Health, which reported a 59% prevalence of carpal tunnel syndrome (CTS) symptoms among Latino workers at selected poultry plants in North Carolina operating under the existing inspection systems; and
- A 2007 study by researchers from the Duke University Medical Center's Division of Occupational and Environmental Medicine, which found that among low-income African-American women in rural North Carolina the prevalence of musculoskeletal symptoms of the upper extremities and neck was 2.4 times higher in those working at poultry plants compared to workers in other local industries.

Most commenters were concerned that an increase in production line speed would lead to increased rates of musculoskeletal disorders, other traumatic injuries, and potentially adverse health effects of psychological and emotional stress among industry workers, particularly in processing jobs involving highly repetitive knife use. These will be discussed below.

4. Inspection Line Speed, Processing Line Speed, and Production Volume

The 2005 GAO report recognized that the speed of the production line may be ''an important factor influencing (worker) safety and health.'' FSIS acknowledges NIOSH's finding of a strong relationship between risk factors, such as prolonged or repetitive hand activity, gripping force and exposure to cold, and MSDs including carpal tunnel syndrome (CTS) in the processing environment. Increasing line speed in processing, without changing other factors, could result in an increase of work pace for establishment employees, and increasing work pace among establishment employees, without taking appropriate mitigation actions, could increase risk of injuries and illnesses among establishment employees.

FSIS believes a key distinction should be made between processing line speed, inspection line speed, and daily production volume. The regulations require that establishments operate processing lines in a manner that maintains sanitary conditions and that will result in the production of poultry and poultry products that are not adulterated (9 CFR 381.65(a)). As the GAO report and many comments have pointed out, the poultry regulations limit the speed of poultry inspection lines to enable FSIS inspectors to effectively inspect each carcass presented to them. The current poultry regulations and this final rule do not prevent industry from running a processing line faster or slower than the inspection line. Slaughter establishments have always had the ability, at their discretion, to balance operating hours, staffing levels, and production line speed in processing departments to match the output of the inspection line. For example, an establishment could choose to operate its processing department at twice the speed of the inspection line, for half of the operating hours. Likewise, it could increase staffing in a processing department and slow the line speed proportionally to handle the volume of birds coming from the inspection line. These are operational and economic decisions made by each establishment, rather than a matter of FSIS regulations.

Slaughter establishments must make operational and economic decisions balancing staffing levels, production line speeds, and operating hours to accommodate daily production volume. While inspection line speed does influence daily production volume, establishments determine their own maximum production volume through the number of inspection lines they choose to operate.

We also note the difference between line speed and work pace. While work pace in processing departments is influenced by inspection line speed, factors such as staffing levels, plant layout, and product flow are more important predictors of work pace, as described in the following examples. FSIS does not directly regulate these factors.

For example, if a single inspection line feeds a single processing line (e.g., manual deboning), the work pace of processing workers will depend on the number of workers assigned to that line. If the birds from a single processing line are exiting the chiller at a maximum of 140 bpm, and if ten workers are assigned to that processing line, each worker will have an average work pace of 14 bpm. Adding an eleventh worker would reduce the work pace to an average of 12.7 bpm per worker. Additional staffing would reduce the workload proportionally.

If, under this same scenario, the establishment changes its layout to add a second identical processing line staffed with 10 additional workers, the work pace for each worker would decrease from 14 bpm to 7 bpm. These are just some examples of how factors other than line speed are more likely to affect work pace.

Industry employees' actual exposure to MSD risk factors, such as repetitive or prolonged hand activity, will be affected by the number of birds presented to each worker during a shift and the amount of time each bird is in position to be worked on. In the simplest model of an equal number of inspection and processing lines, it may be that inspection line speed will influence the maximum processing line speed. The Agency does not believe, however, that this model adequately represents the industry as a whole, where a single inspection line may feed multiple processing lines or different end products. Although the inspection line speed is a potential factor, economic factors (e.g., consumer

demand and staffing/equipment capacity) will ultimately determine the number of birds presented to each worker for processing during a shift. These economic factors are addressed by industry and not regulated by FSIS.

5. Factors Influencing Inspection Line Speed

Many comments seem to assume that the faster line speeds for poultry inspection included in the proposed rule (but not included in the final rule) that would necessarily have been authorized under the NPIS would result in a very large increase in the volume of poultry products being processed by workers. However, as discussed earlier, line speed is not directly equivalent to production work pace; inspection line speed does not directly impact plant employees in further stages of an establishment (e.g., on the processing line).

The proposed faster line speeds for inspection—not included in this final rule—would have allowed establishments to slaughter the birds more efficiently but would not necessarily have led to a substantial increase in processed output; consumer demand for poultry products determine the number of birds slaughtered rather than line speeds.

FSIS thinks that establishments choosing to operate under the NPIS will determine their line speeds based on the same factors that establishments considered when setting line speeds under HIMP.

6. Inspection Line Speed and Inspector Safety Under the NPIS

Comment: A labor union expressed concern about the potential effects to the online CI if the proposed faster maximum line speed that would have been authorized under the NPIS. The comment said that the purpose of the NIOSH study described in the proposed rule is to assess the effects of line speeds on establishment personnel. The comment stated that the faster line speeds that would have been permitted under the NPIS would also likely affect inspection personnel.

The comment noted that the NIOSH will study ''a maximum of five non-HIMP establishments that applied through the SIP to receive waivers of existing regulations restricting line speeds.'' The comment expressed concern that the NIOSH study is only intended to gather additional data of the effects of line speeds on the worker safety without saying how increased line speeds have the potential to cause unintended or foreseeable safety issues. The comment questioned how this plan to gather additional data will relate to ensuring FSIS online CIs are adequately protected, or how actual safety issues will be remedied. The comment said that before FSIS decides to implement the NPIS, it should make a serious, scientific inquiry into the potential dangers related to the online inspector's new position.

Response: Under the NPIS, establishment employees rather than online inspectors will be responsible for conducting sorting activities. Therefore, the online inspection procedures under the NPIS do not require that the CI touch or handle each carcass. Thus, because CIs will have infrequent contact with the carcasses, their inspection activities will involve less frequent head and hand motions than are conducted under the existing non-HIMP inspection systems. In addition, as discussed above, FSIS has revised the proposed facilities requirements for the online carcass inspection platform to require that the platform be height-adjustable to accommodate the individual CI. Based on recent studies published in the occupational health literature, FSIS believes the reduction in hand activity under the new inspection system will lead to a reduction in the risk of musculoskeletal disorders for inspection personnel.

7. Industry Efforts To Address Worker Safety

Comment: Some comments from trade associations agreed that worker safety must be considered when establishing line speeds, and stated that establishments do take worker safety into account. However, the comments maintained that worker safety should be addressed separately from food safety. The comments said the poultry industry has a strong record of working with OSHA to help in OSHA's efforts to protect the safety and health of employees, most recently with a formal OSHA Alliance from 2007–2009. The comments expressed support for working with the government and industry to maintain a strong safety record.

Response: FSIS will support effective industry efforts to protect the health and safety of employees. FSIS also supports industry collaboration with OSHA and NIOSH, and encourages the industry to work with OSHA to further protect the health and safety of employees. FSIS is willing to work with industry when it is appropriate and useful to do so to move collaborative efforts forward with OSHA.

Comment: Two trade associations representing the poultry industry stated that after 13 years of the HIMP pilot program, the data indicate that the rate of worker injuries in HIMP establishments has been on average at or below industry average rates. One comment said that, in many instances, turkey HIMP establishments have reported worker injury rates well below the already low industry average.

One comment stated that a recent survey of broiler establishments participating in the Agency's HIMP pilot shows that, for both Total Recordable Injury Rates and Days Away, Restricted, or Transferred (DART) Rates, HIMP establishments are as safe for workers as establishments that operate under non-HIMP inspection systems. According to the comment, there is no statistical difference between establishments involved in the HIMP pilot project and establishments that operate under non-HIMP inspection systems with respect to Total Recordable Injury Rates and DART Rates.

Response: The information provided in the comment suggests that worker injury rates in HIMP establishments may be at or below the worker injury rates in non-HIMP establishments. However, because the comment did not discuss the details on how the survey was conducted, the Agency is unable to assess the findings. As noted above, FSIS encourages the trade association and its members to work with OSHA on worker safety issues. It may be useful for the trade association to submit its survey and findings to OSHA, since OSHA has the expertise in evaluating this type of information regarding worker health and safety.

8. Reporting of Work-Related Injuries

Comment: Several comments said that although the data show that workers in the poultry slaughter and processing industry suffer adverse health and safety effects under the existing line speeds, studies indicate, and statements by poultry workers confirm, that the official injury statistics fail to accurately represent the extent to which worker injuries and musculoskeletal diseases and disorders affect workers in the poultry slaughter and processing industry.

The comments said that workers in the poultry industry are regularly discouraged by their employers from reporting work-related health conditions or seeking relief under the workers' compensation system. The comments also stated that workers do not report injuries for a variety of reasons, including concern about work hours, job security, and residency status in the United States. The comments added that injuries sustained by workers who are dismissed or resign during their initial

three month probationary period are also not reported. The comments noted that OSHA has recognized that there are problems related to the under reporting of work-related injuries and established a Special Emphasis Program on underreporting in 2009. According to the comments, OSHA identified poultry processing as a targeted industry under this program.

Response: OSHA is the appropriate agency to address issues associated with the reporting of worker injuries. As discussed above, OSHA has provided several recommendations that poultry slaughter establishments can implement to improve surveillance for worker injuries. FSIS strongly encourages establishments to adopt these recommendations.

FSIS recognizes that systematic underreporting of work-related injuries and illnesses could make it difficult to accurately assess the extent to which poultry workers suffer from work-related injuries and musculoskeletal diseases and disorders.

9. Attestation to FSIS on Work-Related Conditions

As discussed above, in both the proposed rule and the **Federal Register** document extending the comment period, FSIS acknowledged the potential for increased inspection line speed to affect the safety of establishment workers (77 FR 4423–4424 and 77 FR 2487). FSIS also ''recognize[d] that the evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety'' (77 FR at 4423). And as noted above, commenters raised concerns about the effects that increased line speeds might have on the health and safety of workers in poultry slaughter establishments.

Most of these comments expressed concern that workers subject to faster line speeds could suffer increased numbers of occupational injuries and illnesses, particularly musculoskeletal disorders (MSDs) such as carpal tunnel syndrome, and that potential negative effects on workers could also have an adverse effect on poultry safety. The comments specifically noted that MSDs could affect workers to the extent that they could not do their jobs properly, and also addressed the possibility of bacterial contamination between workers and poultry, exposure to other pathogens, and risk of laceration. Moreover, comments also expressed concern that poultry processors' injury and illness logs may not reflect the full extent of work-related conditions experienced by poultry workers. A number of commenters requested that FSIS either withdraw the proposal because of the increased risk of injury to workers, or at least delay implementation of a final rule until NIOSH, a part of the Centers for Disease Control and Prevention in the Department of Health and Human Services, completed a comprehensive study of the effect of line speed on worker safety and health.

As discussed above, in the proposed rule FSIS explained that it asked NIOSH to evaluate the effects of increased inspection line speeds on establishment worker safety by collecting data from establishments that had been granted waivers from line speed restrictions under the SIP (77 FR 4423–4425). NIOSH initiated such a study in one non-HIMP establishment that is operating under a waiver from line speed restrictions under SIP (77 FR 4423 and 77 FR 2487). NIOSH has completed its evaluation and made its final report available to the public in March 2014 (Evaluation of *Musculoskeletal Disorders and Traumatic Injuries Among Employees at a Poultry Processing Plant*; Report No. 2012–0125–3204, March 2014; available on the Internet at: *http://www.cdc.gov/niosh/hhe/reports/pdfs/2012-0125-3204.pdf*). The results from this study lend support to the concerns noted in the comments that poultry processors' injury and illness logs often do not reflect the full extent of work-related conditions experienced by poultry workers.

To address these concerns, FSIS is establishing a new subpart H ''Attestation on Work-Related Conditions.'' Subpart H includes an annual attestation requirement (9 CFR 381.45) and a severability clause (9 CFR 381.46). The attestation provision requires that each establishment that operates under the NPIS provide an annual attestation to the management member of the local FSIS circuit safety committee stating that the establishment maintains a program to monitor and document any work-related conditions that arise among establishment workers. The elements of this program include:

(1) Policies to encourage early reporting of symptoms of work-related injuries and illnesses, and assurance that the establishment has no policies or programs intended to discourage the reporting of injuries and illnesses.

(2) Notification to employees of the nature and early symptoms of occupational illnesses and injuries, in a manner and language that workers can understand, including by posting in a conspicuous place or places where notices to employees are customarily posted, a copy of the FSIS/OSHA poster encouraging reporting and describing reportable signs and symptoms.

(3) Monitoring on a regular and routine basis of injury and illness logs, as well as nurse or medical office logs, workers' compensation data, and any other injury or illness information available.

As discussed earlier in this document FSIS has decided to allow the 20 young chicken establishments that have been granted SIP waivers to operate under the HIMP inspection system to continue to operate under a SIP waiver to run at line speeds of up to 175 bpm. FSIS will also update these SIP waivers to remove aspects of HIMP that are inconsistent with the NPIS, such as the OCP performance standards. To ensure that the updated SIP waivers are consistent with the NPIS, the Agency will also require that establishments operating under the updated waivers submit the annual attestation discussed above as a condition of their waivers.

The severability clause states that should a court of competent jurisdiction hold any provision of part 381 to be invalid, such action shall not affect any other provision of part 381 (9 CFR 381.46).

As OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health, FSIS will forward the annual attestations to OSHA for further review. OSHA, in turn, may use the information in the attestations in its own enforcement program. FSIS employees will not be responsible for determining the merit of the content of each establishment's monitoring program or enforcement of noncompliance with this section. FSIS will work with OSHA to develop the poster that establishments must display providing information on the signs and symptoms of occupational injuries and illnesses experienced by poultry workers, and about workers' rights to report these conditions without fear of retaliation.

Consistent with the mandate of E.O. 12866, OSHA has advised FSIS that the development and implementation of such a monitoring program will enable establishments both to protect their workers and to identify illnesses and injuries. Prompt intervention will also reduce the costs associated with worker injury by enabling establishments to adjust their processes or implement other appropriate measures before additional employees are affected.

G. Changes That Affect All Establishments That Slaughter Poultry Other Than Ratites

In addition to proposing to establish the NPIS, FSIS also proposed changes to

the regulations that would apply to all establishments that slaughter poultry other than ratites. The Agency proposed that all poultry slaughter establishments develop, implement, and maintain written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller and that they incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs (77 FR 4426). The Agency also proposed to require that all poultry slaughter establishments develop, implement, and maintain, as part of their HACCP systems, 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 process, and that they maintain daily records sufficient to document the implementation and monitoring of those procedures (77 FR 4427). The Agency proposed that at a minimum, these procedures must include sampling and analysis for microbial organisms at the pre- and post-chill points in the process to monitor process control for enteric pathogens.

The proposed new requirements are designed to ensure that establishments incorporate process control measures to prevent contamination into their HACCP systems, and that they develop and maintain documentation to verify the effectiveness of their procedures on an ongoing basis. In the preamble to the proposed rule, the Agency explained that it would verify that establishments' procedures are effective by reviewing the establishment's monitoring records, including the establishment's microbiological testing results, observing the establishment implementing its procedures, and inspecting carcasses and parts for visible fecal contamination when performing both online carcass inspection and offline verification inspection (77 FR 4427).

Under the proposed rule, each establishment would be responsible for developing and implementing a microbiological sampling plan, which would be required to include carcass sampling at pre-chill and post-chill (77 FR 4428). The Agency also proposed to rescind the regulations that require that poultry establishments test for generic *E. coli* and to remove the codified *Salmonella* pathogen reduction standard for poultry. The proposed new microbiological sampling requirements would replace the generic *E. coli* testing regulations and would allow establishments to develop sampling plans that are more tailored, and thus more effective for monitoring their process control. FSIS would consider both the establishment's testing results, as well as the results of the Agency's testing Salmonella and Campylobacter performance standards, to assess how well the establishment is maintaining process control.

FSIS received several comments on these proposed new requirements.

1. Procedures and Recordkeeping Requirements for Preventing Contamination by Enteric Pathogens and Visible Fecal Contamination

Comment: A consumer advocacy organization and an individual expressed support for the proposed new requirement that all establishments that slaughter poultry develop, implement, and maintain, as part of their HACCP systems, written procedures to prevent carcass contamination throughout the entire slaughter and dressing process. The consumer advocacy organization also supported the proposal to require that all poultry slaughter establishments develop, implement, and maintain written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller, and incorporate these procedures into their HACCP systems. According to the comments, the proposed new requirements address a weakness of the current poultry inspection system, which is that verification checks performed at the end of the slaughter and chilling process encourage the industry to focus its activities on post-process interventions to reduce contamination rather than prevention throughout the slaughter process.

The comments also expressed support for the proposed requirement that establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for preventing contamination by enteric pathogens and fecal material. The comments noted that many establishments may have in place process control measures that attempt to address contamination by enteric pathogens and fecal material, but nothing currently requires that the establishments develop and maintain documentation to verify on an ongoing basis that these procedures are effective. The comments said that without this documentation, establishments can quickly lose process control or rely on procedures that contribute to an ongoing risk of contamination. The comments stated that the documentation proposed by the Agency will allow both the establishment and the Agency to identify points of weak process control, and can provide a roadmap for corrective action.

Response: FSIS agrees that requiring establishments to keep daily written records to document the implementation and monitoring of their process control procedures is a positive step forward for public health. This ongoing 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. This will allow the establishment to take the necessary corrective action to prevent further product contamination.

Comment: One trade association stated that it is unclear what additional steps will be required in regard to sanitary dressing. According to this trade association, all of its members already have significant sanitary procedures in place.

Response: As noted above, in the preamble to the proposed rule, FSIS acknowledged that many establishments have in place process control measures to address the prevention of contamination by enteric pathogens and fecal material, but that they are not maintaining documentation to verify the effectiveness of these procedures on an ongoing basis (77 FR 4427). Under this final rule, establishments will be required to incorporate these procedures into their HACCP systems, and to maintain ongoing documentation to demonstrate that the procedures are effective. As noted above, this ongoing 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.

2. Sampling and Testing Requirements To Monitor Process Control

a. Sampling Plan and Sampling Sites

Comment: Several consumer advocacy organizations and a member of academia disagreed with the Agency's proposal to allow each establishment to develop its own sampling plan. These comments argued that the sampling program needs to be standardized. According to one comment, in other countries, such as New Zealand, the government sets the testing frequencies and indicator pathogens for the industry.

