DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 309, and 310

[Docket No. FSIS–2016–0017]

RIN 0583–AD62

Modernization of Swine Slaughter Inspection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to establish an optional new inspection system for market hog slaughter establishments that has been demonstrated to provide public health protection at least equivalent to the existing inspection system. Market hog slaughter establishments that do not choose to operate under the new swine inspection system may continue to operate under their existing inspection system. The Agency is also making several changes to the regulations that will affect all establishments that slaughter swine, regardless of the inspection system under which they operate or the age, size, or class of swine. These changes will allow all swine slaughter establishments to develop sampling plans that are more tailored to their specific operations, and thus more effective in monitoring their specific process control, unlike the current requirements in the regulations.

DATES:

Effective date: December 2, 2019.

Notification date: All market hog establishments will initially have until March 30, 2020 to notify their FSIS District Office (DO) of their intent to operate under the New Swine Slaughter Inspection System (NSIS). Establishments that do not notify their DO of their intent by March 30, 2020 will be deemed to have chosen to continue operating under their existing inspection system. For additional information, see section II.G. Implementation.

Applicability dates: The regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process in 9 CFR 310.18(c), and the regulations that prescribe recordkeeping requirements in 9 CFR 310.18(d), will be applicable as follows:

(1) In large establishments, defined as all establishments with 500 or more employees, on December 30, 2019;

(2) In small establishments, defined as all establishments with 10 or more employees but fewer than 500 employees, on January 29, 2020; and

(3) In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million, on March 30, 2020.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Executive Summary

On February 1, 2018, FSIS published a proposed rule to modernize swine slaughter inspection (83 FR 4780). This final rule adopts, with modifications, the provisions in the proposed rule.

FSIS is establishing an optional new inspection system for market hog slaughter establishments, NSIS, informed by the Agency's experiences under its Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP). FSIS is establishing NSIS to improve the effectiveness of market hog slaughter inspection; make better use of the Agency's resources; and remove unnecessary regulatory obstacles to industry innovation by revoking maximum line speeds and allowing establishments flexibility to reconfigure evisceration lines. NSIS may also facilitate pathogen reduction in pork products and improve compliance with the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901 *et seq.*).

Because this final rule requires establishment personnel in NSIS establishments to sort and remove unfit animals before ante-mortem inspection by FSIS inspectors and trim and identify defects on carcasses and parts before post-mortem inspection by FSIS inspectors, the Agency's inspectors will be presented with healthier animals and carcasses that have fewer defects, allowing them to conduct a more efficient inspection of each animal and each carcass. As a result, under NSIS, FSIS can assign fewer inspectors to online inspection, freeing up Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, such as verifying compliance with sanitation and HACCP, as well as humane handling requirements.

Key elements of the NSIS include: (1) Requiring establishment personnel to sort and remove unfit animals before ante-mortem inspection by FSIS inspectors and to trim and identify defects on carcasses and parts before post-mortem inspection by FSIS inspectors; (2) requiring establishment personnel to identify animals or carcasses, that they have sorted and removed for disposal before FSIS inspection, with a unique tag, tattoo, or similar device, and to develop, implement, and maintain written procedures in their HACCP system to ensure that animals and carcasses sorted and removed for disposal do not enter the human food supply and are properly disposed of according to 9 CFR part 314; (3) requiring establishments to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal; (4) requiring establishment personnel to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (*e.g.,* African swine fever, classical swine fever, or Nipah virus encephalitis); (5) shifting Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which allows for up to two offline verification inspectors per line per shift and reduces the number of online inspectors to a maximum of three per line per shift; (6) requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the new definition of ready-to-cook (RTC) pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor which is suitable for cooking without need of further processing; and (7) revoking maximum line speeds and authorizing establishments to determine their own line speeds based on their ability to maintain process control for preventing fecal contamination and meeting microbial performance measures for carcasses during the slaughter operation. FSIS retains the ability to slow or stop the line, as needed (9 CFR 310.26(c)). Based on its experience under HIMP, the NSIS is unlikely to result in a higher prevalence of *Salmonella* on market hog carcasses and may result in a lower prevalence of *Salmonella* on market hog carcasses, which in turn may lead to fewer human illnesses. In addition, FSIS expects that the new inspection system will improve animal welfare and compliance with the HMSA because more FSIS resources will be available to verify the humane handling of animals.

Under the NSIS, establishment sorters will be required to incise mandibular lymph nodes and palpate the viscera to

detect the presence of animal diseases (*e.g., Mycobacterium (M.) Avium*) as part of their sorting activities before FSIS post-mortem inspection (9 CFR 310.26(b)). The Agency determined that it needs more information on the public health impact of these sorting activities before it can allow establishments to decide, on a lot-by-lot basis, whether establishment sorters need to incise lymph nodes and palpate the viscera to detect the presence of animal diseases. To gather this information, FSIS has decided to allow establishments that operate under the NSIS to apply for waivers to 9 CFR 310.26(b) under 9 CFR 303.1(h). As a condition of the waiver, establishments operating under waivers are required to submit data to FSIS. FSIS then assesses that data to determine whether changes to the regulations are appropriate and necessary. The Agency will announce the criteria for these waivers in a future **Federal Register** document.

Under this final rule, market hog slaughter establishments that do not choose to operate under the NSIS may continue to operate under traditional inspection (*i.e.,* inspection described in current regulations). Establishments that slaughter swine other than market hogs are not eligible to operate under the NSIS unless they obtain a waiver under the *Salmonella* Initiative Program (SIP) (79 FR 633, January 6, 2014).

Under this final rule, FSIS is also making several changes that will affect all establishments that slaughter swine, regardless of the inspection system under which they operate. Specifically, all official swine slaughter establishments must develop, implement, and maintain in their HACCP plans, sanitation standard operating procedures (sanitation SOPs), or other prerequisite programs (hereafter collectively referred to as their ''HACCP systems''), written procedures to prevent the contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk throughout the entire slaughter and dressing operation. These procedures must include sampling and analysis for microbial organisms to monitor process control for enteric pathogens, as well as written procedures to prevent visible fecal material, ingesta, and milk contamination.

As part of their written procedures, establishments will be required to collect and test two carcass samples for microbial organisms, one at pre-evisceration and one at post-chill (*i.e.,* the point in the slaughter process after the carcass has chilled in the cooler and after all slaughter interventions are completed), or, for very low-volume establishments, a single post-chill carcass sample. Establishments that bone their products before chilling (*i.e.,* hot-boned products) will be required to collect the pre-evisceration sample and a sample after the final wash instead of at post-chill, because these products are not chilled before further processing.

Under this final rule, establishments, except for very low-volume establishments, are required to collect carcass samples and test for microbial organisms pre-evisceration and post-chill, or, for hot-boned products, pre-evisceration and after the final wash, at a frequency of once per 1,000 carcasses. Very low-volume establishments are required to collect at least one carcass sample during each week of operation starting June 1 of each year. If, after consecutively collecting and testing 13 weekly carcass samples, very low-volume establishments can demonstrate that they are not exceeding their upper control limit for microbial organisms and that they are effectively maintaining process control, they can modify their sampling plans to collect samples less frequently. FSIS provides more information on upper control limits in its guideline titled *Developing Effective Microbiological Sampling Programs in Swine Slaughter Establishments to Assess Process Control and Sanitary Conditions* (hereafter referred to as the sampling guideline). The sampling guideline is available on FSIS's website at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.*

This final rule rescinds the current requirement that swine establishments test carcasses for generic *E. coli* post chill to monitor process control and replaces this requirement with the new testing requirements described above. The new testing requirements will allow establishments to develop sampling plans that are more tailored to their specific operation, and thus more effective in monitoring their specific process control than the current generic *E. coli* criteria. This final rule also removes the codified *Salmonella* pathogen reduction performance standard for hogs (carcasses) because verifying the codified standard was not a good use of Agency resources. As FSIS explained in the proposed rule (83 FR 4780, 4786), the Agency discontinued its *Salmonella* verification sampling program for market hogs in 2011 because the estimated prevalence of *Salmonella* on hog carcasses was low, and FSIS did not find enough pathogen positives to justify the resources needed (*e.g.,* time and supplies) to conduct carcass swabbing.

This final rule does not allow establishments to collect samples for microbial organisms at alternative sampling locations or frequencies, as was proposed. FSIS made this change from the proposed rule in response to comments that it may be too difficult for inspection personnel to review and verify sampling plans with alternative sampling locations or frequencies. Establishments that currently operate under SIP waivers from the former generic *E. coli* regulations may continue to conduct process control sampling at the alternative frequencies provided for in their waivers. All other SIP waivers (*e.g.,* waivers for 9 CFR 310.1(b)(3)—line speed; 9 CFR 310.25(b)—Salmonella performance standards; 9 CFR 310.18(a)—contamination of organs; and 9 CFR 310.14—handling of bruised parts) will end. FSIS will allow other establishments that would like to experiment with alternative sampling locations and frequencies to submit waiver requests under the SIP to FSIS. FSIS will announce new waiver criteria in a future **Federal Register** document. This final rule also does not require swine slaughter establishments to develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens, as was proposed. FSIS has decided to withdraw this part of the proposal until the Agency considers its options and timing for gathering more data on contamination in the pre-operational environment. A summary of changes to the proposed rule is included below under section I. Background.

In Table 1 below, FSIS presents the estimated costs and benefits of the final rule. The regulatory impact analysis section below contains an explanation of the assumptions, provides alternative adoption scenarios, and includes a discussion of the uncertainty surrounding the net benefits associated with how much of the industry will choose to adopt NSIS.