One consumer advocacy organization argued that requiring all establishments to conduct testing for the same organisms, at the same frequency, and at the same locations along the production line will provide the Agency and

stakeholders with valuable data on the impacts of incremental changes in production on contamination levels both within a specific establishment and industry-wide. According to this comment, under the proposed rule, data analysis will be difficult for anyone (e.g., the Agency, inspectors, and establishment management) trying to study the data because of the variations in sampling at each establishment. Another consumer advocacy organization stated that a uniform sampling program can help identify additional steps that should be taken to address hazards, modernize the system, and ensure facilities are operating at line speeds that do not cause poultry contamination to rise.

Response: The purpose of the proposed new sampling requirement is to ensure that establishments monitor and evaluate the effectiveness of their procedures to prevent contamination of carcasses by enteric pathogens and visible fecal material on an ongoing basis. It is not intended to generate data to compare establishment performance across the industry. The data that FSIS collects from its *Salmonella* and *Campylobacter* sampling programs serves that purpose. Because establishments have differences in their operations, FSIS believes that each establishment should have the flexibility to develop a sampling plan that will accurately monitor the effectiveness of its process control procedures while holding the establishment accountable through the Salmonella and Campylobacter performance standards. As discussed below, the Agency is prescribing a minimum frequency with which all poultry establishments will need to collect samples.

FSIS will scrutinize an establishment's monitoring records, including its microbial testing results, to verify the effectiveness of the establishment's process control procedures. The Agency will continue to assess and compare establishment performance across the industry through the Agency's sampling program for *Salmonella* and *Campylobacter.* Under this program, the samples are collected by FSIS inspectors and analyzed by FSIS laboratories, ensuring that the sampling and testing program is consistent, and that the Agency is able to compare establishment performance and industry trends over time.

Comment: Several trade associations and an industry member stated that, instead of requiring sampling at pre- and post-chill, FSIS should allow establishments the flexibility to select the number and sampling sites for their individual operations to demonstrate process control. These comments argued that each establishment is different and that sampling programs must be scientifically based and statistically valid and are most effective when they are establishment specific. According to these comments, sampling in one location could demonstrate process control in one establishment because of certain interventions, but sampling in two locations may be more appropriate to demonstrate process control in another establishment. One trade association believed that providing flexibility in sampling is consistent with HACCP principles, encourages industry innovations in operations and processing, and enables processors to develop new methods for demonstrating process control through sampling.

Response: As stated in the preamble to the proposed rule, FSIS believes that microbiological test results that represent levels of microbiological contamination at key steps in the slaughter process are necessary for establishments to provide comprehensive, objective evidence to demonstrate that they are effectively maintaining process control to prevent carcasses from becoming contaminated before and after they enter the chiller (77 FR 4427). Process control in the context of poultry slaughter consists of the programs and procedures an establishment implements to ensure its processes are operating as intended in preventing contamination (including contamination with microbial pathogens and fecal material) of poultry carcasses and parts throughout the slaughter and dressing process and to ensure that the resulting products meet applicable regulatory standards or definitions. Establishments must demonstrate that their process is in control by implementing verification procedures, collecting data, and developing and maintaining accurate records to demonstrate that their processes and procedures are performing as intended and as required.

An effective process control system entails an establishment responding effectively to re-establish control when its ongoing verification activities show that its processes or procedures are not producing the expected results. Effective process control procedures should lead to lower rates of pathogen contamination because establishments will discover deficiencies in processing sooner and more reliably than would be the case without effective process control procedures.

FSIS considers the microbial characteristics of poultry carcasses at pre-chill to be a valuable source of data about how well an establishment is minimizing contamination with fecal material and enteric pathogens on live birds coming to slaughter and on carcasses throughout the evisceration and dressing process. FSIS considers the microbial characteristics of poultry carcasses post-chill to be a valuable source of data about how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions the establishment has chosen to apply throughout its process. Because most establishments apply one or more antimicrobial interventions between the pre- and post-chill sampling points to help control microbiological hazards, FSIS would expect that a reduction in microbiological contamination between these two points to be an indication of the effectiveness of those controls.

Therefore, FSIS is finalizing the proposed requirements that establishments collect samples for microbial analysis at the pre- and post-chill locations to monitor for process control, with an exception for very small and very low volume establishments operating under the Traditional Inspection System. This exception is described below.

Comment: One trade association noted that if the Agency requires sampling pre- and post-chill, the Agency needs to clarify that establishments have the flexibility to select the sampling locations where testing would occur before and after chilling. This comment also argued that the Agency should not require a third sampling location at re-hang because it would be overly prescriptive, burdensome, and would not further food safety.

Response: Under this final rule, establishments will need to collect pre-chill samples before the chiller at the end of the evisceration process. The pre-chill testing is intended to monitor the effectiveness of all process controls up to the point of the chiller. An establishment will need to collect post-chill testing after it has completed all interventions, which is the same point in the process that FSIS collects samples for *Salmonella* and *Campylobacter* verification testing.

As stated in the preamble to the proposed rule, FSIS had considered requiring a third verification test at the re-hang position to monitor the incoming load of pathogens but the Agency concluded that it was not necessary to impose the additional costs that would be associated with testing at this point (77 FR 4428).

Comment: A consumer advocacy organization argued that allowing each establishment to use different tests with different indicator organisms and standards for verifying that their process controls are effective will create problems for inspectors. According to the comment, FSIS inspectors will have to determine on a case-by-case basis whether each test chosen is validated for that purpose and whether the standard used by the establishment is adequate. This comment stated that determining whether a HACCP plan is effective would be more complex for inspectors, whereas the current generic *E. coli* testing program that FSIS proposed to rescind provides an objective test and standard which are familiar to FSIS and industry.

Response: As stated in the preamble to the proposed rule, because an establishment's microbiological sampling plan will be part of its HACCP system, each establishment will be required to provide scientific or technical documentation to support the judgments made in designing its sampling plan (77 FR 4428). FSIS inspection personnel will verify the effectiveness of the establishment's sampling plan by reviewing the supporting documentation and verifying that the establishment is implementing its sampling plan as designed. These procedures are consistent with the methodology that inspectors use to verify the effectiveness of other measures incorporated into an establishment's HACCP system. In addition, FSIS intends to provide training to its inspectors and guidance to industry on all of the new requirements under this final rule, including the new sampling plans. The Agency's inspection personnel will be prepared to carry out their responsibilities to ensure the effectiveness of establishments HACCP systems, including the new sampling requirements, when this final rule becomes effective.

b. Very Small and Very Low Volume Establishment Sampling

Comment: A State Department of Agriculture said that there should be two sampling locations for all establishments, but that the sampling frequency should be scale-dependent, e.g., the frequency should be decreased for very small establishments. The comment noted that it is just as important in a very small establishment as a large one to maintain and document process control, but very small establishments will have proportionally more difficulty than large establishments in absorbing the costs for a second sampling location.

One industry member stated that sampling at small and very small establishments should be the same as at all other establishments. This industry member believed that the specific processes and programs in place, not the size of the establishment or the volume of production, should determine how process control is demonstrated.

Response: In the preamble to the proposed rule, FSIS noted that small and very small low volume establishments that choose to operate under the revised Traditional Inspection System may not need to conduct testing for microbial organisms at two points in the slaughter process to adequately monitor process control (77 FR 4428). These establishments typically are less automated and run at slower line speeds than larger establishments operating under SIS, NELS, and NTIS. The lower level of automation and the slower line speeds require less complicated measures for maintaining and monitoring process control on an ongoing basis. Therefore, after considering this issue, FSIS has decided to revise the proposed rule to allow very small and very low volume establishments that operate under the modified Traditional Inspection System to collect and analyze samples for microbial organisms at the post-chill point in the process only. As stated in the preamble to the proposed rule, very low volume establishments would include those classified as very low volume establishments under the existing generic *E. coli* testing regulations (77 FR 4428). To make this clear, the Agency is establishing a codified definition for very low volume establishments that is based on the existing very low volume establishments definition under 9 CFR 381.94(2)(v), i.e., establishments that annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

Under this rule, if FSIS has evidence to indicate that a very small or very low volume establishment conducting sampling at a single point in the process is not maintaining process control, such as not meeting FSIS's pathogen performance standards, the establishment will need to conduct additional testing or implement additional measures to ensure that its process remains in control.

c. Sampling Frequency

Comment: Several consumer advocacy organizations requested that FSIS explain how it developed the estimates on how frequently establishments will conduct testing to monitor their process control procedures. The comments noted that FSIS estimated that large establishments will perform the prescribed tests 15 times a day, small establishments 7 times a day, and very small establishments 3 times a day. One of the consumer advocacy organizations asked that the Agency explain the justification for the presumed sample size. The comment stated that by providing clarification on the source of these estimates, stakeholders can better ascertain whether they represent a reasonable estimate of testing frequency.

Response: The estimates on how frequently establishments will conduct sampling under the proposed rule are from the proposed rule's Paperwork Reduction Act paperwork burden estimates. These estimates were based on the frequency with which establishments operating under a SIP waiver conduct sampling. Under SIP, FSIS grants establishments a waiver of regulations under the condition that the establishment collects and analyzes samples for microbial organisms and shares the results with FSIS. As discussed below, FSIS is revising the proposed rule to prescribe a minimum frequency with which all establishments that slaughter poultry will need to conduct testing for microbial organism to monitor their process control procedures. Thus, FSIS has updated its paperwork burden estimates to reflect these changes.

Comment: Several consumer advocacy organizations and a member of academia asserted that FSIS needs to prescribe the frequency with which establishments must conduct sampling. One consumer advocacy organization stated that establishments need to collect samples at a specified frequency to evaluate whether any changes implemented by the establishment as a result of the proposed rule have positive or negative effects on rates of contamination. A consumer advocacy organization argued that FSIS needs to require a specific testing frequency per line and per shift to ensure that establishments achieve sufficient testing for pathogens. Another consumer advocacy organization suggested that FSIS require testing frequency per production day based on production volume. One comment expressed concern that poultry establishments have little incentive to incur costs to test beyond a very minimum frequency that may not be sufficient to monitor process control.

One trade association stated that FSIS should not remove the generic *E. coli*

testing regulation because it includes 9 CFR 381.94(a)(2)(v), which establishes definitions for very low volume establishments and provides sampling frequencies for very low volume establishments. This trade association asserted that specific testing frequencies for very low volume establishments should remain in the regulations.

Several trade associations stated that FSIS should not prescribe how often establishments must collect samples for testing. These trade associations supported the flexibility in sampling frequency because they believed sampling should be specific to an individual establishment's programs and processes.

Response: After considering the comments from the consumer advocacy organizations, FSIS believes that there is merit to requiring a minimum frequency of testing to ensure that establishments will be able to detect changes in processing or inconsistencies that may occur. FSIS expects that for their sampling plans, most establishments will adopt sampling frequencies that are similar to what is required under the existing generic *E. coli* testing regulations because sampling less frequently may affect the establishment's ability to detect problems with their process controls in a timely manner. However, as indicated by some of the comments, there is some concern that some establishments may attempt to reduce sampling to a very low frequency. While a very low testing frequency may be sufficient if the establishment is able to consistently maintain process control, it could also decrease the establishment's ability to detect changes or inconsistencies in processing that may occur.

Therefore, to address concerns about minimal sampling frequencies expressed by the consumer advocacy organizations, FSIS is revising the proposed sampling requirements to prescribe a minimum frequency with which establishments will be required to collect a pair of samples, one at pre-chill and one at post-chill, or, for very small and very low volume establishments that operate under Traditional Inspection, a single post-chill sample. Under this final rule, establishments will be required to collect samples at a frequency of once per 22,000 processed carcasses for chickens and once per 3,000 processed carcasses for turkeys, ducks, geese, guineas, and squabs. These frequencies reflect the frequencies prescribed under the existing regulations for generic *E. coli* testing.

Under the existing generic *E. coli* testing regulations, very low volume establishments that slaughter turkeys, ducks, geese, guineas, squabs, or ratites in the largest number must collect at least one sample during each week of operation each year but may stop sampling after 13 samples have been collected (9 CFR 381.94(a)(2)(v)). This final rule includes a similar provision that will apply to very low volume establishments to minimize the additional sampling costs to these establishments, many of which are also small or very small establishments. Thus, under this rule, if, after consecutively collecting 13 weekly samples, a very low volume establishment demonstrates that it is effectively maintaining process control, FSIS will allow it to modify its sampling plan. For example, after collecting 13 weekly samples, a very low volume establishment could collect samples less frequently, such as once a month, and use visual observation and documentation at control points to monitor process control. FSIS will provide guidance to very low volume establishments in developing alternative sampling plans and establish criteria, e.g., lower limit (m) and upper limit (M) values for test results, that will allow them to effectively monitor process control.

Because ratites were not subject to the proposed rule, establishments that slaughter ratites will continue to follow the generic *E. coli* testing regulations in 9 CFR 381.94(a). These regulations have been revised to remove all other poultry classes.

As noted in the preamble to the proposed rule, the frequency with which establishments will need to conduct testing to monitor for process control will depend on a number of factors, including their production volume, the source of their flocks, their slaughter and dressing processes, and the consistency of their microbial test results (77 FR 4428). Therefore, the prescribed minimum sampling frequencies may not necessarily be appropriate for every establishment to monitor process control. Some establishment may need to sample more frequently to effectively monitor process control. Because the testing frequency will be an integral part of an establishment's HACCP system verification procedures, establishments will need to collect and maintain data to demonstrate that their testing frequency is adequate to verify the effectiveness of their process control procedures.

Comment: Several trade associations stated that the source of flocks should not be a factor in determining the frequency of establishment testing. According to some of the comments, interventions at establishments ensure that only unadulterated product leaves the establishment, no matter where poultry is raised. One trade association added that the best methods of controlling *Salmonella* occur in the establishments, not on the farm. This trade association stated that the decontamination process during slaughter has allowed the industry to reduce its carcass swab incidence of *Salmonella* to less than 1.75 percent. Additionally, this comment noted that during a September 23, 2011, meeting, USDA's NACMPI rejected efforts to tie flock source to process control because adequate science doesn't currently exist to support such a relationship.

Additionally, one trade association believed that production volume and slaughter and dressing processes should not be factors in determining sampling frequencies. This comment argued that the manner with which establishments demonstrate process control does not vary with the operations being conducted. Several trade associations stated that sampling frequency depends on an establishment's total food safety system, not variables like volume or flock source that are already accounted for.

Response: The proposed rule did not prescribe specific factors that establishments would need to consider when developing their microbiological sampling plans. However, because establishments are required to incorporate their sampling plans into their HACCP systems, they will be required to provide scientific or technical documentation to support the judgments made in designing their sampling plans. In the preamble to the proposed rule, the Agency stated that the frequency with which establishments will need to collect samples for analysis will depend on a number of factors, including, among other factors, their production volume, and source of their flocks. As noted above, even though the Agency is establishing a minimum testing frequency for establishments to monitor process control, establishments will be required to consider any factors that are relevant to their production process to determine the sampling frequency that will be effective for their operation to meet regulatory requirements.

FSIS is not requiring that establishments address specific factors, such as flock source, to determine sampling frequency. However, because establishments are required to incorporate their sampling programs into their HACCP systems, they will need to provide scientific support for

the decisions made in determining the sampling frequency.

d. Indicator Organisms and Baseline

Comment: Several consumer advocacy organizations argued that instead of allowing establishments to choose which organism to test for, FSIS should require that establishments test for *Salmonella* and *Campylobacter.* The comments said that these are the two pathogens of greatest public health concern in the products affected by the proposed rule and together account for nearly half of all poultry-related outbreaks in the United States. One comment added that establishments could still test for additional pathogens or indicator organisms as warranted. One member of academia suggested that rapid testing be used for *Salmonella* at pre- and post-chill testing locations, rather than an indicator organism such as generic *E. coli,* because *Salmonella* is the leading cause of bacterial foodborne disease.

Response: As discussed above, the purpose of the proposed new testing requirements is to ensure that establishments are effectively monitoring process control on an ongoing basis. FSIS has determined that this can be achieved by sampling pre- and post-chill for enteric pathogens, such as *Salmonella* and *Campylobacter,* or for an appropriate indicator organism. The comments did not include any data to cause FSIS to question this conclusion.

As discussed above, to effectively monitor their process control procedures, establishments will need to conduct testing at a frequency that is sufficient to detect a loss of process control soon after it occurs so that they can take the necessary corrective actions to prevent further product contamination. Because the percentage of carcasses that are expected to show positive test results for *Salmonella* and *Campylobacter* is small when compared with the percentage of carcasses that are expected to show positive results for indicator organisms, establishments would need to analyze a large number of samples for *Salmonella* or *Campylobacter* to detect a loss of control, much larger than when using an appropriate indicator organism, everything else being equal. The cost to analyze samples for *Salmonella* and *Campylobacter* is much greater than that to analyze for indicator organisms.[15] Thus, the costs to effectively monitor a process using *Salmonella* and *Campylobacter* measurements would likely be considerably more expensive than the costs to monitor the process using measurements of levels of indicator organisms. FSIS has concluded that such costs would not be justifiable when measurements of indicator organisms are as effective for monitoring process control as measurements of pathogens.[16] [17] [18]

Comment: Several consumer advocacy organizations and a member of academia recommended that FSIS require that establishments conduct testing for a specific period of time that can be statistically justified to provide baseline testing data before the Agency moves forward with any changes to its poultry slaughter inspection program. One of the comments added that the baseline testing data will allow FSIS and the establishment to determine how changes to the poultry slaughter system impact pathogen rates at the establishment. Another comment stated that FSIS should require the continuous generation of baseline data for a period of at least 90 days prior to implementing other substantive changes to the poultry inspection system.

Response: FSIS is requiring that establishments collect and analyze samples for microbial organisms to monitor the effectiveness of their process control procedures. As noted above, establishments will be responsible for determining which microbiological organisms will best help them to monitor the effectiveness of their process controls. The establishment's baseline for its sampling plan will depend on the organism that it selects. Establishments that choose to collect and analyze samples for indicator microbial organisms rather than pathogens, such as *Salmonella* and *Campylobacter,* will be responsible for developing their own baseline for these organisms because the Agency is not establishing performance standards for indicator organisms. Of course, some establishments may already have data that they can use to develop a baseline. For those that do not, the length of time an establishment will need to develop a baseline will depend on several factors, including the volume of birds it slaughters, the number of lines, and the number of sources from which the establishment receives birds.

Establishments must have developed their sampling plans before the effective dates established in this final rule. The sampling plan must be made part of the establishment's HACCP system, and as such, the establishment is required to provide scientific or technical documentation to support the effectiveness of its sampling plan, which may include the development of an appropriate baseline to allow them to detect changes or inconsistencies in microbial levels that may occur during the slaughter and evisceration process.

3. Rescind Testing for Generic E. coli for Establishments That Slaughter Poultry Other Than Ratites

In the proposed rule, FSIS explained that it was proposing to rescind the generic *E. coli* testing requirements in 9 CFR 381.94 and replace them with a new testing requirement that allow establishments to sample for other, potentially more useful indicator organisms. The new testing requirements were discussed above. FSIS received some comments on this aspect of the proposed rule (77 FR 4428).