TABLE 1—NET COSTS AND (BENEFITS)

[M$]

	Number of establishments	One-time	Recurring
Costs to Industry		$3.14	$22.72
Voluntary *	** 40	0.84	22.15
Mandatory	612	2.30	0.58
Health Benefits ***			(9.33)
Industrial Efficiency			(87.64)
Impacts to Agency's Budget		2.80	(8.73)

Totals

One-Time Cost	$5.94
Recurring Cost	(82.98)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	(62.56)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	(60.00)

* Further explanation and details on the NSIS adoption rate are provided in section G. Potential Cost of the Final Rule, Table 6: NSIS Adoption Rate and section J. Net Benefits, Table 26: Quantified Cost and (Benefits) of Various Adoption Rates

** Note, this includes 5 HIMP establishments, which are not expected to incur any costs or benefits associated with the NSIS.

*** Further explanation and details on the range of health benefits have been provided in section H. Potential Benefits of the Final Rule, Table 18: Health Benefits from Averted Cases of *Salmonella.* The value of health benefits ranges from a $6.33 million decrease to a $24.62 million increase in health benefits, with a mean increase in benefits of $9.33 million, assuming a cost per illness of $3,682.

**** Note, some of the totals may not equal the sum due to rounding.

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I. Background

FSIS began experimenting with new approaches to slaughter inspection based on HACCP principles shortly after publishing the Pathogen Reduction/HACCP rule in 1996. In 1997, the Agency developed the HIMP pilot study to determine whether applying new government slaughter inspection procedures, with new establishment responsibilities, could promote industry innovation and provide at least the same food safety and consumer protection as the other available slaughter inspection systems. FSIS initiated the HIMP pilot study in 20 young chicken, five young turkey, and five market hog establishments on a waiver basis.

In 2014, the Agency amended the poultry products inspection regulations to establish an optional new inspection system for young chicken and all turkey slaughter establishments informed by the Agency's experiences under HIMP (79 FR 49566, August 21, 2014). The New Poultry Inspection System (NPIS) was designed 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.

In addition to establishing the NPIS for young chickens and turkeys, FSIS also amended the poultry products inspection regulations that apply to all establishments that slaughter poultry other than ratites. The new requirements ensure that all poultry slaughter establishments implement appropriate measures in their HACCP systems to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material throughout the entire slaughter operation and ensure that both FSIS and establishments have the documentation they need to verify the effectiveness of these measures on an ongoing basis.

Proposed Rule

On February 1, 2018, FSIS proposed to amend the meat inspection regulations to establish an optional new slaughter inspection system for market hog establishments (83 FR 4780). FSIS also proposed several changes to the regulations that would affect all establishments that slaughter swine, regardless of the inspection system under which they operate or the age, size, or class of swine.

The proposed rule's comment period closed on May 2, 2018, 90 days after its publication. After reviewing comments on the proposed rule, FSIS is finalizing, with some changes, the provisions in the February 2018 proposed rule. In this final rule, the Agency is modifying its proposal to:

- Establish a phased approach to implement the NSIS;
- 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 swine. The applicability dates will provide additional time for small and very small establishments to comply with these provisions;
- Revise the disposal requirements to require establishments operating under the NSIS to develop, implement, and maintain written procedures in their HACCP systems to ensure that animals and carcasses that have been sorted and removed for disposal do not enter the human food supply and are properly disposed of according to 9 CFR part 314;
- Require establishments operating under the NSIS to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal and make these records available for review and evaluation by FSIS;
- Clarify that all establishments operating under the NSIS must provide a mirror at the carcass inspection station;
- Clarify that establishments that bone their products before chilling (*i.e.,* hot-boned products) must collect a carcass sample pre-evisceration and after the final wash instead of at post-chill. These establishments must also collect a sample at the pre-evisceration point in the process;

• Withdraw the proposal to allow establishments to use alternative sampling locations and sampling frequencies;

• Revise the sampling regulations to require very small establishments that slaughter more than 20,000 swine, or a combination of swine and other livestock exceeding 6,000 cattle and 20,000 total of all livestock to collect two carcass samples, one at pre-evisceration and one at post-chill, at a frequency of 1 per 1,000 carcasses, instead of a single post-chill sample;

• Require establishment sorters to incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (*e.g., M. Avium*) as part of their sorting activities before FSIS post-mortem inspection;

• Revise the definition of ''RTC pork product'' to clarify that the standard is a performance standard for non-food safety defects and not a zero-tolerance standard; and

• Withdraw the proposed requirement for swine slaughter establishments to develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens.