Comment: Comments from a consumer advocacy organization and a member of academia said FSIS should not rescind the existing regulations that prescribe testing for generic *E. coli.* A consumer advocacy organization said that rescinding this regulation will remove performance standards as a regulatory matter, expose consumers to greater risks from contaminated poultry, and reduce options for enforcement. One member of academia also stated that given that USDA studies have shown that *E. coli* can serve as a reservoir or source of transferable genetic determinants for antimicrobial resistance in foodborne pathogens, testing for generic *E. coli* should not be rescinded.

A consumer advocacy organization presented various arguments that, according to the organization, show that FSIS did not adequately support its decision to rescind the generic *E. coli* sampling requirements. First the comment asserted that FSIS inappropriately relied on a 2004 report of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as a basis for rescinding the rule. Second, the comment argued that

[15] Laboratory cost for analyzing for *Salmonella* and *Campylobacter* could exceed $300 per sample though we expect costs would vary, and could be less, depending upon number of tests and laboratory availability. The costs of analyzing these pathogens we expect to be more than 10-fold greater than the costs for analyzing for indicator organisms.

[16] Altekruse, S.F., Berrang, M.E., Marks, H., Patel, B., Shaw, W.K., Sani, P., Bennett, P.A., and Baily, J.S., 2009, Enumeration of Escherichia coli Cells on Chicken Carcasses as a Potential Measure of Microbial Process Control in a Random Selection of Slaughter Establishments in the United States, *Applied and Environmental Microbiology,* 75(9): 3522–3527.

[17] Berrang, M.E., Bailey, J.S., Altekruse, S.F., and Shaw, W.K., 2008, *J. Appl. Poultry Res* 17: 354–360.

[18] Habib, I., De Zutter, L, Van Huffel, X., Geeraerd, A.H., and Uyttendaele, M., 2012, Potential of Escherichia coli as a Surrogate Indicator for Postchill Broilers with High Campylobacter Counts, *Food Control* 25: 96–100.

the studies that FSIS referenced that indicate that the presence of generic *E. coli* on young chicken carcasses may be a result of infectious process or air saculitis, and do not provide a basis for rescinding the generic *E. coli* testing regulations. According to the comment, regardless of whether the source of contamination is fecal or an infected carcass, testing and performance standards are still relevant because detecting generic *E. coli* would be evidence of problems in the establishment's process controls.

Response: As discussed in the preamble to the proposed rule, the Agency's experience with the generic *E. coli* testing regulations has led the Agency to conclude that such testing may not be the most effective way for establishments to monitor the effectiveness of their process control procedures.

The existing generic *E. coli* performance criteria represent the distribution of measured generic *E. coli* results observed in FSIS's 1994 baseline survey of young chicken slaughter establishments. Since FSIS implemented the generic *E. coli* testing requirements, establishments have made changes to their processes that have led to further reductions in the detectable levels of generic *E. coli* on carcasses post-chill. The most recent young chicken baseline conducted from 2007–2008 shows that the levels of detectable generic *E. coli* on post-chill carcasses are well below the performance criteria in the existing regulations and that over 60 percent of the sample measurements had non-detectable levels of generic *E. coli.*

Data from FSIS's 2007–2008 Young Chicken Baseline survey show that there were 12 establishments from which 10 or more samples were analyzed during the survey and none with detectable levels of generic *E. coli.* FSIS analyzed 22 samples each in 2 of these establishments. All 44 samples had detectable Aerobic Plate Count (APC) measurements even though none had detectable generic *E. coli* measurements. Thus, for these establishments, it might be more efficient to use APC counts instead of generic *E. coli* counts to monitor for process control because a higher percentage of samples would be expected to have measurable APC levels even when generic *E. coli* levels are not detected.

In addition, FSIS used the most recent baseline survey of young chicken establishments to perform correlation analyses of pathogen presence and measured levels of indicator organisms on carcasses. The results indicate that measured APC levels at re-hang were more highly correlated with *Salmonella* presence at re-hang than were measured *E. coli* levels. Such results suggest that APC measurements might provide a better measure of process control.

Although the Agency has determined that the existing post-chill testing for generic *E. coli* may not be the most effective means for monitoring process control, establishments may sample for generic *E. coli* or any other indicator organism pre- and post-chill, or for very small and very low volume establishments operating under Traditional Inspection, post-chill only, if the establishment provides scientific or technical documentation to demonstrate that the use of a specific indicator organism is appropriate for monitoring the establishment's process control procedures.

4. Rescind Codified Salmonella Performance Standards

In the preamble to the proposed rule, FSIS explained that because it can effectively address pathogen reduction in poultry establishments through its new *Salmonella* and *Campylobacter* performance standards and the SIP, the Agency was proposing to rescind the codified *Salmonella* pathogen reduction performance standards in 9 CFR 381.94(b). The Agency also explained that, since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc.* v. *USDA,* the Agency's ability to directly enforce the codified *Salmonella* pathogen reduction performance standards has been limited. FSIS received several comments from consumer advocacy organizations on its decision to rescind the codified standards.

Comment: A consumer advocacy organization said that in developing the proposed rule, FSIS should have considered the alternative of retaining both the generic *E. coli* testing requirements and the codified *Salmonella* performance standards as a way to ensure that an establishment's processes are under control and its products meet a minimum level of sanitation. The comment said that FSIS should retain its ability to monitor end-products for fecal and microbial contamination through mandated testing and performance standards. The comment asserted that in rescinding the *E. coli* and *Salmonella* testing provisions and their associated performance standards, FSIS is removing a useful verification check.

Response: FSIS disagrees with the comments. The Agency does not believe that it needs to retain the existing codified generic *E. coli* performance criteria and the existing codified *Salmonella* performance standards to verify that establishments' processes are in control and that the products meet a minimum level of sanitation. The reasons the Agency is rescinding the generic *E. coli* testing requirements were discussed above. The new testing requirements will give establishments the flexibility to sample for other potentially more useful indicator organisms to monitor for process control.

As noted above, the Agency is rescinding the codified Salmonella performance standards because it can effectively address pathogen reduction in poultry establishments through its new *Salmonella* and *Campylobacter* performance standards and the SIP. FSIS will continue to collect verification samples and analyze them for *Salmonella* and *Campylobacter* and compare the results to the Agency's most recent performance standards for these pathogens. The Agency will also continue to post the names of establishments that fail to meet the new performance standards on the Agency's Web site and will continue to use an establishment's failures to meet the standard as a basis for conducting an in-depth evaluation of the establishment's food safety system.

Comment: Some comments disagreed with the Agency's proposal to rescind the codified *Salmonella* performance standards. The comments said that under the existing regulations, an establishment's consistent failure to comply with the *Salmonella* performance standards or take the corrective actions necessary to comply with the standards constitutes a failure to maintain sanitary conditions and to maintain an adequate HACCP plan. The comments said that the codified *Salmonella* performance standard is important because it informs poultry establishments of their responsibilities to control their processes and the consequences of repeated failures to do so.

The comments stated that rather than removing the codified performance standards, the Agency should instead focus on updating them. The comments noted that the Agency has developed new performance standards for *Salmonella* and *Campylobacter* in young chicken and turkey slaughter establishments. The comments suggested that the Agency replace the existing codified *Salmonella* performance standards with the new *Salmonella* and *Campylobacter* performance standards.

Response: One difficulty with establishing codified pathogen

reduction performance standards, as suggested by the comments, is that, although these standards may represent an appropriate level of pathogen reduction at the time they were established, over time, as establishments make adjustments to their processes to meet these standards, the standards may no longer be an effective means for accomplishing pathogen reduction. The Agency's codified *Salmonella* performance standards demonstrate the need for flexibility to update performance standards based on changes in baseline levels for the pathogens of concern.

As discussed in the preamble to the proposed rule, since 2001, after the ruling in *Supreme Beef Processors, Inc.* v. *USDA,* the Agency's ability to directly enforce the codified *Salmonella* pathogen reduction performance standards has been limited (77 FR 4412). Therefore, after the *Supreme Beef* ruling, the Agency began using *Salmonella* failures as a basis to conduct an in-depth evaluation of an establishment's food safety system. 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 chickens, FSIS initiated policies to reduce *Salmonella.* One of those initiatives was to create three establishment performance categories for *Salmonella* based on the codified performance standards. The new performance Category 1 represented the best performing establishments and was defined as not more than half the regulatory standard. Category 2 was set at more than half, but, did not exceeding the regulatory standard. Category 3 establishments exceeded the standard, and represented the worse performing establishments. FSIS began publishing the names of young chicken establishments in Category 2 and 3 in March 2008, and has continued to publish the names of establishments in Category 3 on or about the 15th of each month.

After it established the new *Salmonella* performance categories, FSIS completed new young chicken and turkey baselines in 2008 and 2009 respectively. In May 2010, the Agency announced that it had developed tightened performance standards for *Salmonella* and a new performance standard for *Campylobacter* for chilled carcasses in young chicken and turkey slaughter establishments based on the new baseline results. In March 2011, the Agency announced that it would implement the new standards starting in July 2011 and that when two sets per establishment are completed, the Agency will post the names of young chicken and turkey establishments that fail the new *Salmonella* standards, i.e., Category 3, on the Agency's Web site. The new, more stringent standards are used in place of the codified *Salmonella* performance standards.

H. Elimination of Time/Temperature Chilling Requirements

In the January 2012 proposed rule, FSIS proposed to replace the regulations that prescribe the specific time and temperature parameters needed to chill RTC poultry with a requirement that poultry slaughter establishments develop written procedures, and implement and maintain these procedures to control the levels and prevent the multiplication of spoilage organisms and pathogenic bacteria in the product after evisceration (77 FR 4430). Establishments would be required to incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. The Agency also proposed to define ''air chilling'' as the method of chilling raw poultry carcasses and parts exclusively with air. In the preamble to the proposal, the Agency explained that under the proposed definition, an antimicrobial 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. FSIS received comments on the proposed revision to its poultry chilling requirements as well as on the proposed definition of air chilling.

Comment: One comment supported the Agency's decision to permit establishments to develop and validate their own chilling processes while still retaining the current chilling processes as a validated safe harbor. The comment said that this approach was consistent with the Agency's policies favoring a scientifically based approach to food safety. The comment suggested that FSIS provide guidance on how establishments should validate new chilling processes to facilitate compliance and encourage innovative chilling processes. The comment also said that the Agency should also reiterate the safe harbor provisions in the final rule.

Response: As discussed in the proposed rule, establishments will be required to incorporate their procedures for chilling into their HACCP systems. Thus, establishments will need to validate their chilling procedures as prescribed in the HACCP validation regulations (9 CFR 417.4(a)). Under these regulations, establishments are required to: (1) Document the scientific or technical support for the judgments made in their chilling process and (2) repeatedly test the adequacy of their chilling process controls to demonstrate that their chilling process will perform as expected. As stated in the preamble to the proposed rule, FSIS will consider the existing time and temperature chilling regulations as safe harbors and will incorporate these requirements into compliance guidance on meeting the new chilling requirements.

Comment: Two labor unions commented that it is unsound for the Agency to eliminate time and temperature chilling requirements and replace them with a performance-based approach that permits establishments to develop their own validated chilling procedures. One of the labor unions said that because the proposed rule will allow poultry slaughter establishments to select any chilling technique they please, small and medium establishments may eviscerate 175 bpm now and worry about adequate chilling later. According to the comment, the proposal to eliminate the time and temperature requirements is an attempt by the Agency to accommodate those small and medium-sized slaughter establishments that cannot safely increase production to 175 bpm under the NPIS but that have no choice but to adopt the new system.

Response: The comments that suggest that the prescribed new chilling requirements will allow poultry slaughter establishments to increase line speeds before they have developed effective chilling procedures is incorrect. Under this final rule, establishments are required to develop, implement, and maintain validated chilling procedures that will effectively control the levels and prevent the multiplication of spoilage organisms and pathogenic bacteria before they may operate at any given line speed. In addition, the maximum line speed under the NPIS is 140 bpm and not 175 bpm, as was proposed.

FSIS also disagrees with the comment that the decision to amend the poultry chilling requirements is not a sound proposal. To the contrary, and as noted in the preamble to the proposal, FSIS has granted SIP waivers from the time and temperature regulations to six poultry slaughter establishments. The data collected from these establishments demonstrate that alternative chilling procedures can be as effective as the prescribed time and temperature requirements in controlling the levels and preventing the multiplication of spoilage organisms and pathogenic bacteria in the product after

evisceration. Under this rule, establishments will be required to incorporate procedures for chilling into their validated HACCP systems. These written procedures will include the conditions of use affecting carcass chilling and microbial multiplication identified by the establishment.

Comment: A trade association recommended that FSIS clarify the definition of air chilled poultry to accommodate reasonable applications of antimicrobials using small amounts of water. The comment said that these applications are not designed to affect cooling or moisture pick-up, but that a strict technical reading of the proposed rule might be interpreted to prohibit their use. The comment suggested that the Agency revise the air chilling definition to permit antimicrobial applications applied with water if the water is used for a short duration and does not materially contribute to the chilling process or result in a material amount of water pick-up. According to the comment, this change would align the proposal with industry practice currently permitted by the Agency.

A company that has created a combination air chilling system that begins with antimicrobial dips of birds at the end of the slaughter process requested that the Agency revise the proposed definitions of air chilling to make clear that poultry chilled using this process qualify as ''air chilled.''

The comment explained that under its chilling system, poultry carcasses are subject to an antimicrobial dip that lasts for 20–90 seconds at the end of the slaughter process and then are air chilled without any water or sprays. According to the company, the combination system results in no moisture pick-up when the entire process is viewed from start to finish, but there is an unavoidable reduction of product temperature because of the antimicrobial dip tanks prior to the start of air chilling. The company requested that FSIS permit the use of an ''air chilled'' claim for a process that begins with antimicrobial dips of limited duration immediately prior to air chilling, regardless of a reduction in product temperature because of the antimicrobial treatment, provided there is no pick-up of moisture for the entire process.

According to the company, antimicrobials are generally more effective if applied when the carcasses are warm, i.e., directly after evisceration and before chilling, and its combination system has been shown to reduce *Salmonella* and *Campylobacter.* The company argued that allowing products chilled with this combination system to bear an ''air chilled'' label will provide marketing benefits and encourage establishments to adopt this food safety innovation.

The company also stated that its combination system has been recognized as an air chill system by the European Union. According to the comment, if FSIS were to adopt the proposed ''air chilled'' definition, poultry chilled using the combination system would be allowed to be labeled as ''air chilled'' in the European Union but not in the United States because the system reduces the product temperature. The company stated the FSIS should allow establishments to choose when chilling begins, so that establishments could treat the antimicrobial dip tanks in a combination system as an intervention in the slaughter process, so that the chilling would begin after the intervention.

Alternatively, the company requested that FSIS revise proposed 9 CFR 381.66(e) to read ''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 antimicrobial intervention with water may be used provided its use does not result in any pick-up of water or moisture and the majority of the chilling time consists of chilling exclusively with air.''

Response: After carefully considering these comments, FSIS believes they have merit. Therefore, FSIS is revising the proposed definition of air chilling to read as follows:

''Air chilling is the method of chilling raw poultry carcasses and parts predominantly with air. An antimicrobial intervention may be applied with water at the beginning of the chilling process if its use does not result in any net pick-up of water or moisture during the chilling process. The initial antimicrobial intervention may result in some temperature reduction of the product only if the majority of temperature removal is accomplished exclusively by chilled air.''

FSIS believes the revised definition will allow change and innovation by industry, while still meeting the essential criteria for approval of the ''air-chilled'' labeling claim, i.e., that the majority of chilling is accomplished with air and the process does not result in any pick-up of water or moisture. By allowing an antimicrobial intervention to reduce to a non-material extent the product temperature, FSIS will provide more opportunities for industry to apply antimicrobial interventions without delaying the start of the chilling process. This may well provide industry with more options to develop and apply innovative antimicrobial interventions to improve the microbiological characteristics of poultry products by reducing the numbers of foodborne pathogens and spoilage organisms. By applying antimicrobial interventions at a temperature that results in partial chilling of the poultry products, industry may be able to make those interventions more effective, while also decreasing the overall time to chill the product.

FSIS has determined that this change in the definition of ''air chilling'' will not result in mislabeling or the misleading of consumers because it preserves the two essential characteristics that FSIS considers when reviewing ''air chilled'' labeling claims: (1) That the product does not gain moisture from the chilling process and (2) that the majority of the temperature reduction is done by chilled air.

I. Online Reprocessing

In the January 2012 proposed rule, FSIS proposed to permit poultry slaughter establishments to use approved online reprocessing antimicrobial systems and offline reprocessing antimicrobial agents including chlorinated water containing 20 ppm to 50 ppm available chlorine or other antimicrobial agents that have been approved as safe and suitable for reprocessing poultry (77 FR 4432). The Agency proposed to require that establishments address the use of online or offline reprocessing in their HACCP plans, or sanitation SOPs, or other prerequisite programs. FSIS received a few comments on these proposed new requirements.

Comment: Two trade associations expressed support for amending the regulations to permit the use of safe and suitable substances for both online and offline reprocessing, thereby eliminating the need for individualized waivers for the use of these technologies.

One trade association recommended that the Agency eliminate the distinction between online and offline reprocessing and instead require that establishments justify the appropriate use of safe and suitable antimicrobials in their HACCP plans. According to the comment, establishments already must validate their processes, including the antimicrobials used in reprocessing. The comment asserted that a formalistic FSIS distinction serves no meaningful purpose and may confuse issues and deter innovation. The comment said that limiting uses of certain antimicrobials to online or offline

reprocessing overlooks the fact that all poultry must meet the same standards. The comment said that relying on individual establishment validations would reflect a more scientifically sound approach. The comment said if FSIS has concerns about the appropriateness of particular antimicrobials for certain applications, the Agency can limit the conditions of use for the antimicrobial when listing the antimicrobial as safe and suitable for use in poultry products.

Response: FSIS is maintaining the distinction between online and offline reprocessing in this final rule because there are differences between the two processes that require separate regulatory requirements.

Establishments that use offline reprocessing remove the carcasses accidentally contaminated with digestive tract contents from the main slaughter line and reprocess them at a designated offline station in any manner that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. Establishments that reprocess carcasses online are permitted to leave the contaminated carcasses on the main slaughter line. The carcasses then proceed to an online reprocessing station where the contamination is removed by an approved antimicrobial agent that is applied to all carcasses on the line. The provisions in this final rule that permit poultry slaughter establishment to use approved online reprocessing antimicrobial systems and offline reprocessing antimicrobial agents do not affect the separate procedures used for offline or online reprocessing. Thus, this final rule maintains the distinction between the two processes.

Comment: A member of academia commented that issues related to online reprocessing are complex and suggested that instead of addressing online reprocessing provisions in this rulemaking, FSIS should provide for online reprocessing in a separate rulemaking. According to the comment, two problems arise from online reprocessing. The comment said that first, carcasses will be allowed to remain on the line despite visible fecal contamination, and second, that the use of online reprocessing antimicrobial agents requires that all carcasses be treated with unspecified antimicrobial agents whether contaminated or not. The comment asserted that the data on online reprocessing that FSIS described in the preamble to the proposed rule do not provide sufficient information to determine whether the process can meet sanitary standards. The comment said that, before FSIS finalizes the rule, it needs to ensure that establishments conduct more pilot testing under the supervision of disinterested parties.

Response: FSIS disagrees with the commenter. With respect to the comment that all carcasses will be treated with ''unspecified antimicrobial agents,'' as noted in the preamble to the proposed rule, before a new substance can be used as an online reprocessing agent, the Food and Drug Administration (FDA) will determine the safety of the substance for use in online reprocessing and FSIS will determine its suitability (77 FR 4433). Establishments opting to use online reprocessing will 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. 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.*''

FSIS also disagrees with the comment that the data on online reprocessing do not provide sufficient information to determine whether the process can meet sanitary standards. As discussed in the preamble to the proposed rule, when FSIS published the proposed rule, 144 poultry slaughter establishments were operating under waivers that allowed them to use online systems to reprocess carcasses accidentally contaminated with digestive tract contents (77 FR 4432). The data generated from the in-plant trials conducted under these waivers show that various online antimicrobial treatments have differing but equally effective results with respect to pathogen reduction. Thus, FSIS disagrees that it needs to ensure that establishments conduct more pilot testing on online reprocessing before the Agency finalizes the proposed rule. There are extensive data available to show that the use online reprocessing systems is an effective method for removing digestive tract contents from accidentally contaminated carcasses and that the process meets sanitary standards.

J. Animal Welfare Considerations

FSIS received thousands of comments from private citizens and comment letters from animal welfare advocacy organizations that expressed concerns about the potential impact that the NPIS may have on the welfare of the live birds at slaughter. These comments raised several issues related to the handling of live birds under the NPIS.

1. Welfare of Live Birds

Comment: Several animal welfare organizations stated that FSIS did not adequately consider the impact that the NPIS will have on animal welfare. The comments expressed concern that the NPIS would negatively impact the welfare of birds. Numerous individuals and several animal welfare organizations expressed their view that the NPIS is inconsistent with FSIS's policy that ''considers humane methods of handling animals and humane slaughter operations a high priority,'' and it would undermine the Agency's food safety and humane slaughter policies.

Response: FSIS regulations require that establishments slaughter poultry in accordance with good commercial practices in a manner that results in thorough bleeding of the poultry carcasses and that ensures that breathing has stopped before scalding so that the birds do not drown (9 CFR 381.65(b)). In September 2005, the Agency published a **Federal Register** notice to explain that poultry products are more likely to be adulterated if, among other circumstances, they are produced from birds that have not been treated humanely because such birds are more likely to be bruised or to die other than by slaughter (70 FR 56624). The PPIA (21 U.S.C. 453(g)(5)), as well as the regulations (9 CFR 381.90), provide that carcasses of poultry showing evidence of having died from causes other than slaughter are considered adulterated and condemned. The Agency did not propose changes to these regulations and this final rule maintains these requirements without change. Establishments operating under the NPIS will absolutely be required to comply with these requirements. FSIS does not have a basis to believe the NPIS will negatively impact bird welfare and does not expect the new system to do so. Nonetheless, FSIS does consider humane handling and good commercial practices to be a high priority and will continue to be diligent in enforcing these requirements.

2. Line Speed and Animal Welfare

Comment: Approximately 1,000 individuals and several animal welfare organizations said that the proposed increase in maximum slaughter line speeds under the proposed rule would adversely impact humane handling of poultry. Many examples were suggested by individuals and animal welfare organizations of ways in which these adverse impacts could potentially occur.

These encompass concerns about potential workers frustrations over faster line speed and taking these frustrations out on the birds, potential increased injuries that may occur from shackling birds at faster line speeds, potential injuries from birds vigorously flapping their wings while in shackles, and the potential for ineffective stunning and throat cutting at faster line speeds.

Response: As discussed above, under this final rule, the maximum line speed permitted under the NPIS will be 140 bpm for young chickens rather than 175 bpm, as was proposed. Thus, the maximum line speed for the NPIS will be no faster than the maximum line speed permitted under the existing inspection systems under SIS.

As the Agency explained in the previous response, under the NPIS, establishments are now and will continue to be required to slaughter poultry in accordance with good commercial practices, in a manner that results in thorough bleeding of the poultry carcasses and ensures that breathing has stopped before scalding (9 CFR 381.65(b)). FSIS also considers poultry carcasses showing evidence of having died from causes other than slaughter to be adulterated and as such must be condemned (21 U.S.C. 453(g)(5) and 9 CFR 381.90). For example, poultry that are still breathing on entering the scalder die from drowning not from slaughter and are, therefore, considered adulterated and unfit for human food. Establishments operating under the NPIS will be subject to these requirements regardless of an establishment's specific line speed. If an establishment fails to meet these requirements, it will have to adjust its operations to ensure that is does meet these requirements. For example, some establishments may reduce line speeds, others may station additional employees in the receiving-to-pre-scald areas to ensure compliance.

Further, FSIS believes that employing humane methods of handling and slaughtering that are consistent with good commercial practices increases the likelihood of producing unadulterated product. In addition, if an establishment chooses the NPIS, FSIS inspection resources will be allocated to more offline food safety-related inspection activities, including verification tasks to systematically observe the conditions in the receiving to pre-scald area. When verifying good commercial practices in this area, offline inspection personnel observe whether establishment employees are mistreating birds or handling them in a way that will cause death, injury, prevent thorough bleeding, or result in excessive bruising. Offline inspection personnel also verify that the birds are stunned before being bled and determine whether there is other evidence that birds died other than by slaughter. If offline inspection personnel observe that the establishment is not following good commercial practices, they will take appropriate enforcement action and require corrective and remedial measures.

3. Animal Welfare and the Reduction in Number of Online FSIS Inspectors

Comment: Many individuals, several animal welfare organizations, and a consumer advocacy organization commented that a reduction in the number of online FSIS inspectors will harm animal welfare because FSIS inspectors will have less of an opportunity to observe and address inhumane handling. The comments expressed concern that current duties regarding handling and treatment of birds will not be adequately performed under the NPIS because there will be fewer FSIS inspectors. One consumer advocacy organization asserted that industry may also have less incentive to prevent injury to animals because of the Agency's new approach to OCP defects.

Response: Under this final rule, the NPIS will become one of the poultry inspection systems. FSIS disagrees that decreasing the number of online FSIS inspectors under the NPIS will harm animal welfare or impair its ability to carry out its human handling work effectively. As with HIMP, VIs under the NPIS will conduct food safety related inspection activities, including verification tasks to systematically observe the conditions in the receiving to pre-scald area, and will continuously monitor and evaluate establishment process control. For example, FSIS offline VIs will be verifying that establishments are following good commercial practices and will be checking for mistreatment or improper handling of birds. If inspection personnel observe that the establishment is not following good commercial practices, they will take appropriate enforcement action. If an establishment's line speed is seen as a cause of failure to follow good commercial practices, or if food safety related or non-food safety related conditions impair the online CI's ability to conduct the inspection of each carcass, the IIC will take appropriate remedial action and will be authorized to require that the establishment slow the line speed.

K. Environmental Impact

In the preamble to the proposed rule, FSIS explained that each USDA agency is required to comply with 7 CFR part 1b of the USDA regulations, which supplement the National Environmental Policy Act (NEPA) regulations (77 FR 4451). Under 7 CFR part 1b, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect. FSIS is among the agencies categorically excluded from the preparation of an EA or EIS. In the preamble to the proposed rule, FSIS explained that the Agency determined that the proposed rule was subject to the categorical exclusion from the preparation of an EA or EIS because the proposed rule will not have individual or cumulative effects on the human environment. FSIS received a few comments on the categorical exclusion.

Comment: Comments from an animal welfare advocacy organization and a consumer advocacy organization asserted that FSIS did not adequately analyze the environmental impacts of the proposed rule and therefore, did not meet the burden to show that the proposed rule is appropriately subject to the NEPA categorical exclusion. According to the comments, the proposed increase in line speeds that would have been permitted under the NPIS would allow establishments to slaughter more birds, thereby increasing demand on water supplies, truck traffic and carbon emissions from the transportation for each facility, and consumption of electricity to run each facility. The comments also asserted that an increase in birds slaughtered will result in an increase in condemned and inedible carcasses and parts that will need to be disposed of.

Response: As discussed above, under this final rule the maximum line speed permitted under the NPIS will be 140 bpm for young chickens rather than 175 bpm, as was proposed. Thus, the maximum line speed for the NPIS will be no faster than the maximum line speed permitted under the existing inspection systems under SIS. While the NPIS may give establishments the flexibility to slaughter and process birds more efficiently, consumer demand for poultry products will determine the number of birds slaughtered rather than line speeds. Thus, this final rule will not have a significant individual or cumulative effect on the human environment.

Comment: Some comments said that the provision in the proposed rule that permits establishments to use online and offline antimicrobial systems to reprocess contaminated carcasses will increase the discharge of antimicrobial chemicals into the water supply. The comments stated that one such substance, trisodium phosphate (TSP), can cause high levels of phosphorus in water and cause algae blooms. The comment noted that in the proposed rule, FSIS stated that only 5 to 7 of the 144 facilities with online reprocessing systems use TSP, and that the water is recycled and does not enter public water supplies. The comment said that the proposed rule did not account for whether there will be a foreseeable increase in facilities using online reprocessing systems that use TSP as a result of the proposed rule and what they will do with their TSP-laden water.

A comment from a member of academia agreed with FSIS's conclusion that the proposed rule was appropriately subject to a categorical exclusion from the preparation of an EA or EIS. The comment noted that although TSP may affect the aquatic environment, establishments that use this substance for online reprocessing are required to meet all local, State, and Federal environmental requirements. The comment said that water from slaughter facilities is treated appropriately and should continue to be treated appropriate within waste water treatment facilities.

Response: FSIS considered the potential environmental effects of the provision in this rule that will permit poultry slaughter establishments to use approved online reprocessing antimicrobial systems. As noted by the comment, TSP is used in a few online reprocessing antimicrobial systems. However, regardless of the substances that an establishment uses in its online reprocessing system, it is required to meet all local, State, and Federal environmental requirements. The waste water from all poultry establishments is handled routinely by existing water treatment systems or recycled as by-product without entering the establishment's water system, municipal water system, or ground water.

L. Economic Impact

1. General

Comment: One consumer advocacy organization stated that under the NPIS, FSIS would have authorized establishments operating under the NPIS to increase their maximum line speeds to allow establishments to operate more efficiently. The comment stated that this would allow large corporations that own multiple establishments to close some and still produce the same volume of product. The comment said that establishment closures will result in worker layoffs and community disruption, especially in locations where the establishment is the largest employer.

Response: As discussed above, under this final rule the maximum line speed permitted under the NPIS will be 140 bpm for young chickens rather than 175 bpm, as was proposed. Thus, the maximum line speed for the NPIS will be no faster than the maximum line speed permitted under the existing inspection systems under SIS.

Regardless of line speed, establishments may choose to implement the NPIS by adjusting shifts, reducing overtime, increasing output, reducing the number of lines, or consolidating establishments.

Comment: One trade association stated that the NPIS will create new jobs. According to the comment, even in the current economy, members of the trade association that participate in the HIMP pilot have hired additional in-plant personnel. The comment said that slaughter and processing establishments are only able to increase line speeds as staff levels permit, otherwise quality control could be adversely affected. The comment said that some establishments that have joined the HIMP pilot have expanded their facilities, hired new workers, and purchased additional equipment and technology, further fueling rural economies.

Response: While it is difficult to predict, FSIS agrees that establishments adopting the NPIS will likely initially 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 (refer to number 1 under Summary of Estimated Costs and Cost Savings of the Rule).

Comment: A consumer advocacy organization questioned the incentive structures that would be in place with the NPIS. The comment questioned whether the NPIS would result in pathogen reduction and would lead to a reduction in health benefits. The comment questioned how the NPIS would limit the number of recalls.

Response: It is within the establishment's economic interest to take whatever actions are necessary to produce products that are safe, wholesome, and free from excessive trim and dressing defects. FSIS is responsible for ensuring that the establishment's process control procedures for preventing contamination by enteric pathogens and fecal material and for controlling OCP defects are effective. The NPIS gives establishments the flexibility to more efficiently utilize their resources to design systems that ensure their process control. As a result, the NPIS is expected to improve food safety and the effectiveness of inspection systems. FSIS estimates that this rule could reduce the number of human illnesses attributed to young chicken and turkey products by an average of about 3,980 *Salmonella* illnesses and about 840 *Campylobacter* illnesses.

The records that all establishments that slaughter poultry other than ratites would be required to keep under this rule, including the records of the establishment's testing results, will provide establishments and FSIS with ongoing information on the effectiveness of the establishment's process controls. This will allow FSIS and establishments to identify situations associated with 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 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.

2. Environmental Justice

Comment: Several comments from human and worker rights advocacy organizations and a public health professional trade association said that the Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule failed to consider costs to workers' health and safety. The comments noted that FSIS estimated that the benefits of the proposed rule would amount to at least $258.9 million, but that the Agency did not present any data or estimates of the cost of injury, illness and disability of the proposed increased in maximum line speed that would have been permitted on the affected poultry plant workers. One comment stated that PRIA must also consider costs associated with increased worker's compensation, increased social service costs for State and local government, and reduced tax and Social Security payments.

Response: Under this final rule the maximum line speed permitted under the NPIS will be 140 bpm for young chickens rather than 175 bpm, as was proposed. Thus, the maximum line speed for the NPIS will be no faster than the maximum line speed permitted under the existing inspection systems

under SIS. The FRIA for this final rule has been updated to reflect this change from the proposal.

The effect of line speed on establishment employee safety is an important issue. As discussed above, the 2005 GAO Report, which linked production line speed to occupational injury and illness rates in the slaughter industry, called for independent research to better understand this relationship. As discussed earlier in this document, to obtain at least preliminary data on the matter, FSIS has asked NIOSH to evaluate the effects of increased line speeds on worker safety by collecting data from establishments that had been granted waivers from line speed restrictions under the SIP. NIOSH has completed such a study in one non-HIMP establishment. FSIS considers the NIOSH study to be an important first step in better assessing the impact of line speeds on the health and safety of workers in poultry slaughter and processing establishments.

3. Small Business Considerations

Comment: Some consumer advocacy organizations stated that the NPIS will lead to further consolidation in the poultry industry and that large producers will benefit at the expense of smaller processors. The comments said that the proposed increase in line speeds that would have been authorized under the proposed rule would cause small processors that typically do not run at line speeds of up to 175 birds to go out of business because the market will be flooded with poultry products from the larger processors. One trade association and a member of academia believed that the proposed rule adequately addressed considerations for small and very small establishments. According to the comments, the option to remain under Traditional Inspection will benefit establishments that do not have the resources to absorb the costs associated with facility and personnel changes. One comment stated that because establishments will have an opportunity to opt-in or opt-out of the NPIS, smaller businesses that have ''niche'' markets will not be adversely affected. The comments said that poultry sold in smaller markets has the appeal of being locally harvested and slaughtered under less commercial conditions. According to the comment, smaller establishments that have ''niche'' markets for their poultry product may see an increase in consumer purchase as a result of larger slaughter facilities choosing the new system.

Response: Under this final rule, establishments that do not choose to operate under the NPIS may continue to operate under their current inspection system, i.e., SIS, NELS, NTIS, or Traditional Inspection. FSIS expects little to no impact on small producers. Very small establishments that operate under Traditional Inspection 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.[19] An ability to charge a higher price based on product differentiation enables the very small establishments to continue to compete in the market. The same pricing power based on product differentiation holds for establishments that slaughter birds other than young chickens and turkeys. Moreover, FSIS has revised the rule to reduce the sampling requirements for very low volume and very small establishments, which further reduces their cost to operate under the Traditional Inspection System, as modified by this final rule.

4. Implementation Costs

Comment: One trade association stated that the proposed rule did not address the significant costs of implementation, such as developing training materials and training employees, developing new recordkeeping based on the new system, and retraining or hiring new personnel to manage those recordkeeping systems. This trade association also noted that implementation of the NPIS will require significant capital investments. This trade association argued that the potential costs of implementation are exacerbated because it is unclear how the Agency plans to implement the NPIS and establishments cannot yet begin to make financial plans.

Response: FSIS carefully considered the costs associated with the final rule and included establishment costs associated with implementing the NPIS and complying with the mandatory recordkeeping and testing requirements of the rule in its FRIA. Annualized costs associated with the hiring of additional labor of sorters, both one-time and ongoing training as well as capital expenditures for the NPIS total $16.0 million (Table 7a). Annualized costs and cost savings associated with both additional microbial testing, the elimination of *E. coli* testing, recordkeeping and updating HACCP plans total $9.1 million (Table 7b).

[19] 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.

Comment: One trade association questioned the Agency's estimated industry savings in the PRIA. This trade association believed that some of the assumptions that the estimate are based on are unrealistic, such as, how many establishments will choose to or are capable of operating at higher line speeds. Additionally, this trade association stated that FSIS failed to take into account overall consumer demand when estimating industry-wide output. However, this trade association asserted that the benefits to food safety and the overall efficiencies to be gained are worth the cost and investment.

Response: Under this final rule the maximum line speed permitted under the NPIS will be 140 bpm for young chickens rather than 175 bpm, as was proposed. Thus, the maximum line speed for the NPIS will be no faster than the maximum line speed permitted under the existing inspection systems under SIS. The FRIA for this final rule has been updated to reflect this change from the proposal. In the proposed rule, FSIS took into account overall consumer demand by using demand elasticity to predict the increase in young chicken and turkey products produced as a result of an increase in line speed. However, because the maximum line speed under the NPIS will now be no faster than the maximum line speed authorized under the existing inspection systems, the impact of consumer demand on consumer and producer benefits has been removed.

IV. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess 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 final rule has been designated a ''significant'' regulatory action, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget, under Executive Order 12866.

Introduction

FSIS updated the PRIA to take into account recently published data and to reflect changes in the final rule in response to public comments. The changes to the costs and benefits

sections incorporate the following factors:

- Maximum line speeds permitted under the NPIS will be 140 bpm for young chickens.
- Very small HACCP size establishments are required to only test at one location instead of two and the sampling frequency for very low volume establishments remains unchanged from the existing regulation.
- Additional Labor Cost Due to Attestation of Work-Related Conditions is added to total cost.
- Changes to the rule's implementation plan, which are reflected in the Expected FSIS budgetary effects, establishment costs, and public health benefits.
- Changes to the costs of illness estimate, including changes to the average cost per illness and to the averted number of illnesses estimated in FSIS's risk assessment as a result of the latest peer review.
- Establishments are also now required to have a height-adjustable CI stand (the proposed rule did not have the height-adjustable requirement). FSIS has not included the price difference between height-adjustable and non height-adjustable inspection stands in the Final Regulatory Impact Analysis (FRIA) since the difference in cost is expected to be minimal.