Hog HIMP Report

The proposed rule was informed by the Agency's comprehensive analysis of data collected from HIMP market hog establishments. In 2014, the Agency evaluated inspection findings in market hog slaughter establishments participating in HIMP to determine whether the HIMP inspection system performs as well as the existing inspection system in terms of safety and wholesomeness of the products produced and of overall consumer protection. FSIS summarized its findings in its report titled ''Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs'' (hereafter the ''Hog HIMP Report'') [1] and in the proposed rule (83 FR 4780, 4789). The Hog HIMP Report concluded that market hog slaughter establishments participating in HIMP are performing as well as comparable large non-HIMP market hog establishments.

The Hog HIMP Report is based on two time periods: The years CY2006–CY2010 and the years CY2012–CY2013. The evaluation compared 5 HIMP market hog establishments with a comparison set of 21 non-HIMP market hog slaughter establishments selected to be comparable with HIMP market hog establishments with respect to production volume, line speed, and days of slaughter operation.

The Hog HIMP Report found that HIMP market hog establishments received more off-line food safety related inspection verification checks than the traditional non-HIMP market hog establishments. HIMP market hog establishments had higher compliance with Sanitation SOP and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella* verification testing positive rates than traditional non-HIMP market hog establishments, and lower levels of violative chemical residues. The Hog HIMP Report also found that under HIMP, market hog establishments received an increased level of Sanitation SOP and HACCP inspection. Based on these findings, HIMP has been demonstrated to provide public health protection at least equivalent to the traditional inspection system.

Risk Assessment

The proposed rule was also informed by FSIS's *Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments.* The risk assessment [2] used available data from FSIS's microbiological baseline studies [3] and the Agency's *Salmonella* verification results from swine slaughter establishments. FSIS employed a stochastic simulation model using multi-variable logistic regressions to identify correlations between (1) the numbers of offline food-safety inspection procedures, both scheduled and unscheduled, along with the numbers of non-compliances and scheduled-but-not-completed procedures,[4] and (2) contamination of hog carcasses with *Salmonella.* The correlations were used to predict the potential effect that devoting more resources to those offline procedures might have on human illness attributable to the consumption of pork products. Stochastic simulations were used to account for statistical uncertainty in the estimates relating inspection procedures in an establishment to detection of *Salmonella* in samples from hog carcasses.[5] Illness estimates were based on data from the Centers for Disease Control and Prevention (CDC), and uncertainty distributions were used to account for the variability in annual *Salmonella* illnesses and statistical uncertainty about the relationship between the pathogen prevalence levels at the establishments and the corresponding annual number of illnesses that could be attributed to the pathogens.

As with any risk assessment, FSIS's risk assessment relies on a number of assumptions. FSIS assumed that the differences between the approach to slaughtering hogs and slaughtering poultry would not alter the relationship between the presence of *Salmonella* contamination on carcasses and the likelihood of contamination of meat and human illness. Furthermore, hog slaughter establishment specialization has been facilitated by vertical integration within the industry, much like the poultry industry.[6] FSIS also assumed, for the purpose of this risk assessment, that the relationship between *Salmonella* contamination of hog carcasses and downstream products such as pork parts (*e.g.,* pork chops) and ground pork closely mirrors that of the established relationship between *Salmonella* contamination of poultry (*e.g.,* chicken) carcasses and downstream products such as chicken parts and ground chicken. On the other hand, the likelihood of positive Salmonella findings on hog carcasses is significantly lower than on chickens. While FSIS did not conduct any specific analyses to examine this assumption, the Agency has conducted numerous peer-reviewed analyses of the relationship between Salmonella contamination frequency on chicken

[1] The Hog HIMP Report is available on the FSIS website at: *http://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AJPERES.*

[2] As FSIS explained in the proposed rule, the Agency used a similar approach to estimate the public health benefits associated with the final rule titled *Modernization of Poultry Slaughter Inspection* (79 FR 49565).

[3] FSIS baseline data is available at: *https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/baseline/baseline.*

[4] Scheduled procedures are assigned to inspectors at an establishment by the Public Health Information System (PHIS). Before FSIS implemented the PHIS, scheduled procedures were assigned by the Performance-Based Inspection System (PBIS). Unscheduled procedures are performed according to inspector needs at an establishment and may include verification checks for fecal material, ingesta, and milk, or they may be a response to unforeseen hazards or unsanitary conditions arising from sanitation SOP failures, or the need to verify corrective actions taken under the establishment's HACCP plan.

[5] For the risk assessment, FSIS used data from The Nationwide Microbiological Baseline Data Collection Program: Market Hogs Survey August 2010–2011 available at *http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES*).