Need for the Rule

The current systems of poultry inspection are rooted in principles of command and control regulation, where broad, rigid standards are applied across finished products and establishments. As food processing and food safety technology becomes more diverse, FSIS has worked to reform its regulations with a focus on HACCP-based process control, enabling establishments to have more flexibility in tailoring their food safety plans to their products and processes. The new system of poultry slaughter will help to further this effort. 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 spp.* and *Campylobacter spp.*) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP or other prerequisite program.

Summary of the 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. FSIS expects this action to impact 194 establishments (70 small establishments plus 149 large establishments minus 25 HIMP establishments);

(2) A limit of one FSIS online carcass inspector per evisceration line. FSIS expects this action to impact 194 establishments;

(3) Removal of the existing Finished Product Standards (FPS) and subsequent replacement with a requirement to maintain records that document that the 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 online 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. FSIS expects this action to may impact up to 219 establishments;

(4) 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 expects that this action would affect, at a maximum, about 219 establishments that may choose to adopt this new inspection system out of 270 official federally inspected establishments that slaughter young chickens and turkeys (refer to Table 4 for further explanation of the number of establishments affected). This 219 total includes HIMP establishments, though they will have already installed this equipment, meaning that 194 establishments are affected; and

(5) a requirement that each establishment that participates in the New Poultry Inspection System (NPIS) shall submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers, and that the program includes the elements listed in the preamble.

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* and *Campylobacter*) as part of an establishment's HACCP plans, sanitation SOPs, or other prerequisite programs. FSIS is requiring 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 (except for very small HACCP size establishments and very low volume establishments, which are required to sample only at post-chill);

(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 SOPs, or other prerequisite programs;

(3) Removal of the 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; and

(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.

Baseline

Table 2 compares the components or requirements of the actions of the final rule to the current regulatory regime for all federally inspected establishments that slaughtered all poultry other than ratites. From the FSIS Animal Disposition Reporting System (ADRS), we identified 289 establishments in 2010 slaughtering poultry (excluding ratites). Actions include requirements for young chicken and turkey establishments and requirements for all poultry slaughter establishments

excluding ratites. Table 2 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, up to four FSIS inspectors are stationed on the same side of a processing line that runs at a maximum of 140 birds per minute (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 2—COMPARISON OF KEY COMPONENTS OF THE BASELINE REGULATORY ENVIRONMENT AND THE RULE

Key features or provisions of the rule	Very small and small HACCP size establishments traditional		Small and large non-traditional		
	Baseline	Rule	Current inspection systems	HIMP	NPIS
Number of Establishments	70		194	25.	
Carcass Sorting Activities	FSIS	FSIS	FSIS	Establishment	Establishment.
Online Inspector per Line	1–4	1–4	2–4	1	1.
Online Inspector Limit	No	No	No	Yes	Yes.
Addition of Online Establishment Workers because of Relocation of Online IPP.	No	No	No	Yes	Yes.
Line Speed Maximum Birds per minute for Young Chickens.	25–46	25–46	70–140	175	140.
Line Speed Maximum Birds per minute for Mature Chickens.	≤66	≤66	N/A [1]	N/A	SIP Waiver determined.
Line Speed Maximum Birds per minute for Turkeys.	16–25	16–25	21–51	55	55.
Line Speed Maximum Birds per minute for Other Poultry.	≤66	≤66	N/A	N/A	SIP Waiver determined.
Records to document that products meet the definition of RTC poultry.	No	No	No	No	Yes.
New Facilities Requirements	No	No	No	Yes	Yes.
New carcass inspection station for each evisceration line.	No	No	No	Yes	Yes.
New carcass inspection area online for avian leukosis for each evisceration line.	No	No	No	No	Yes.
Underline Trough for each evisceration line.	No	No	No	Yes	Yes.
HACCP System—written to prevent Sep/Tox carcasses from entering chiller.	No	No	No	No	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.[2]	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.

[1] N/A—does not apply.
[2] Very small HACCP size establishments and very low volume establishments are required to test in one location.

Under the final rule, any of the young chicken and turkey establishments (assumed to be limited to the 219 large and small non-Traditional establishments) that adopt the new inspection system (some while operating under updated SIP waivers), will have one online inspector per line. Currently, there are two to four online inspectors per line under the current non-traditional systems (SIS, NELS, and NTIS); however, there is one online inspector per line under HIMP. Even though FSIS, in the analysis that follows, only quantifies costs, rather than benefits, of switching to NPIS, FSIS predicts that some small and large non-traditional establishments alike will choose to adopt the NPIS because it will give them greater control over their production process and more flexibility to design, develop, and implement new technologies. Comments received from industry indicate that the benefits to food safety and the overall efficiencies to be gained by the NPIS would be worth the cost and investment to

industry. These comments were submitted in response to the proposed rule that would have allowed a maximum line speed of 175 bpm under NPIS. Thus, the change in policy between the proposed and final rule may change the appropriate interpretation of some of these comments. However, one industry trade association commented that the proposed rule's Preliminary Regulatory Impact Analysis contained unrealistic assumptions of how many establishments would have chosen to, or would have been capable of, operating at the faster line speeds that would have been permitted under the proposed NPIS. Nevertheless, regardless of line speed, this trade association believed that the benefits to food safety and the overall efficiencies to be gained by the NPIS would be worth the cost and investment to industry as noted throughout this document. Establishments will have the flexibility to design and implement measures for producing ready-to-cook poultry tailored to their operations. The NPIS would also give establishments the ability to investigate and develop new and more efficient technologies.

The Agency's experience under HIMP demonstrates that young chicken establishments have incentives to participate and remain in the HIMP pilot for reasons other than the ability to operate faster line speeds. Experience from the HIMP pilot shows that HIMP establishments operate with an average line speed of 131 bpm, and that although they are authorized to do so, most of the young chicken HIMP establishments do not operate line speeds at 175 bpm. Thus, the faster line speeds authorized under HIMP do not appear to be the primary incentive for establishments to participate in the pilot because the average line speed of establishments operating under the HIMP inspection is slower than the 140 bpm maximum line speed authorized under the existing inspection systems.

The Agency's experience under HIMP also shows that once establishments are selected to participate in the HIMP pilot, they choose to remain under the HIMP inspection system. In 2002, after FSIS had selected 20 young chicken establishments to participate in the HIMP pilot, the Agency informed the industry that it would limit the pilot to 20 establishments. At that time, over 40 establishments were placed on a waiting list to participate in the HIMP pilot. Since then, two establishments left the pilot because they closed. These establishments were replaced by establishments on the waiting list, and more than 40 establishments remain on the list. Thus, the Agency's experience under HIMP shows that young chicken establishments continue to be interested in participating in the HIMP pilot, and those that are selected for the pilot choose to remain under the HIMP inspection system even though many are not operating at the maximum line speeds authorized under HIMP.

Table 3 shows the baseline characterization of the U.S. poultry market for birds other than ratites in 2010. Domestic federally inspected establishments slaughtered and dressed about 8.8 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). Establishments slaughtered about 8.64 billion young chickens and turkeys.

TABLE 3—BASELINE CHARACTERIZATION OF THE U.S. POULTRY MARKET

	Young chickens	Other chickens	Turkey	Other poultry
Market price ($/bird) [1]	$3.38	$1.34	$22.74	$9.02
Market quantity [2] (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

[1] Market price is calculated by multiplying the wholesale price per pound by the average dressed weight.

[2] Market quantities in thousands of birds (dressed carcasses), or animal (dressed carcass) equivalence, other than ratites. Source: Muth, M.K., Beach, R.H., Viator, C.L., Karns, S.A., & Taylor, J.L. (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.

A summary of the types of young chicken and turkey operations and the sizes of these official establishments is in Table 4 (FSIS ADRS 2010). Table 4 summarizes the 270 federally inspected establishments that slaughtered young chickens (231 establishments) and turkeys (39 establishments) along with the 19 that slaughtered other chicken (such as fowl and capon) (6 establishments) and only other poultry (such as squabs, pheasants, quail, ducks or geese) (13 establishments) in 2010.

Table 4: 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[1]	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%)
Turkeys	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%)[2]**

[1] Establishments that slaughter primarily young chickens.
[2] Totals do not add up due to rounding.

FSIS ADRS 2010 records indicated that there were 663 line-shifts in 270 establishments that slaughter young chickens and turkeys, as shown in Table 5.[20] 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 from multiplying the number of lines by the number of shifts. Table 5 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 systems 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 5 also summarizes the maximum potential transition over five years, assuming available resources and institutional readiness, of the young chicken and turkey industry to the new inspection system. This table shows the 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 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 lines, there were 27 establishments under NTIS inspection, and 5 under the HIMP inspection. Altogether, this suggests a maximum of 219 of the 270 young chicken and turkey establishments, or 81 percent, which have about 598 lines, have the opportunity to convert to NPIS.

[20] Included in this number are the very small establishments that annually slaughter a relatively small number of young chickens and turkeys by methods that do not use a high-speed line.

Table 5: Potential Maximum Transition of 270 Official Establishments and Line-Shifts that Slaughtered Young Chickens and Turkeys under Federal Inspection Systems to the New Inspection System and the Modified Traditional Inspection System (source: FSIS ADRS, 2010)[1]

<table>
<tr><th colspan="6">Inspection Systems Before the Rule</th></tr>
<tr><td colspan="6"><u>Slaughter Processing – with Lines in 2010</u>
270 Establishments
663 Line-shifts</td></tr>
<tr><td colspan="5"><u>Large and Small</u>
219 Establishments
598 Line-shifts</td><td><u>Very Small</u>
51 Establishments
65 Line-shifts</td></tr>
<tr><td colspan="3"><u>Young Chickens</u>
187 Establishments
542 Line-shifts</td><td colspan="2"><u>Turkeys</u>
32 Establishments
56 Line-shifts</td><td><u>Young Chickens and Turkeys</u>
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">Potential Inspection Systems Under Assumption of 100% Implementation</th></tr>
<tr><td colspan="5"><u>New Inspection System (Young Chickens and Turkeys)</u>
219 Establishments
598 Line-shifts</td><td><u>Modified Traditional</u>
51 Establishments
65 Line-shifts</td></tr>
</table>

Notes: The number of line shifts results from multiplying the number of lines by the number of shifts. Each shift is about 8 hours of operation per day.

1 FSIS cannot definitively predict potential transitions and therefore presents this data on potential maximum transition as background information.

Table 6 shows that of the 187 young chicken establishments (not under the Traditional Inspection System) with 542 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 lines, 22 were HACCP large establishments and 10 were HACCP small establishments.

Table 6: 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 Federally Inspected 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 Only Other 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

Sources: FSIS PBIS, March 2011 -these federally inspected establishments have 03J HACCP codes for slaughter operations. FSIS ADRS, March 2011 - these federally inspected establishments slaughtered poultry in 2010.

Notes: 1-shift is about 8 hours of slaughter operation; 2-shifts are about 16 hours of slaughter operation, each workday. Some establishments have more than one line per shift. Therefore, the total number of evisceration line-shifts (column 2) will be greater than the total number of establishments with 1 and 2-lineshifts (columns three and four).

Estimated Number of Establishments Predicted To Opt for the Modified Traditional Inspection System

FSIS estimates that about 70 federally inspected establishments will switch from their current Traditional Inspection System to the modified Traditional Inspection System for the slaughter of poultry, other than ratites. The 70 establishments consist of 51 very small HACCP size establishments, or about 19 percent of the 270 official federally inspected establishments that slaughter young chickens and turkeys, and 19 establishments that slaughter poultry but not young chicken or turkey (or ratites). The very small HACCP size young chicken and turkey establishments, in general, do not have sufficient output volume over which to spread the initial set-up costs of any of the more automated systems 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,[21] under all poultry inspection systems in 2010. Based on FSIS's ADRS records, these 70 establishments slaughtered about 1 percent of all poultry (other than ratites) of the domestic poultry industry in 2010. Furthermore, 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.

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

Summary of Estimated Costs and Cost Savings of the Rule

In the following sub-sections, FSIS presents the costs and cost savings that would be generated over a range of assumptions with respect to how much of the industry will choose to adopt NPIS within five years. These estimates are scaled from an illustrative calculation that assumes that all 219 small and large non-Traditional establishments adopt NPIS, which, while used to calculate potential maximum effect, is not necessarily FSIS's assumption of the most likely outcome. Later portions of the regulatory impact analysis contain discussion of the uncertainty surrounding the net benefits associated with how much of the industry will choose to adopt NPIS.

Items 1–7 are Costs and Cost Savings Associated With the New Poultry Inspection System

1. Addition of Online Establishment Workers Because of the Relocation of Online Inspection Program Personnel and Online Sorters—Annual Cost Associated With the New Poultry Inspection System

FSIS estimates that young chicken and turkey establishments that transition to NPIS will initially expand their labor resources by employing about an average of 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 rule. This substitution rate is based on information provided by 12 young chicken establishments in 2001 who participated in the HIMP pilot program.[22] If all of the 219 establishments eventually slaughtered young chickens and turkeys under the NPIS, this would translate to between 663 and 770 FSIS online inspection program personnel shifted from online inspection to verification inspection activities and online inspection of carcasses (carcass inspection, after the final wash and before the chiller). However, as noted above, there is not a way to predict how many of the establishments will transition to NPIS, or over what time frame FSIS would have the resources to accommodate requests after the initial 6 month period. As such, table 8b suggests that the range of personnel under assumptions that span 0 and 100 percent range from 0 to 770 online inspectors. FSIS estimates that the 770 shifted FSIS online inspection program personnel is the upper bound if indeed all the 219 establishments estimated earlier opt to transition to NPIS during the first five years.

Using the expected substitution rate of 0.8 (8 for 10), under the 100 percent adoption assumption for analytic purposes, the estimated 219 establishments would initially need about 616 (770×0.8) 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 the range of reassignments by FSIS would be between 0 and about 770 inspection program personnel to other inspection activities within the establishments (e.g. carcass inspection, verification inspection, and relief coverage). The upper bound of this range, or 770 inspection program personnel, however, may be an over-estimate, because of attrition. The Bureau of Labor Statistics (BLS) indicated that the expected standard rate for establishment labor is about $13.96 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 2,000 hours[24] per staff-year). Therefore, the average cost if 219 establishments were to adopt NPIS within five years, would be for the initial additional 616 staff-years of online sorter labor is about $17.2 million annually ($616 \times \$27{,}900$).

2. Training Online Sorters, Under the New Inspection System—One-time Cost Associated With the New Poultry Inspection System

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 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 5) 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 rule.

FSIS assumes that the, using the maximum potential upper bound of establishments, 219 establishments will need about 3.5 to 4 times the replacement staff-years, or about 2,310 (3.75×616) establishment employees who are trained to perform online sorting and CI helper activities. Therefore, initially, an average of about 2,310 establishment employees would need to be trained at a one-time average cost of about $400 each, or a total for estimated 219 establishments, of about $0.92 million ($2{,}310 \times \$400$).

3. Training, Annually—for Replacement Sorters Due to Labor Turnover—Annual Cost Associated With the New Poultry Inspection System

Annual training 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 establishment sorters is, on average, 40 percent, establishments will need to train about 924 ($0.4 \times 2{,}310$) new establishment sorters annually.[25] FSIS projects that the initial training costs are expected to be about $200 to $600, or an average of about $400 per employee (sorter). Using the $400 per employee values, additional training costs will average about $0.37 million ($924 \times \$400$), annually.

[22] Most of the cost estimates in this section are also based on the data collected from these 12 establishments.

[23] According to the 2011 Bureau of Labor Statistics employment cost index, hourly wages for slaughtering and meatpacking workers is $11.63. Estimates of benefits as a percent of total wages range from 20 to 39 percent according to the American Meat Institute. Since the poultry industry is at the low end of the wage scale, we are estimating benefits to be 20 percent of total wages.

[24] This is a simplifying assumption.

[25] BLS reported that the overall private industry turnover rate was approximately 41 percent in 2011. FSIS is rounding to 40 percent. U.S. Department of Labor. Bureau of Labor Statistics. (2011). Job Openings and Labor Turnover Survey. Washington, DC: U.S. Department of Labor.

4. Continuing Education & Training, Annually—for Existing Sorter Labor—Annual Cost Associated With the New Poultry Inspection System

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 2,310 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. Using this average value, the total average cost would be about $0.40 million (2,310 × $175), annually.

5. Additions to Facilities: Carcass Inspection Stations, Avian Leukosis Inspection Area, and Underline Troughs One Time Costs Associated With the New Poultry Inspection System

Under the rule, all of the poultry establishments participating in the NPIS will need to add capital investments to install a carcass inspection height-adjustable station.

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 (Table 5) will not need new trough installations under the new rule. 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. FSIS estimates that as many as 194 establishments (Table 5, based on a projection that up to 219 establishments may adopt the NPIS, minus the 25 HIMP establishments) will need 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.

For the carcass inspection station, this cost is for the construction of a stainless steel height-adjustable 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 541 eviscerating lines now installed in the 194 non-HIMP establishments (Table 5) that may implement the NPIS. Therefore, the calculated cost for adding carcass and verification inspection stations for the 194 establishments is about $8.39 million (541 × $15,500).

6. Carcass Dressing for Meeting the Definition of Ready-to-Cook (RTC) Poultry and the Removal of the Finished Product Standards (FPS) Associated With the New Poultry Inspection System

FSIS is removing 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 and may have minimal savings. These savings are not included in the benefits estimate.

FSIS online 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.

7. Additional Annual Labor Cost Due to Attestation of Work-Related Conditions

Each establishment operating under the NPIS will need to submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers. The cost of this attestation is estimated to take 2 minutes at a wage rate of $13.96 per hour for a total of $102 annually.

Total Costs and Cost Savings Associated With the New Poultry Inspection System

FSIS assumes that the projected adoption of NPIS will take place over a five year time period.[26] FSIS expects that HACCP size large establishments will be the first to convert to the new inspection system because they have greater resources available to them to make the necessary changes. For the purposes of estimating costs, FSIS assumed that 68% of all establishments that convert to NPIS will have implemented NPIS by the third year, with approximately 1/3 of these establishments converting each of the first three years. For the small establishments that implement NPIS, FSIS assumed that half would convert in year four, and half would convert in year five. If all large and small establishments adopt NPIS, this pattern would result in the complete conversion of establishments to the new inspection system within the five year period used for this analysis. FSIS is uncertain about how many and how fast establishments might opt into NPIS, as such, FSIS presents the data in table 8b to reflect that uncertainty.

As such, the costs to industry associated with making the necessary changes to implement NPIS will fluctuate over the initial five years. FSIS used establishment information including HACCP size, line-shift data (see Table 5), and approximate volume contributions[27] to estimate how one-time industry costs will be spread across

[26] Please refer to the ''Baseline'' section for further explanation on the projected adoption rate of NPIS.

[27] The USDA, GIPSA 2012 Packers and Stockyards Annual Report states that the four largest broiler slaughterers posted a 52 percent market share in 2011. The share of the four largest turkey slaughterers was 55 percent in 2011. The U.S. Census Bureau 2007 Economic Census of the United States reports that the 50 largest Poultry Processing Companies (2007 NAICS 311615) post a 91.5% share of the total value of shipments. For the purposes of this analysis, FSIS assumed that large establishments accounted for 90% of the production volume and small establishments accounted for the remaining 9.9%. According to our analysis, very small establishments account for the remaining 0.1%.

the first five years. FSIS also used this information to approximate the recurring costs to industry over time. These estimated costs are summarized in Table 7a. Annualized costs were calculated using a discount rate of 7 percent over a ten-year period.[28]

TABLE 7a—ESTIMATED YEAR-BY-YEAR COST OF THE RULE IF ALL LARGE AND SMALL NON-TRADITIONAL ESTABLISHMENTS SELECT THE NEW POULTRY INSPECTION SYSTEM

[Millions of dollars]

	Year 1	Year 2	Year 3	Year 4	Year 5	Recurring
Annual sorting labor	5.01	10.03	15.04	16.12	17.20	17.20
Knowledge costs (human capital):						
Initial one-time training of sorting workers	0.27	0.27	0.27	0.06	0.06	.....
Training annual sorting labor-turnover rate of 40%	.....	0.11	0.22	0.32	0.35	0.37
Continuing annual education and training	.....	0.12	0.24	0.35	0.38	0.40
One-time capital expenditure	2.44	2.44	2.44	0.53	0.53	.....
Paperwork cost due to attestation of work-related conditions	**	**	**	**	**	**
Total costs to establishments from NPIS	7.73	12.97	18.21	17.38	18.51	17.97
Annualized (7%, 10 year) total cost to establishments from NPIS	16.00					
Annualized (3%, 10 year) total cost to establishments from NPIS	16.27					

** less than $1000, which rounds to zero.

Items 8–12 Are Costs and Cost Savings Associated With the Mandatory Component of the 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

FSIS is requiring microbial testing to demonstrate process control regarding the prevention of contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. FSIS is requiring establishments to incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs, and to maintain records sufficient to document the implementation and monitoring of these procedures.

The regulation requires most establishments for each poultry type to sample at two locations: pre-chill and post-chill. The exceptions are for very small HACCP size establishments that choose to operate under the modified Traditional Inspection System, which FSIS will permit to conduct sampling only at post-chill. For two samples per sampling event, FSIS assumes that it would take about 25 minutes for a QC technician to collect these samples; for one sample, FSIS assumes it would take 15 minutes to collect the sample. FSIS assumes costs of $3.75 for material and time needed to provide sampling record identification at the laboratory for two samples, and one-half that amount of time for one sample. For two locations, the cost per sampling event is $45.85; for one location, the cost per sampling event is $24.13.[29] FSIS assumes a cost of sending material and samples between the establishment and laboratory of about $15 per sampling event, if the laboratory is not on-site. Most large establishments have laboratories on premises; FSIS assumes that 90 percent of large HACCP size establishments have laboratories on the premises, and thus would not incur a cost for sending samples to the laboratory. FSIS assumes that 25 percent of small and very small HACCP size establishments have laboratories onsite. Accounting for our assumed percentages of samples that would need to be sent to laboratories, FSIS assumes a cost of $47.35 per sampling event for large HACCP size establishments, $57.10 per sampling event for small HACCP size establishments, and $35.38 per sampling event for very small HACCP size establishments (at one location).[30] For record keeping (discussed in a later section), FSIS assumes 5 minutes for a sampling event for 2 locations, and 2.5 minutes for 1 location, at the same $29.03 per hour wage.

To establish a baseline, for other than very low volume establishments, FSIS assumes that large HACCP size establishments would collect 150 pairs of samples, on average; small HACCP size establishments, 75 pairs; and very small HACCP size establishments, 30 samples. For very low volume establishments,[31] FSIS assumes that sampling would be minimal, and that for these establishments there would be no baseline. The number of samples that establishments would collect for each poultry type is proportional to the number of slaughtered birds for the different poultry types.

To estimate the recurring annual cost for sampling, FSIS assumes sampling at a rate of 1 sampling event per 22,000 carcasses for sampling chicken, and 1 per 3,000 carcasses for sampling other species. For very low volume establishments, FSIS assumes at least one sample per week to a maximum of 16 samples per year, because some low volume establishments might need to take more than 13 samples to demonstrate process control.[32] Based on

[28] FSIS assumes first-year costs are incurred at the end of the year.

[29] FSIS assumes that establishments would not necessarily use generic *E coli* because the cost per analysis of this organism is greater than that for other indicator organisms. While costs per sample can vary greatly depending on many factors, we assumed an average cost of $15 per sample, plus a modest laboratory labor cost ($3.75) for handling paper. Therefore, the cost per sampling event collecting two samples, excluding sending cost, is $30 + $3.75 + $29.03(25/60) = $45.85. The cost per sampling event collecting one sample is $15 + $1.87 + $29.03(15/60) = $24.13.

[30] For example, for large HACCP size establishments, the cost per sampling event is: [(0.9) ($45.85) + (0.1) (45.85 + 15)] = $47.35, because we assumed that 90 percent of the samples would not need to be sent by mail.

[31] FSIS assumes these establishments would remain under Traditional Inspection.

[32] For the original HACCP rule, FSIS required 13 samples provided that statistical criteria that FSIS used were satisfied. The expected number of samples for this to occur is about 16.

these assumptions, we calculated an expected number of sampling events that establishments would take, and multiplied these numbers by the appropriate costs per sampling event (weighted sum with weights equal to the appropriate cost for the sampling event). We provide cost estimates in Table 7b.

FSIS expects industry to incur a savings by reducing present costs associated with sampling for satisfying the present Finished Product Standards (FPS), and that additional cost to industry due to our Other Consumer Protection (OCP) requirements, if any, would be minimal. Thus, FSIS did not include costs associated with the replacement of the present FPS requirements with the and new OCP requirements.

9. Additional Annual 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. FSIS assumes that the time spent for a QC technician salaried at $29.03 per hour for recording results (including review) for each sample is 2.5 minutes. If two samples are collected (pre-chill and post-chill), FSIS assumes 5 minutes are needed. For the present required generic *E. coli* testing, FSIS assumes 2.5 minutes per sample.

10. (a.) Modification of the HACCP Plans and Process Control Plans—One-time Cost Associated With the Mandatory Component of the Rule

Establishments will need to modify their HACCP plans, sanitation SOPs, or other pre-requisite programs to address septicemic and toxemic carcasses and food safety hazards that are reasonably likely to occur. Establishments will also be required to maintain records to document that their product meets the definition for ready-to-cook poultry. Under the 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 based its estimates on information provided by establishments participating in the HIMP pilot program regarding initial costs for modifications to their HACCP plans. FSIS estimates that, on average, the initial costs will be about $5,000 for small HACCP size establishments and about $9,000 for large HACCP size establishments. For the very small HACCP size establishments, FSIS projected a cost of about $2,000, on average. Therefore, we estimate the one-time cost to be equal to about $1.89 million ((84 × $5,000) + (151 × $9,000) + (54 × $2,000)) for the 289 establishments.[33] Moreover, once establishments design and implement these modifications, they will incorporate them in their present HACCP plans, and thus we assume no additional recurring cost associated with these modifications. FSIS does not expect these costs to vary by the type or species of bird that the establishments slaughter.

10. (b.) Written Procedures To Ensure That Carcasses and Parts With Visible Fecal Contamination Do Not Enter the Chiller, After Evisceration Operations—One-time Cost Associated With the Mandatory Component of the Rule

FSIS is requiring that all federally inspected establishments that slaughtered poultry (other than ratites) develop, implement, and maintain, as part of their HACCP plans, 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 is included in the costs of changing the HACCP system as discussed above in item 10.a.

10. (c.) Written Procedures To Ensure That Young Chicken and Turkey Carcasses Contaminated With Septicemic and Toxemic Conditions Do Not Enter the Chiller, for the New Poultry Inspection System Associated With the Mandatory Component of the Rule

FSIS is requiring that the 219 federally inspected establishments that may decide to slaughter young chickens and turkeys under the NPIS develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chiller. Establishments must incorporate these procedures into their HACCP plans, sanitation SOPs, or other prerequisite programs. The cost for developing these written procedures is accounted for in the costs given in section 10.a.

11. Elimination of Generic *E. coli* and Salmonella Standards—Annual Cost Savings Associated With the Mandatory Component of the Rule

FSIS is removing the current requirement that poultry establishments that slaughter more poultry than other species test for generic *E. coli.* Additionally, the agency is removing the codified *Salmonella* pathogen reduction performance standards for poultry because our existing *Salmonella* and *Campylobacter* performance standards are better able to contribute to food safety. We used the same assumptions for the cost of sampling as described above in section 9, with the exception of assuming the analytical cost for generic *E. coli* is $20 instead of $15.[34]

FSIS assumes the cost savings associated with eliminating the *Salmonella* performance standards are minimal, because typically establishments are sampled, on average, roughly once every two years; more than 95 percent of the sample sets' results satisfy FSIS's criteria; [35] and establishment-recording costs for FSIS sampling are minimal. Therefore, FSIS did not account for savings due to eliminating this requirement.

12. Elimination of Carcass Cooling Standards—Possible Cost Savings Associated With the Mandatory Component of the Rule

FSIS projects that the 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.

[33] FSIS did not exclude HIMP establishments from this calculation, though FSIS believes that the cost for these establishments on average will be less. To the extent that this is true, the above estimate is high, given everything else being true.

[34] The cost of analyzing generic *E. coli* is greater than that of analyzing for Aerobic Plate Count (APC) because the former involves extra steps for identifying *E. coli* cells. Based on its experience with contracting, FSIS estimates that the analytical cost per sample for *E. coli* is about $5 more.

[35] U.S. Department of Agriculture. Food Safety and Inspection Service. (2011). Progress Report on Salmonella and Campylobacter Testing of Raw Meat and Poultry Products, 1998–2011. Washington, DC: U.S. Department of Agriculture. Retrieved from *http://www.fsis.usda.gov/PDF/Progress_Report_Salmonella_Testing_1998-2011.pdf#page=14.*

In the years 2009–2011, FSIS sent a yearly average of about 125 sample sets to establishments that slaughter young chicken and about 26 to establishments that slaughter turkey. Thus, per year, roughly 50 percent of the establishments received sample sets. Over 95 percent of the sets show results that are in compliance with the performance standard.

Total Costs and Cost Savings Associated With the Mandatory Component of the Rule

Table 7b shows the implementation costs of complying with the mandatory actions of the rule, over time, for the 289 affected poultry establishments. For the 70 establishments expected to transition to the modified Traditional Inspection System, FSIS assumed that half would convert in year four, and the remaining half would convert in year five, mirroring the implementation of the small young chicken and turkey plants converting to NPIS. Again, annualized costs are calculated using a discount rate of 7 percent over a ten year planning period.

TABLE 7b—ESTIMATED ANNUAL COST (COST SAVINGS) OF THE RULE TO ALL ESTABLISHMENTS FOR ELEMENTS ASSOCIATED WITH THE MANDATORY COMPONENT OF THE RULE

[Millions of dollars]

	Year 1	Recurring
Additional PC microbial testing:*		
One-time baseline	1.34	
Annual recurring testing	23.59	23.59
Annual recordkeeping, monitoring, and record storage	1.17	1.17
Eliminated generic *E. coli* testing recordkeeping	(0.59)	(0.59)
One-time HACCP system and Process Control (PC) plan development	1.89	
Reduced annual microbial testing—generic *E. coli*	(15.51)	(15.51)
Total costs to establishments from mandatory component	11.90	8.67
Annualized (10 year, 7% discount) total mandatory costs	9.10	
Annualized (10 year, 3% discount) total mandatory costs	9.04	

For the poultry industry, as shown in Table 7a, the annualized costs incurred if all establishments convert to NPIS are about $16.0 million over 10 years at a 7 percent discount rate. To comply with the mandatory component, the rule will cost establishments about $9.1 million over 10 years at a 7 percent discount rate. Net total costs to industry annualize to $25.1 million ($16.0 + $9.1).[36]

FSIS expects the 51 very small HACCP size establishments that slaughter young chicken and turkey and the three very small establishments that slaughter other poultry to adopt the modified Traditional Inspection System instead of NPIS. These establishments will only incur mandatory costs associated with items discussed above and listed in Table 7b. FSIS assumes a smaller analytical cost per sample for these establishments, and in some cases for establishments with large production volume, fewer numbers of samples.[37]

Table 7c lists estimated mandatory costs for the 54 very small HACCP size establishments. Estimated annualized costs to very small establishments are approximately $11,760, which is about $218 per establishment. This represents an average annual cost per bird of approximately 0.098 cents, or 0.025 cents per pound, based on the assumption that very small establishments slaughter about 12 million birds annually, at an average weight of about 4 pounds per bird.

TABLE 7c—ESTIMATED ANNUAL COST (COST SAVINGS) OF THE RULE TO VERY SMALL HACCP SIZE ESTABLISHMENTS (54) FOR ELEMENTS ASSOCIATED WITH THE MANDATORY COMPONENT OF THE NEW RULE

[Thousands of dollars]

	Year 1	Recurring
Additional PC microbial testing—plate counts, collection, packaging, shipping		
One-time baseline (including recordkeeping)	4.25	
Annual recurring testing	22.47	22.47
Annual recordkeeping, monitoring, and record storage	0.77	0.77
Eliminated generic *E. coli* testing recordkeeping	(0.77)	(0.77)
One-time HACCP system plans and Process Control (PC) plan development (item 11.a)	108.00	
Reduced annual microbial testing—generic *E. coli* plate counts	(25.64)	(25.64)
Total costs to establishments from mandatory component	109.07	(3.18)
Annualized total costs (7% for 10 years)	11.76	
Annualized total costs (3% for 10 years)	9.60	

Expected FSIS Budgetary Effects

Table 8 shows the potential FSIS budgetary net savings from the rule for the slaughter of all poultry other than ratites and including the NPIS for the slaughter of young chickens and turkeys.

FSIS used the following scenario assumptions to project the potential FSIS budgetary effects of the rule:

- Of the 219 establishments that may adopt the NPIS, an estimated 175 establishments (150 young chicken establishments and 25 turkey establishments) may be affected by FSIS

[36] These costs annualized to about $25.3 million over 10 years using a 3 percent discount rate.

[37] In the final rule, FSIS is permitting very small HACCP size establishments to sample at one location, post-chill. Moreover, FSIS is permitting very low volume establishments to sample at a frequency similar to what is required presently. FSIS expects cost per sample to decrease because FSIS is no longer requiring establishments to sample for generic *E. coli,* but is permitting establishments to sample for other indicator organisms that are less expensive to analyze and expected to be more predictive of food safety concerns.

personnel changes. The estimated 175 establishments do not include the 25 young chicken and turkey establishments currently operating under the HIMP program. FSIS also excluded approximately 19 other poultry establishments currently operating under the SIP waivers, even though FSIS expects them to choose to participate in the NPIS because FSIS expects the impact on these 19 establishments to be relatively small. Establishments that change operations but continue to produce will continue to have FSIS inspectors.

- 1,498 food inspector grade increases (from GS–7 to GS–8) (1,284 inspectors in young chicken establishments and 214 inspectors in turkey establishments)
- 241 relief inspector grade increases (GS–7 to GS–8) [38]
- FSIS is uncertain of the size of any reduction of food inspector positions through managing vacancy or refill rates. Some personnel are also expected to voluntarily retire. The range of potential reductions is 0 to 630 (see table 8b). For purpose of this analysis, FSIS includes the maximum potential change to calculate the maximum potential effect. Approximately 190 of the 630 inspector positions will be relocated to existing vacancies within the agency.
- FSIS is uncertain of the size of any reduction of approximately 140 Supervisory Consumer Safety Inspector (SCSI) positions. The range of potential reductions is 0 to 140 (see table 8b). For purpose of this analysis, FSIS includes the maximum potential change to calculate the maximum potential effect. Of those 140 SCSI personnel, approximately 112 will be relocated to existing vacancies within the agency with the remaining number expected to retire.
- Training costs to include training of promoted personnel and training for all personnel on the NPIS implementation processes.

TABLE 8—ESTIMATED POTENTIAL ANNUAL COST (COST SAVINGS) OF THE RULE TO FSIS: ELEMENTS ASSOCIATED WITH THE NEW POULTRY INSPECTION SYSTEM

[Millions of dollars]

Category	Year 1	Year 2	Year 3	Year 4	Year 5	Recurring
Cost from Grade Increases (Salary & Benefits)	$1.2	$3.5	$5.8	$7.0	$7.4	$7.6
Savings From Positions Eliminated	($5.2)	($16.9)	($28.6)	($36.1)	($38.1)	($39.0)
Training Costs	$2.0	$2.0	$2.0	$0.3	$0.3	$0.0
Relocation Costs	$1.4	$1.4	$1.4	$0.2	$0.2	$0.0
Total Cost (Savings)	($0.6)	($10.0)	($19.4)	($28.5)	($30.1)	($31.4)

Source: FSIS, Office of the Chief Financial Officer.

TABLE 8b—ESTIMATED POTENTIAL BUDGETARY EFFECTS TO FSIS BY ADOPTION RATE: ELEMENTS ASSOCIATED WITH THE NEW POULTRY INSPECTION SYSTEM

Category	Adoption Rate						
	0%	10%	25%	50%	75%	90%	100%
Food Inspector Grade Increases	.....	150	375	749	1,124	1,348	1,498
Relief Inspector Grade Increases	.....	24	60	121	181	217	241
Reduction in Food Inspector Positions	.....	63	158	315	473	567	630
Reduction in Supervisory Consumer Safety Inspectors	.....	14	35	70	105	126	140

FSIS expects a potential net cost savings of $0.6 million in the first year of implementation. FSIS expects potential net cost savings to total $10.0 million the second year of implementation. Cost savings from position elimination (potentially totaling $16.9 million) scale with the number of establishments that opt into NPIS and will therefore more than offset the increase in one-time costs the agency will incur the second year. Potential annual cost savings are expected to total $31.4 million after the fifth year. The Agency's potential annual costs for FSIS food and relief inspectors upgrades from GS–7 to GS–8 will increase to $7.6 million after the fifth year of adoption. These additional costs will be more than offset by the Agency's annual cost savings from position elimination, potentially totaling $39.0 million.