[6] Muth, M. (2007). Pork Slaughter and Processing Sector Facility-Level Model. *https://www.rti.org/sites/default/files/resources/muth_pork-slaughter_final.pdf.*

carcasses and chicken parts.[7] These analyses indicate that the prevalence of *Salmonella* contamination on downstream products (*e.g.,* parts) often exceeds the frequency of measurement of *Salmonella* contamination in upstream products (*e.g.,* carcasses), and the Agency expects this relationship would apply to other amenable species slaughtered in FSIS establishments. The assumption of higher prevalence is logical given that samples of downstream products contain primals from multiple carcasses, increasing the likelihood of a single sample being contaminated.

The regression analysis of the historical data included in the market hog risk assessment showed a statistically significant correlation between (1) increased scheduled and unscheduled offline procedures and decreased scheduled but not performed procedures and (2) reduction in the prevalence of *Salmonella* positive samples from carcasses. Based on these results, the redeployment of Agency resources to scheduled and unscheduled offline activities, along with a reduction in scheduled but not performed procedures, is likely to contribute to food safety resulting from a lower prevalence of carcasses contaminated with *Salmonella,* which in turn the Agency expects to lead to fewer human illnesses. FSIS will evaluate policy effectiveness by routinely analyzing inspection task data in PHIS (*e.g.,* NRs for regulations on the PHR list, including NRs for HACCP, sanitation SOP, and Livestock Zero Tolerance tasks).

In April 2018, the Agency conducted an external peer review of the risk assessment. On August 6, 2018, FSIS posted a revised version of the risk assessment on its website at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules.* The revised risk assessment addressed reviewers' comments that FSIS should have used different modeling approaches. The revised risk assessment also included an in-depth power analysis, multicollinearity diagnostics, model parameters and estimates when more complex crossover and mixed-effects modeling approaches were applied, and a summary of all alternative models (Appendix H). The revisions made in response to the reviewers' comments did not produce changes to the risk assessment's conclusions that would require modifications of the proposed rule. However, the Agency gave interested persons 30 days (until September 5, 2018) to comment on the changes made to the risk assessment. To be transparent, FSIS has decided to add text to the risk assessment to better characterize the two different models that were conducted (see Tables 13 and 14 in the risk assessment and accompanying text). Specifically, FSIS has added additional language to the risk assessment—both in the summary and in the discussion—to highlight the results of the modeling without simulated data. To that end, the results of the modeling with simulated data—which, as would be expected, had less uncertainty around the estimated change in illnesses—are not used in support of this rule. The modeling without simulated data is now carried through in the Regulatory Impact Analysis. The result of those additions is that the uncertainty around estimated illnesses avoided is greater; however, the most likely estimated illnesses avoided are not affected. Notably, FSIS received a comment questioning FSIS's use of simulated data. FSIS believes that this change addresses the commenter's questions.

Additionally, minor edits and corrections for clarity and consistency were made in the main body of the risk assessment report. The most likely estimates of illnesses avoided from converting from traditional inspection to the NSIS did not change with incorporation of these additional analyses and other minor changes to the risk assessment.

The final risk assessment is available on FSIS's website at *https://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments.* FSIS is responding to comments received regarding the risk assessment in Part C of section II. ''Comments and Responses'' below.

II. Comments and Responses

FSIS received over 83,000 comments in response to the February 2018 proposed rule and five comments on the revised risk assessment. Most of these comments were form letters submitted as part of various write-in campaigns initiated by consumer advocacy organizations, animal welfare organizations, labor unions, and worker advocacy organizations. FSIS also received individual comments from private citizens.

In addition to the form letters and individual comments, the Agency also received comments from trade associations representing the meat industry, companies that conduct swine slaughter operations, consumer advocacy organizations, public health organizations, animal welfare organizations, labor unions, worker advocacy organizations, foreign countries, FSIS inspectors, an environmental organization, and a State Department of Agriculture. Below is a summary of the comments and FSIS's responses.

A. Requests for Public Meetings, Comment Extensions, and Documents

Comments: Several consumer advocacy organizations, labor unions, and worker advocacy organizations stated that FSIS should have held public meetings to discuss the proposed rule. According to the comments, public meetings focused on the proposed rule may have helped to clarify the pros and cons of important proposed changes. A few consumer advocacy organizations argued that FSIS should have submitted the risk assessment for peer review before publishing the proposed rule, or, at least, extended the comment period for the proposed rule until all stakeholders had the opportunity to read and respond to the peer reviewed version of the risk assessment.

Response: Rather than hold a public meeting on the proposed rule, the Agency held two webinars in March and April 2018, to provide an overview of the proposed rule and provide the public with an opportunity to ask questions about the proposed rule. (Transcripts of the webinars are available on the FSIS website at *https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings.*) During the webinars, FSIS provided the public with all the information that it would have provided during a public meeting.

The Agency explained during the webinars and monthly consumer and industry stakeholder meetings that it would reopen the comment period for the proposed rule if the Agency had to make significant changes to the risk assessment based on peer review comments. And, even though FSIS did not have to make significant changes to the risk assessment, the Agency reopened the comment period on the risk assessment for an additional 30 days to give stakeholders an opportunity to comment on the revised document.