Expected Benefits Associated With the New Poultry Inspection System—Public Health Benefits From Reallocating FSIS Inspection Activities

FSIS hypothesizes that switching existing FSIS IPP activities towards more offline verification activities (such as sanitation performance standards, sampling, other inspection requirements, and fecal inspections) will reduce pathogen levels in poultry slaughter establishments. This is supported by the regression analysis of historical data presented in the FSIS Risk Assessment (July 2014), which found a significant correlation between more offline 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.

In Table 5 of FSIS' Risk Assessment (July 2014), FSIS presents estimates that industry-wide adoption of NPIS would reduce the number of human illness attributed to young chicken and turkey products by an average of about 3,980 (with a range of 1,510 to 6,960) *Salmonella* illnesses and about 840 (with a range of 100 to 1,860) *Campylobacter* illnesses. Annual *Salmonella* cost savings from an averted

[38] Some inspection personnel will be promoted from GS–7 to GS–8 due to assuming higher graded duties. These new Carcass/Verification Inspector positions will perform routine and directed inspection verification tasks to evaluate the establishment's regulatory compliance and process control. The inspector collects samples for pathogen testing, performs certain sample analysis, and conducts post-mortem and ante-mortem inspection. The inspector also performs verifications of good commercial practices, zero tolerance for fecal and septicemia/toxemia, establishment microbiological testing for preventing contamination throughout operations, food safety systems, and sanitary dressing requirements.

case is estimated to be $2,423 [39] and the annual *Campylobacter* cost savings from an averted case is estimated to be $2,067.[40] Thus, FSIS estimates that the potential monetized value of the human illness reductions is an annual average of about $11.38 million (with a range of $3.87 million to $20.71 million). These estimates may underestimate the average cost of illness because they include medical costs and loss-of-productivity costs. They do not include pain and suffering costs or, in the case of *Salmonella,* the cost of accelerated mortality.

TABLE 9—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 young chicken and turkey establishments have the anticipated increase in unscheduled offline inspection procedures?[1 2 3 4 5]		
	Range		
	Expected Value	10th Percentile	90th Percentile
Annual *Salmonella* Cost Savings [6] and Averted Illnesses:	$9.64 million (3,980 illnesses averted)	$3.66 million (1,510 illnesses averted)	$16.86 million. (6,960 illnesses averted).
Annual *Campylobacter* Cost Savings [7] and Averted Illnesses:	$1.74 million (840 illnesses averted)	$0.21 million (100 illnesses averted)	$3.84 million. (1,860 illnesses averted).
Annual Total Cost Savings	$11.38 million	$3.87 million	$20.71 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. FSIS selected this scenario to represent expected reduction in illnesses because it involved an increase in targeted off-line inspection activities and not a random increase in all off-line inspection activities, as represented in the indiscriminate scenario.

[3] Totals may not add up due to rounding.

[4] These estimates represent a lower bound for an average cost of illness because they only include medical costs, loss-of-productivity costs (*Salmonella* and Campylobacter), and the value of reduced mortality (*Campylobacter* only). They do not include pain and suffering costs.

[5] FSIS explored—using a modified database—the effect of the very small plants on the output of the risk assessment. Specifically, it used additional regression modeling post-analysis to look at what impact the removal of very small establishments would have on the risk assessment results (see the risk assessment for further details). That post-analysis showed no discernible difference from inclusion of very small establishments in the changes in attributable human illnesses due to the poultry slaughter rule.

[6] The FSIS estimate for the average cost of *Salmonella* illnesses ($2,423 per case—2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June-2011). FSIS updated the ERS calculator to include Scallan case distribution for *Salmonella.* Scallan, E., Hoekstra, R., Angulo, F., et.al. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases,* 17 (1), 7–15.

[7] The FSIS estimate for the average cost of *Campylobacter* illnesses ($2,067 per case—2009 dollars, the latest cost per illness data available) is based on Hoffman (2012). Annual Cost of Illness and QALY-Adjusted Life Year Losses in the United States Due to Fourteen Foodborne Pathogens. *Journal of Food Protection, 75*(7), 1292–1302. The ERS Cost calculator does not include an estimate for *Campylobacter* illnesses.

Potential annual benefits as shown in Table 9 would not be realized fully unless and until all establishments convert to NPIS. Since the adoption of NPIS may occur over a five year period, FSIS estimated the incremental public health benefits that would be achieved under this scenario as establishments make the transition to the new system. FSIS used approximate volume distributions [41] along with the assumed implementation timeline to calculate these estimates, displayed in Table 10.

TABLE 10—ESTIMATED INCREMENTAL PUBLIC HEALTH BENEFITS IF ALL LARGE AND SMALL NON-TRADITIONAL ESTABLISHMENTS ADOPT NPIS WITHIN 5 YEARS

	Year 1	Year 2	Year 3	Year 4	Recurring
Salmonella Cost Savings	2.89	5.78	8.68	9.16	9.64
Campylobacter Cost Savings and Incremental Longevity Value	0.52	1.04	1.57	1.65	1.74
Total Cost Savings and Incremental Longevity Value	3.41	6.83	10.24	10.81	11.38
10th Percentile	1.16	2.32	3.48	3.68	3.87
90th Percentile	6.21	12.42	18.63	19.67	20.70

	Expected value	10th Percentile	90th Percentile
Annualized total cost savings and Incremental Longevity Value (7% for 10 years)	9.56	3.25	17.39
Annualized total cost savings and Incremental Longevity Value (3% for 10 years)	9.79	3.33	17.81

[39] The FSIS estimate for the average cost of *Salmonella* illnesses ($2,423 per case—2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June-2011). FSIS updated the ERS calculator to include Scallan case distribution for *Salmonella.* Scallan, E., Hoekstra, R., Angulo, F., et.al. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases,* 17 (1), 7–15.

[40] The FSIS estimate for the average cost of *Campylobacter* illnesses ($2,067 per case—2010 dollars) is based on Hoffman (2012). Annual Cost of Illness and QALY-Adjusted Life Year Losses in the United States Due to Fourteen Foodborne Pathogens. *Journal of Food Protection, 75*(7), 1292–1302. The ERS Cost calculator does not include an estimate for *Campylobacter* illnesses.

[41] See footnote 27.

Unquantifiable Benefits and Costs Associated With NPIS and the Mandatory Portion of the Rule—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 benefits associated with an increase in line speed for turkey establishments. Turkey establishments will have the option of increasing their line speed from a maximum of 51 to 55 birds per minute. Establishments will determine their line speeds based on their equipment and facilities, bird size and flock conditions, and their ability to maintain process control when operating at a given line speed.

FSIS also expects public health benefits from the mandatory component of the rule, which will apply to all poultry slaughter establishments. FSIS is requiring 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 requiring 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. The exceptions are for very small HACCP size establishments and very low volume establishments that choose to operate under the modified Traditional Inspection System for which FSIS will permit sampling at post-chill only if they show that testing at one location is sufficient. 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 enhance compliance with this requirement, FSIS is requiring that establishments develop, implement, and maintain written procedures that ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller.

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, this result generally cannot be effectively accomplished unless establishments implement appropriate measures to prevent contamination from occurring throughout the slaughter and dressing operation and implement process controls for them.

Although many establishments do have process control measures in place 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 measures and process controls or to maintain records to verify the effectiveness of their process controls in preventing contaminated carcasses from entering the chiller. Written plans that describe an establishment's procedures and controls, including monitoring and evaluation criteria, will greatly aid establishments in consistently ensuring compliance with preventing fecal material on carcasses from entering the chiller. The written plans and record keeping requirement of this rule will also aid FSIS's inspectors in evaluations of an establishment's procedures that are designed to ensure compliance with the regulations.

In addition, under the existing regulations, official poultry slaughter establishments are required to comply with 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 might not be the most effective way to prevent contamination from occurring throughout the slaughter and dressing operation. Therefore, FSIS is removing the generic *E. coli* testing requirements and replacing them with a more microbiological-focused testing scheme that provides for testing at the pre-chill and post-chill locations. Such a testing scheme has the benefit of allowing poultry slaughter establishments to have the flexibility they need to determine which microbiological organisms and measurement procedures will best help them to monitor the effectiveness of their process control procedures. This will lead to more tailored, and thus more effective process monitoring and quicker response to out of control processing, thereby reducing contamination of pathogens on carcasses.

The information and procedural enhancements described above may be followed by the disposal of contaminated product, cooking the product longer, or other cost-generating actions by the establishment. Thus, any unquantified public health benefits of the rule may be accompanied by unquantified industry costs.

In summary, FSIS is requiring 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 rule, including the records of the establishment's testing results, will provide an establishment with ongoing information on the effectiveness of its process controls, and allow it to identify situations associated with an increase in microbial levels so that it can take the necessary corrective actions to prevent further potential contamination. The documentation could result in the lower probability of recall, resulting in enhanced product reputation when a product is not subject to recall, which would benefit the implementing establishment. The rule's documentation requirements could also lower the costs of identifying contaminated product of a recall as well as limit the scope of a product recall should a recall occur, since the establishment records would allow it to identify the point when a lack of process control could have resulted in product contamination.

Summary of Net Benefits

Considering the benefits and costs discussed, if we were to assume for purposes of analysis that all small and large non-Traditional establishments were to switch to NPIS, FSIS expects average benefits to the public health and FSIS of about $32.4 million (annualized, 10-years at 7 percent). In this case, annualized (10-years, at 7 percent) industry costs are an estimated $25.1 million. Annual net benefits, therefore, would be an estimated $7.3 million. Table 11 provides the summary of estimated annualized net benefits for various possible percentages of the industry that switch to NPIS. As noted above, NPIS may provide an incentive for establishments to switch from their current inspection systems to NPIS; however, it is possible that the costs associated with NPIS adoption will be

greater than the potential benefits for some establishments. Given the lack of data with which to make cost-benefit comparisons across the industry, Table 11 presents a wide range of possibilities for the percentage of large and small non-Traditional establishments that will choose to adopt NPIS.

TABLE 11—ESTIMATED NET SOCIAL BENEFITS FROM THE RULE (MILLIONS OF DOLLARS), ANNUALIZED OVER 10 YEARS WITH A 7% DISCOUNT RATE, FOR VARYING PERCENT CHANGES THAT SWITCH TO NPIS

	Percentage of Industry that Switches to NPIS [1]						
	0%	10%	25%	50%	75%	90%	100%
NPIS: [2]							
Benefits:							
Public health benefits (10%, 90%)	0.0	1.0 (0.3 to 1.7)	2.4 (0.8 to 4.3)	4.8 (1.6 to 8.7)	7.2 (2.4 to 13.0)	8.6 (2.9 to 15.7)	9.6 (3.3 to 17.4)
FSIS net savings	0.0	2.3	5.7	11.4	17.1	20.5	22.8
Unquantified benefits [3]	Increased flexibility for establishments to design and implement production measures tailored to their operations, in some cases possibly including increased line speed up to 140 chickens or 55 turkeys per minute						
Costs:							
Costs to establishments	0.0	1.6	4.0	8.0	12.0	14.4	16.0
Unquantified costs [3]	Industry costs of responding to new NPIS inspections in a manner that may lead to public health benefits (e.g., discarding contaminated food or cooking it longer)						
Mandatory Component:							
Costs to establishments	9.1	9.1	9.1	9.1	9.1	9.1	9.1
Unquantified benefits	Potential additional public health benefits from documentation and testing						
Unquantified costs	Industry costs of responding to information generated by documentation and testing in a manner that may lead to public health benefits (e.g., discarding contaminated food or cooking it longer)						
Total benefits (10%, 90%)	0.0	3.3 (2.6 to 4.0)	8.1 (6.5 to 10.0)	16.2 (13.0 to 20.1)	24.3 (19.5 to 30.1)	29.1 (23.4 to 36.2)	32.4 (26.0 to 40.2)
Total costs	9.1	10.7	13.1	17.1	21.1	23.5	25.1
Net benefits (10%, 90%)	−9.1	−7.4 (−8.1 to −6.7)	−5 (−6.6 to −3.1)	−0.9 (−4.1 to 3.0)	3.2 (−1.6 to 9.0)	5.6 (−0.1 to 12.7)	7.3 (0.9 to 15.1)

[1] For costs and FSIS net savings, the relevant industry measure is the percentage of large and small establishments that switch to NPIS, whereas for public health benefits, the relevant industry measure is percentage of product volume that is slaughtered in establishments that switch to NPIS.

[2] The switch to NPIS includes two sets of policy changes: (1) the removal of some online FSIS inspectors, which generates labor cost savings for NPIS, costs to industry of training and attestation, and the unquantified benefit to establishments of increased flexibility, and (2) the increase in offline inspection activities by FSIS, which generates the estimated public health improvements, the associated unquantified costs, the quantified costs to industry of installing new inspection stations, and the quantified costs to FSIS of grade increases, training and relocation.

[3] As with quantified costs and benefits, unquantified NPIS-related cost and benefit estimates would be scaled proportionately to reflect the percentage of the industry that switches to NPIS.

4 Annualized Over 10 Years with a 3% discount rate at 100% adoption rate, total benefits (10%, 90%) equal $33.6 million (27.1 to 41.6), total costs equal $25.3 million. Net benefits equal $8.3 million (1.8 to 16.3).

Analysis of Considered Alternatives

TABLE 13—COMPARISONS OF THE CONSIDERED ALTERNATIVES TO THE FINAL POULTRY SLAUGHTER RULE

Considered alternatives	Benefits	Costs [1]	Net benefits
A. Taking No Action	No change in the existing inspection systems for poultry. FSIS does not need significantly more resources.	Establishments would maintain existing practices.	Zero Net Benefits.
B. The Rule	Public health benefits from reduced illnesses and FSIS savings add to total benefits of $26.0 million to $40.2 million annually. Additional unquantified public health benefits from NPIS and mandatory components of the rule.	Annualized costs equal $25.1 million. See Tables 7a and 7b above for explanation of these costs.	Selected Alternative with annualized net benefits equal $7.3 million.
C. The Final Rule Without Offline Inspection Activity.	Additional FSIS cost savings associated with a reduction in offline inspector positions.	Annualized costs equal to Alternative B.	Net benefits will be lower than Alternative B due to loss of public health benefits.

TABLE 13—COMPARISONS OF THE CONSIDERED ALTERNATIVES TO THE FINAL POULTRY SLAUGHTER RULE—Continued

Considered alternatives	Benefits	Costs [1]	Net benefits
D. Requiring Only the New Poultry Inspection System.	Public health benefits from reduced illnesses and FSIS savings add to total benefits of $26.1 million to $40.2 million annually No additional unquantified benefits, as detailed in section titled ''Unquantifiable Benefits Associated with the Mandatory Portion of the Rule.''.	Annualized costs greater than $20.5 million. All establishments not included in Alternative B will accrue additional costs.	The net benefits will be lower than Alternative B due to the increased burden on very small establishments.

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. FSIS rejected this alternative because the NPIS will allow poultry establishments slaughtering young chickens, turkeys and other poultry to benefit and to enhance their food safety efforts through increased flexibility and 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). Therefore this alternative would not result in any public health benefits. This action will have zero net benefits.

B. The Rule

FSIS's preferred alternative is the final rule as discussed above. The final rule has an elective NPIS for young chickens and turkeys; a modified Traditional Inspection System for all poultry other than ratites; requirements 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, two locations for sampling for microbial organisms to monitor process control for enteric pathogens (except HACCP very small and very low volume establishments); and other actions (see Table 2).

The rule gives the individual establishment the choice between the NPIS (with or without the HIMP SIP waiver), the modified Traditional Inspection System, and their current inspection system (SIS, NELS, or NTIS). An establishment will choose the NPIS if the benefits, primarily from the expected increased flexibility of operations, exceed the costs of implementation. While this would probably be true for the HACCP large and HACCP small establishments that slaughter young chickens and turkeys, it may not be true for the HACCP very small establishments. FSIS selected this alternative to minimize the impact on very small establishments and to allow them the flexibility to choose the modified Traditional Inspection System or their current inspection system if they stand to lose from the NPIS.

Public health benefits (as discussed in section titled ''Expected Benefits Associated with the NPIS—Public Health Benefits from Reallocating FSIS Inspection Activities'') of the rule include a reduction in illnesses attributed to young chicken and turkey. The monetized annualized value of this reduction is $3.3 million to $17.4 million. FSIS annualized savings under the rule are expected to equal $22.8 million.

Costs of the rule include $16.0 million annualized for the conversion of establishments to NPIS, and $9.1 million annualized (10 years, 7 percent) for the mandatory component of the rule (see Tables 7a and 7b). This corresponds to total costs of about $25.1 million annualized. Net benefits of the rule are estimated at $7.3 million.

C. The Rule Without Offline Inspection Activities

Removing the offline inspectors would eliminate the health benefits of the rule which is the main purpose of the rule. While removing offline inspectors might affect the savings for FSIS, the Agency could not estimate any additional savings at this time because the offline inspectors were part of an integrated inspections plan so the offline inspectors could not be pulled out of the plan or the estimate. More importantly, any changes to FSIS savings would be insignificant compared to the loss of public health benefits.

D. Requiring the New Poultry Inspection System

FSIS considered requiring that all establishments convert to the NPIS. The benefits from this alternative include, as under the rule, the budgetary savings to FSIS from reallocation of personnel and public health benefits of $9.6 million annually from reduced illnesses.

As shown in Table 7a, costs to firms that adopt the new rule are about $16.0 million annualized over 10 years at 7 percent.

Under this alternative, all firms, including the very small firms that FSIS expects will not adopt the rule, must adopt some measures, as listed in Table 7b. These costs are from plan development, recordkeeping and testing. The benefits [42] of these activities include the conduct of business in a manner more accountable to the public; the support and documentation of production safety decision-making; and the facilitation of oversight and transparency activities like audits and inspections. The recordkeeping requirements are designed to help operators of facilities and the Agency to identify potential sources of contamination as well as contain and mitigate the adverse health effects of contaminated food. Many of these benefits are unquantifiable: the lower probability of recall, the lower costs of identifying contaminated product if a recall occurs, and enhanced product reputation when a product is not subject to recall, all benefit the implementing firms. Table 7c lists the mandatory costs that FSIS expects for the 54 very small establishments that FSIS projects will not adopt the new inspection system.

This alternative would result in higher costs for the industry, specifically for very small establishments that would have difficulty absorbing such costs. The annual benefits would be the same as alternative B, the rule. FSIS rejected this

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

alternative because it would result in lower net benefits.

V. Final Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, FSIS reviewed the rule for its effects on small businesses. In response to public comments received on the impact on small business, FSIS relaxed the proposed requirement for small businesses to sample and test at pre-chill and post-chill to allow very small HACCP size establishments to sample and test only at post-chill. In addition, FSIS is maintaining its present sampling frequency requirement for very low volume establishments. This change reduces the costs imposed on small establishments. The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this rule will not have a significant economic impact on a substantial number of small entities in the United States.