In total, stakeholders had 90 days to review and comment on the proposed rule and 120 days to review and comment on the risk assessment. Executive Order (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

[7] Ebel, E.D., Williams, M.S., Tameru, B. (2019) Relatedness of Salmonella contamination frequency on chicken carcasses and parts when processed in the same establishment. *Food Control* 100: 198–203.

days.'' The Agency believes that the public had ample time to consider the issues raised in the proposed rule and risk assessment to develop their comments.

Comment: A few worker advocacy groups argued that FSIS should have reopened the comment period on the proposed rule because, according to the commenters, the Agency relied on an unpublished data set of Occupational Safety and Health Administration (OSHA) logs to compare worker injury rates between HIMP and non-HIMP establishments.

Response: In the proposed rule, FSIS explained that the Agency compared injury rates between establishments operating under traditional inspection and HIMP (83 FR 4796). FSIS's analysis showed that HIMP establishments had lower mean injury rates than non-HIMP establishments. The analysis used injury rate data available on OSHA's website.

FSIS further explained that the survey captured data from OSHA logs of workplace injuries and illnesses, maintained by employers as mandated by regulations (*see* 29 CFR part 1904), and that 56 FSIS inspected market hog slaughter establishments submitted their injury rate data to OSHA (83 FR 4796). From these 56 establishments, FSIS explained that it excluded 27 low-volume establishments, leaving 29 establishments (5 HIMP and 24 Traditional). The low-volume establishments were excluded to provide a better comparison group of traditional establishments because all HIMP establishments are high-volume establishments. The results showed HIMP establishments had a lower mean number of injuries using three OSHA injury rate measures: Total Case Rate (TCR); Days Away, Restricted or Transferred (DART); and Days Away from Work (DAFW). However, FSIS noted that factors other than line speed may affect injury rates (*e.g.,* automation and number of sorters per line) and requested comments on worker safety issues in the proposed rule as a result.

All the information that FSIS used in its analysis is publicly available. FSIS does acknowledge that it did not provided the web address for OSHA's Establishment Specific Injury and Illness Data, which is available at *https://www.osha.gov/pls/odi/establishment_search.html.* However, it is easy to find on OSHA's website under the ''Data'' tab.

And, while FSIS did not post the exact data that the Agency pulled from its Public Health Information System (PHIS) to select swine slaughter establishments present in the OSHA data set, the same information can be found in other formats on FSIS's website. Establishment level production volume information is available at *https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/data.* This data would allow interested parties to identify the high-volume establishments. Additionally, the list of establishments participating in HIMP is available at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/HIMP-list-of-participating-plants.*

Although FSIS conducted an analysis of injury rates during the development of the proposed rule, FSIS did not use the analysis to draw conclusions on worker safety in HIMP or non-HIMP establishments or whether there is an associated impact on food safety. As discussed in more detail below, while FSIS recognizes that working conditions in swine slaughter establishments is an important issue, the Agency does not have the authority to regulate issues related to establishment worker safety. OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health.

Comment: A few commenters argued that FSIS violated the Administrative Procedure Act (APA, 5 U.S.C. 551 *et seq.*) because the Agency did not identify the 21 non-HIMP establishments that it used to conduct its comparisons for the Hog HIMP Report or post all the raw data that it used to develop the Hog HIMP Report. According to the commenters, the APA requires reasoned decision-making based on an examination of relevant data articulated in a satisfactory explanation. The commenters argued that because FSIS did not provide all its raw data, the Agency failed to provide the public a meaningful opportunity to participate in the rulemaking process.

Response: The APA does not require Federal agencies to post all their raw data. That said, FSIS is committed to being transparent and responsive to stakeholders. FSIS clearly explained in the Hog HIMP Report that FSIS selected the 21 non-HIMP establishments because they were large, high-volume market hog slaughter establishments that had similar production volume, line speed, and days of slaughter operation to the five market hog slaughter HIMP establishments. FSIS also clearly explained in the Hog HIMP Report and the proposed rule (83 FR 4780, 4789) the Agency's analysis of its inspection data and its conclusions based on the data. Moreover, FSIS made every effort to respond to FOIA requests related to the proposed rule before the close of the comment period. The Agency has added all the information that it has recently released to its FOIA Electronic Reading Room.[8]

B. HIMP

Comment: Several consumer advocacy organizations, public health organizations, animal welfare organizations, worker advocacy organizations, and private citizens questioned whether data collected under the HIMP pilot study should be used to inform the NSIS. The commenters argued that the USDA's Office of the Inspector General (OIG) was critical of HIMP in its 2013 report.[9] The commenters stated that OIG found that FSIS: Did not adequately oversee the HIMP program because it did not evaluate whether the program resulted in a measurable improvement of the inspection process; allowed one HIMP establishment to forgo the standard FSIS policy to manually inspect viscera; and did not have formal agreements with the HIMP establishments.