In this final regulatory flexibility analysis, FSIS first analyzes the impact on the Agency-assigned HACCP small and very small size categories. Then, FSIS highlights the minimal impact of the regulation on very small and small companies.

FSIS will modernize and streamline poultry slaughter inspection because of its 2011 regulatory review. 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.

In this final regulatory flexibility analysis, FSIS uses a definition of small entities that is similar, but not identical, to that used by the Small Business Administration [43] and is more appropriate with respect to estimating possible adverse economic effects. The Small Business Administration defines a small business in terms of ownership, while the HACCP production size definition [44] applies to individual establishments and not companies that might own more than one establishment. FSIS considers establishments to be the economic entity of interest in this rule and thus uses the HACCP size definition to characterize establishments that this rule might affect adversely.

FSIS considered requiring the mandatory use of dressing performance standards and the NPIS in all federally inspected establishments that slaughter young chickens and turkeys, but rejected that alternative in order to provide small and very small HACCP size establishments with a choice between using the NPIS, or using the modified Traditional Inspection System. Given a choice, FSIS anticipates that large and small HACCP size establishments that slaughter young chickens and turkeys will find it in their economic interest to adopt the new inspection system. In contrast, FSIS anticipates that HACCP very small establishments that slaughter young chickens and turkeys will choose to operate under the modified Traditional Inspection System. The very small HACCP size young chicken and turkey establishments, in general, do not have sufficient output volume over which to spread the initial set-up costs of the NPIS or the training and maintenance costs resulting from this system. There are 51 such establishments. In addition, HACCP establishments that slaughter poultry other than young chickens and turkeys will operate under the modified Traditional Inspection System. There are 19 establishments that slaughter poultry other than young chickens and turkeys, of which 14 are small HACCP size establishments and three are very small HACCP size establishments. Consequently, we identify 68 establishments that might not realize the full benefits of the rule. Table 14 shows the number of poultry slaughter facilities by HACCP size and type of poultry slaughtered based on the above discussion.

TABLE 14—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 establishments
Young Chicken and Turkeys	51	70	149	270	93
Other Poultry	3	14	2	19	7
Total	54	84	151	289	100

In Table 15, in contrast to Table 15, FSIS classified the 289 establishments into the appropriate SBA categories in order to show the establishment distribution over SBA small and large companies by number of companies and number of establishments.

TABLE 15—DISTRIBUTION OF ESTABLISHMENTS OVER SBA DEFINED SMALL AND NOT-SMALL COMPANIES

Company size (SBA definition)	Number of companies	Number of establishments	Share of establishments
Small	109	110	38%
Large	49	179	61%
Total	158	289	100%

Approximately 38 percent, or 110, of all establishments belong to SBA small companies. Some of the SBA companies are not very low volume slaughter operations and FSIS expects many will choose to operate under NPIS.

[43] The Small Business Administration defines a small business in poultry processing as an entity that is independently owned and operated, is organized for profit, is not dominant, and has 500 or fewer employees.

[44] HAACP production size classes: large establishments, with 500 or more employees; small establishments, with 10–499 employees; and very small establishments, with fewer than 10 employees or annual sales of less than $2.5 million.

Consequently, to measure possible adverse impact on small business, FSIS's analysis concentrates on the 68 establishments identified above.

Cost Impact—Very Small Establishments

FSIS projects the costs of the mandatory component of the rule to be approximately $218, annualized over 10 years at a 7 percent discount rate, per very small HACCP size establishment processing young chickens, turkeys, or other types of poultry, for a total of about $11,759 annualized annualized across the existing 54 very small establishments (Table 7c). FSIS expects net annual recurring cost savings after the sixth year, because the rule permits these establishments to design more efficient process control plans, and sample only at one location. The cost savings associated with eliminating generic *E. coli* testing will more than offset the additional costs associated with the new required microbial testing requirement because the cost of analyzing for generic *E. coli* is more than that of analyzing for other indicator organisms and FSIS does not expect the number of samples per year to increase from the present.

Cost Impact—Small Establishments

For the 14 small HACCP size poultry slaughter establishments covered in this rule that do not process young chickens and turkeys, FSIS projects costs of the mandatory component of the rule to be approximately $11,579, annualized 10 years at a 7 percent discount rate, per establishment, for a total of about $162,100 annualized across all 14 establishments. Net annual recurring costs are approximately $10,319 per establishment after the sixth year, for a total of $144,470 across all 14 small establishments.

Cost Impact—Total

Table 16 presents the combined cost impact for both very small HACCP size establishments (Table 7c) and small HACCP size establishments that do not slaughter young chickens and turkeys.

TABLE 16—ESTIMATED ANNUAL COST (OR COST SAVINGS) OF THE RULE FOR VERY SMALL HACCP SIZE ESTABLISHMENTS THAT PRODUCE YOUNG CHICKENS AND TURKEYS AND SMALL HACCP SIZE ESTABLISHMENTS THAT SLAUGHTER POULTRY OTHER THAN YOUNG CHICKENS AND TURKEYS

HACCP size	Number of establishments	Year 1	Recurring	10 Year annualized	
				7%	3%
Very Small	54	$109,069	($3,177)	$11,759	$9,599
Small	14	$276,960	$144,470	$162,100	$159,549
Total	68	$386,029	$141,293	$173,859	$169,148

VI. Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this final rule is adopted: (1) All State and local laws and regulation that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties ay file suit in court challenging this rule.

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 final 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 Non-Discrimination Statement

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax

(202) 690–7442.

Email

program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

X. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the new information collection requirements included in this final 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 final rule, each official poultry slaughter establishment will need to maintain as part of its HACCP plan, 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 New Poultry Inspection System (NPIS) will also be required to maintain, as part of its HACCP system, written procedures to prevent carcasses afflicted with septicemia and toxemia from entering the chiller. The procedures addressing prevention of contamination by enteric pathogens will need to include microbial testing. In addition, each establishment operating under NPIS will need to maintain records that document that the products resulting from its slaughter operations meet the definition of ready-to-cook poultry. Each establishment operating under the NPIS will also need to submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers.

The requirement that poultry slaughter establishments have written procedures in their HACCP plans, 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). Therefore, this requirement of this rule creates no new burden on establishments.

The requirement that poultry slaughter establishments monitor their systems through microbial testing and recordkeeping creates a new information collection burden. For each sample for which a microbial test is conducted, there are two ''responses'' for the establishment: one response for the actual collecting of the sample and sending it to the laboratory for analysis, and the other for recording the sample result. In its initial paperwork burden estimate, FSIS estimated that large establishments would test and record microbial results at the two prescribed locations (pre- and post-chill), 15 times a day; small establishments, 7 times a day; and very small establishments, 3 times a day. These estimates were based on the frequency with which establishments operating under a Salmonella Initiative Program (SIP) waiver conduct sampling. Under SIP, FSIS grants establishments a waiver of regulations under the condition that the establishment collects and analyzes samples for microbial organisms and shares the results with FSIS.

In this final rule, FSIS has revised the regulations to prescribe a minimum frequency with which all establishments that slaughter poultry will need to conduct testing for microbial organism to monitor their process control procedures. FSIS has also revised the testing requirements to allow very small and very low volume establishments to conduct sampling at the post-chill point in the process only. These revisions are substantive changes that have resulted in a reduction in burden. Therefore, FSIS has updated its paperwork burden estimates to reflect these changes and has submitted the revised information and recordkeeping requirement to OMB for review.

The average burden per response and the annual burden hours are explained below and summarized in the charts which follow.

Estimated Annual Burden: Poultry Slaughter Inspection.

Recordkeeping:

Estimated Annual Recordkeeping Burden for Modernization of Poultry Slaughter Inspection

Respondents: Official poultry establishments.

Estimated Number of Respondents: 289.

Estimated Average Annual Number of Responses (samples) per Respondent: Large establishments 4,322.7; small establishments 1,318; very small establishments 21.3.

Estimated Total Annual Responses: 764,594.

Estimated Total Annual Recordkeeping Burden: 31,858 hours.

Respondents		Estimated number of respondents	Average annual number of responses per respondent	Total annual responses	Time per response in minutes	Total annual burden hours
Large establishments	Microbial testing data record-keeping.	151	4,322.7	652,773	2.5	21,197
Small establishments	Microbial testing data record-keeping.	84	1,318	110,712	2.5	4,613
Very small establishments	Microbial testing data record-keeping.	54	21.3	1,134	2.5	48
Total Recordkeeping Burden		289	2,645.6	764,594	2.5	31,858

Reporting

Estimated Annual Reporting Burden for Poultry Slaughter Inspection

Respondents for this Rule: Official poultry establishments.

Estimated Number of Respondents: 289.

Estimated Average Annual Number of Responses per Respondent: Large establishments 4,322.7; small establishments 1,318; very small etablishments 21.3.

Estimated Total Annual Responses: 764,594.

Estimated Total Annual Reporting Burden on Respondents: 159,339 hours.

Respondents		Estimated number of respondents	Average annual number of responses per respondent	Total annual responses	Time per respone in minutes	Total annual burden hours
Large establishments	Microbial testing	151	4,322.7	652,773	12.5	135,986
Small establishments	Microbial testing	84	1,318	110,712	12.5	23,065
Very small establishments	Microbial testing	54	21.3	1,134	15	288

Respondents		Estimated number of respondents	Average annual number of responses per respondent	Total annual responses	Time per respone in minutes	Total annual burden hours
Total Reporting Burden	.....	289	2,645.6	764,594	.....	159,339

SUMMARY OF BURDEN—POULTRY SLAUGHTER INSPECTION

Total No. respondents	289
Average Annual No. responses per respondent ...	5,291.3
Total annual responses	1,529,188
Average hours per response	.125
Total annual burden hours ...	191,197

In this final rule, FSIS is adding a new regulation that creates a new information collection burden, in that it requires that poultry slaughter establishments operating under the NPIS submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers. This is a new recordkeeping requirement that FSIS has submitted to OMB for approval.

The average burden per response and the annual burden hours are explained below and summarized in the charts which follow.

Estimated Annual Burden: Poultry Slaughter Inspection

Reporting:

Estimated Annual Reporting Burden for Submitting an Annual Attestation on Work-Related to the FSIS Circuit Safety Committee

Respondents: Official poultry establishments that operate under the NPIS.

Estimated Maximum Number of Potential Respondents: 219.

Estimated Average Annual Number of Responses per Respondent: Large establishments 1; small establishments 1; very small establishments 0.

Estimated Maximum Total Potential Annual Responses: 219.

Estimated Total Annual Recordkeeping Burden: 7.27 hours.

Maximum potential respondents: establishments operating under the NPIS		Estimated number of potential respondents	Average annual number of responses per potential respondent	Total annual potential responses	Time per potential response in minutes	Total potential annual burden hours
Large establishments	Attestation on Work-Related Conditions.	149	1	149	2	4.97
Small establishments	Attestation on Work-Related Conditions.	70	1	70	2	2.3
Very small establishments	.....	0	0	0	.....	0
Total Reporting Burden	.....	219	1	219	.....	7.27

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Ave. SW., Room 6065 South Building, Washington, DC 20250–3700; (202) 720–5627.

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 information collection 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 on the proposed information collection may be sent to both Gina Kouba, 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 final rule.

XI. 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 final rule, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Final_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 email 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 email 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.

List of Subjects

9 CFR Part 381

Poultry inspection, Poultry products, Reporting and 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 amending 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. Amend § 381.36 by adding a new paragraph (f) to read as follows:

§ 381.36 Facilities required.

* * * * *

(f) *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(b)(6)(ii), 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 (f)(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 designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. 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 have a safe lift mechanism and 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 effect, 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 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 total number of offline verification inspection 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 foot-candles 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 young chicken 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 foot-candles 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. A new subpart H is added to part 381 to read as follows:

Subpart H—Attestation on Work-Related Conditions

Sec.
381.45 Attestation requirements.
381.46 Severability.

§ 381.45 Attestation requirements.

Each establishment that participates in the New Poultry Inspection System (NPIS) shall submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers, and that the program includes the following elements:

(a) Policies to encourage early reporting of symptoms of injuries and illnesses, and assurance that it has no policies or programs in place that would discourage the reporting of injuries and illnesses.

(b) Notification to employees of the nature and early symptoms of occupational illnesses and injuries, in a manner and language that workers can understand, including by posting in a conspicuous place or places where notices to employees are customarily posted, a copy of the FSIS/OSHA poster encouraging reporting and describing reportable signs and symptoms.

(c) Monitoring on a regular and routine basis of injury and illness logs, as well as nurse or medical office logs, workers' compensation data, and any other injury or illness information available.

§ 381.46 Severability.

Should a court of competent jurisdiction hold any provision of this part 381, subpart H to be invalid, such action shall not affect any other provision of this part 381.

■ 4. Amend § 381.65 as follows:

■ a. Redesignate paragraphs (e) and (f) as paragraphs (f) and (e) respectively.

■ b. Revise newly redesignated paragraph (f).

■ c. Add new paragraphs (g) and (h).

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 chiller. 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 operation.* Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens 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 in accordance with the sampling location and frequency requirements in paragraphs (g)(1) and (2) of this section to monitor their ability to maintain process control.

(1) *Sampling locations.* Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process.

(i) Very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million.

(ii) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

(2) *Sampling frequency.* (i) Establishments, except for very low volume establishments as defined in paragraph (g)(1)(ii) of this section, must, at a minimum, collect and analyze samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) *Chickens.* Once per 22,000 carcasses, but a minimum of once during each week of operation.

(B) *Turkeys, ducks, geese, guineas, and squabs.* Once per 3,000 carcasses, but at a minimum once each week of operation.

(ii) Very low volume establishments as defined in paragraph (g)(1)(ii) of this section must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a very low volume establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan.

(iii) Establishments must sample at a frequency that is adequate to monitor their 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 establishments 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 if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

■ 5. Amend § 381.66 as follows:

■ a. Revise paragraph (b).

■ b. Remove paragraphs (c)(3) and (4).

■ c. Revise paragraph (e).

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 predominately with air. An antimicrobial intervention may be applied with water at the beginning of the chilling process, provided that its use does not result in any net pick-up of water or moisture during the chilling process. The initial antimicrobial intervention may result in some temperature reduction of the product, provided that the majority of temperature removal is accomplished exclusively by chilled air.

* * * * *

■ 6. Add § 381.69 to subpart I to read as follows:

§ 381.69 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 140 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 their 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.

(d) Establishments operating under the line speed limits authorized in this section shall comply with all other applicable requirements of the laws, including, but not limited to, 29 U.S.C. 654(a).

■ 7. Amend § 381.76 as follows:

■ a. Revise the section heading.

■ b. Revise paragraphs (a), (b)(1) introductory text, (b)(1)(iv), and (b)(2).

■ c. Add paragraphs (b)(1)(v) and (b)(6).

The revisions read as follows:

§ 381.76 Post-mortem inspection under Traditional Inspection, the Streamlined Inspection System (SIS), the New Line Speed (NELS) Inspection System, the New Poultry Inspection System (NPIS), the New Turkey Inspection System (NTI), 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)(1) There are six systems of post-mortem inspection: the New Poultry Inspection System (NPIS), which may be used for young chickens and turkeys; the Streamlined Inspection System (SIS) and the New Line Speed Inspection System (NELS), both of which may be used only for broilers and cornish game hens; the New Turkey Inspection (NTI) System, which may be used only for turkeys; Traditional Inspection, which may be used for all poultry, except for ratites; and Ratite Inspection.

* * * * *

(iv) The NPIS 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 paragraph (b)(6) of this section and the Administrator approves the establishment's request. The Administrator may permit establishments that slaughter classes of poultry other than 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).

(v) Traditional Inspection shall be used for turkeys when neither the NTI System nor the NPIS is used. For other classes of poultry, Traditional Inspection shall be used when SIS, NELS, and the NPIS are not used.

(2) Official establishments that operate under Traditional Inspection, SIS, NELS, NTI, or Ratite Inspection must meet the following requirements:

(i) 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.

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

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

* * * * *

(6) The following requirements are applicable to the NPIS:

(i) *Facilities.* The establishment must comply with the facilities requirements in § 381.36(f).

(ii) *Carcass sorting and disposition.* (A) 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.

(B) 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 SOP, or other prerequisite program a process by which parts, other than parts identified as ''major portions'' as defined in § 381.170(b)(22), are available for inspection offline after reprocessing or salvage.

(C) The establishment must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chiller. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program. These procedures must cover, at a minimum, establishment sorting activities required under paragraph (b)(6)(ii) of this section.

(D) The establishment must maintain records to document that the products resulting from its slaughter operation meet the definition of ready-to-cook poultry in § 381.1. These records are subject to review and evaluation by FSIS personnel.

(iii) *Presentation for online carcass inspection.* To ensure the online carcass inspector may properly inspect every carcass, the establishment must present carcasses as follows:

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

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

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

(D) There must be minimal carcass swinging motion;

(E) 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.

(iv) *Inspection for Avian Visceral Leukosis.* (A) 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(f)(3).

(B) 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.

■ 9. 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 (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, or sanitation SOPs, 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 the Administrator. Establishments must incorporate procedures for the use of any offline reprocessing into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

■ 10. Section 381.94 is amended by revising the section heading and paragraph (a) and removing and reserving paragraph (b) to read as follows:

§ 381.94 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards for establishments that slaughter ratites.

(a) *Criteria for verifying process control; E. coli testing.* (1) Each official establishment that slaughters ratites shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter ratites and livestock, shall test the type of ratites or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) *Sampling requirements.* (i) *Written procedures.* Each establishment that slaughters ratites shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* The establishment must collect samples from whole ratites at the end of the chilling process. Samples from ratites may be collected by sponging the carcass on the back and thigh or samples can be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird.

(iii) *Sampling frequency.* Establishments that slaughter ratites, except very low volume ratite establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rate: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation.

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume ratite establishments.* (A) Very low volume ratite establishments annually slaughter no more than 6,000 ratites. Very low volume ratite establishments that slaughter ratites in the largest number must collect at least one sample during each week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June of the following year or until 13 samples have been collected, whichever comes first.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of colony forming units (CFU)/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results. Records shall be retained at the establishment for a period of 12 months

and shall be made available to FSIS upon request.

(5) Establishments shall evaluate *E. coli* test results using statistical process control techniques.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1) through (4) of this section have not been complied with and written notice of same has been provided to the establishment.

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■ 11. 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).

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PART 500—RULES OF PRACTICE

■ 12. 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.

§ 500.6 [Amended]

■ 13. Section 500.6 is amended by removing and reserving paragraph (f).

Done at Washington, DC, on: July 31, 2014.

Alfred V. Almanza,

Administrator.

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