According to the commenters, OIG's audit report also raised issues with the Agency's enforcement policies at all hog slaughter operations, finding that FSIS's policies did not deter establishments from becoming repeat violators of food safety regulations and that FSIS could not always ensure the humane handling of animals.

In September 2013, the U.S. Government Accountability Office (GAO) followed the OIG with a report entitled, *More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections.*[10] According to the commenters, GAO found that FSIS did not collect comparable data from establishments participating and not participating in the HIMP pilot study. The commenters also stated that GAO found that the use of volunteer facilities raised questions about self-selection bias and that information collected from the five market hog slaughter HIMP establishments would not provide reasonable assurance that any conclusions could apply more broadly to all swine slaughter establishments because of the small sample size.

Response: FSIS addressed OIG's concerns in the Agency's responses to the audit. In response to the OIG audit,

[8] FSIS's FOIA Electronic Reading Room is available at *http://www.fsis.usda.gov/readingroom.*

[9] OIG, 2013. Food Safety and Inspection Service, Inspection and Enforcement Activities at Swine Slaughter Plants, *https://www.usda.gov/oig/webdocs/24601-0001-41.pdf.*

[10] GAO, 2013. More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections, *http://www.gao.gov/assets/660/657144.pdf.*

FSIS updated its SIP letters (*i.e.,* formal agreements), requiring all HIMP establishments to conduct the same viscera inspection procedures, and implemented PHIS, enhancing the Agency's ability to better track trends in NRs.

In addition, the Agency implemented required supplemental training after the release of the updated Directive 6900.2, *Humane Handling and Slaughter of Livestock,* to improve inspectors' objective observation and assessment skills. The Situation Based Humane Handling training modules (Module I and Module II) effectively teach inspectors how to interpret an egregious or non-egregious inhumane handling event objectively, and to take appropriate enforcement actions. The training modules contain fictional scenarios of inhumane and egregious events and describe in detail how an inspector is to proceed with regulatory enforcement.

Furthermore, in October 2013, FSIS announced that it hired a Humane Handling Enforcement Coordinator, who conducts ongoing reviews of relevant NRs, suspensions and Notices of Intended Enforcement (NOIEs).[11] To accomplish this, the Humane Handling Enforcement Coordinator maintains a database to track the review of NRs and the review and tracking of suspensions and NOIEs pertaining to violations of the HMSA. The Humane Handling Enforcement Coordinator also conducts correlations with inspectors to help them improve their objective analysis when enforcing the HMSA and related regulations, which serves to reduce subjective interpretation of inhumane events and their regulatory outcome.

To deter repeat violators, the Agency changed the way that it schedules its in-depth reviews of establishments' food safety systems, known as food safety assessments (FSAs).[12] [13] In 2015, FSIS implemented its Public Health Risk Evaluation (PHRE) methodology, which consists of a decision-making evaluation that helps Enforcement, Investigations and Analysis Officers (EIAOs) and DOs determine if an FSA needs to be scheduled and conducted or if enforcement action is warranted for a particular establishment. The decision criteria used in the PHRE include factors such as pathogen testing results, recalls, outbreaks, regulatory findings, and inspection results at an establishment. The PHRE methodology and the decision criteria are described in detail in FSIS Directive 5100.4.[14]

Rather than schedule routine FSAs every four years, FSIS's Office of Planning, Analysis and Risk Management (OPARM) provides DOs with a prioritized list of establishments for PHREs once per month based on public health risk triggers (*e.g.,* if an establishment has produced adulterated product). EIAOs review historical data on the listed establishments and coordinate with inspection program personnel assigned to the listed establishments to determine if an FSA or other enforcement action is needed. DOs can still schedule for cause PHREs at establishments not on the prioritized list (*i.e.,* if there is an illness or outbreak, significant or repetitive contamination or adulteration incidents, or repetitive microbiological sampling failures). The use of the PHRE methodology allows FSIS to better target establishments for FSAs based on risk and to more effectively deploy its investigational resources (EIAOs).

In addition, FSIS developed PHIS alerts for inspection personnel that are triggered when an establishment receives a certain percentage of NRs for regulations on the Public Health Regulation (PHR) list.[15] The PHR list, which is updated annually and posted on the Agency's website, consists of regulations and specific provisions of regulations that historically have higher rates of noncompliance three months before a pathogen positive or enforcement action. Each month OPARM calculates a PHR NR rate for each meat and poultry establishment and determines if an establishment will be issued a PHR alert or if they should be considered by the DO for a PHRE, which may lead to an FSA. PHIS alerts have helped FSIS better identify trends that may warrant an FSIS enforcement action.

The GAO report identified what it believed to be data gaps in the HIMP pilot study and recommended that FSIS collect and analyze information to determine if the HIMP pilot study was meeting its purpose. FSIS agreed with the recommendation and began working on the Hog HIMP Report. GAO also identified strengths in the HIMP pilot study, including that of giving establishments responsibility and flexibility for ensuring food safety and quality and allowing FSIS inspectors to focus more on food safety related activities.

While it is true that the five market hog slaughter HIMP establishments represent a small sample size of establishments, they collectively represent diversity in geography, corporate structure, management styles, product distribution patterns, and other variables. FSIS believes that the volunteer market hog slaughter establishments participating in the HIMP pilot study, viewed collectively, are typical of the broader industry.

Comment: Some consumer advocacy groups questioned why the Agency did not use a third-party contractor to conduct its evaluation of the hog HIMP pilot study.

Response: FSIS did not hire a third-party contractor to draft the Hog HIMP Report because the model and the resulting inspection data had already been reviewed by third-party contractors. As FSIS explained in the proposed rule, the independent consulting firm, Research Triangle Institute (RTI), collected baseline organoleptic and microbiological data in the five market hog slaughter establishments that volunteered to participate in the HIMP pilot study before they implemented HIMP (83 FR 4780, 4788). These baseline data reflect the performance of these five establishments under traditional inspection before they implemented HIMP and provided the basis to establish HIMP performance standards for food safety defects and non-food safety ''Other Consumer Protection'' (OCP) defects.

FSIS also explained in the final rule to modernize poultry slaughter inspection (79 FR 49566, 49573) that in 2002, the Agency contracted with a third-party technical review team (review team, henceforth) 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 pilot study design and method to

[11] *https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-and-transcripts/news-release-archives-by-year/archive/2013/nr-102313-01.*

[12] See FSIS Directive 5100.1, *Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FS) Methodology* available at *https://www.fsis.usda.gov/wps/wcm/connect/31bb8000-fb33-4b51-964b-1db9dfb488dd/5100.1.pdf?MOD=AJPERES.*

[13] See FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology* available at *https://www.fsis.usda.gov/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES.*

[14] FSIS Directive 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology available at *https://www.fsis.usda.gov/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES.*

[15] *See* FSIS Notice 15–18, *Public Health Regulations and Alerts for use in Determining Inspection Program Personnel Actions and Public Health Risk Evaluation Scheduling in Meat and Poultry Establishments* available at *https://www.fsis.usda.gov/wps/wcm/connect/8f218f5b-197e-4813-bf92-be29be36ec08/15-18.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=8f218f5b-197e-4813-bf92-be29be36ec08.*

determine whether FSIS could use the organoleptic and microbial data collected under HIMP to compare the performance of establishments operating under HIMP to the performance of establishments operating under non-HIMP inspection systems. Overall, the review team found that the HIMP study design and method were valid and provided a useful and legitimate comparison of the performance of establishments operating under HIMP and non-HIMP inspection systems. The review team's findings are described in the report titled *Review of the HACCP-Based Inspection Models Project by the National Alliance for Food Safety Technical Team* (The Hargis Report).[16] While the review team did not review data collected from the market hog establishments operating under HIMP, the poultry and market hog HIMP models and the resulting inspection data are very similar. Therefore, FSIS determined there would be no benefit in hiring another review team to evaluate the HIMP market hog inspection data.

Comment: A few consumer advocacy organizations stated that the data used in the Hog HIMP Report is now stale as the Agency analyzed data from CY2006 through CY2010 and then CY2012 through CY2013.

Response: FSIS disagrees. FSIS has not made any significant changes to the HIMP model since 2013, and FSIS inspectors are still performing the same inspection tasks. The Hog HIMP Report findings from CY2006 through CY2010 and CY2012 through CY2013 were very similar. This shows that not much changed over a seven-year period, and that the model is stable. No significant changes in swine slaughter, FSIS inspection, or related regulations have occurred since CY 2013. Therefore, FSIS has no reason to believe that the data in the Hog HIMP Report is no longer useful simply because of the passage of time.

Comment: One consumer advocacy group noted that the Hog HIMP Report shows that there was an increase in total offline verification tasks in HIMP establishments during CY2012 and CY2013. However, according to the same commenter, tables 3–2 and 3–3 in the Hog HIMP Report show that inspectors performed fewer verification tasks in HIMP establishments than they did in non-HIMP establishments for more than half of the PHRs in CY2012 and CY2013. According to the commenter, the Agency treats a total pooled increase in inspection tasks across all regulations as outweighing the decreases in some inspection tasks. The commenter argued that FSIS needs to justify why a decrease in any inspection task for any regulation will not be detrimental to food safety. The commenter further argued that FSIS did not explain why the PHRs are relevant.

Another consumer advocacy group complained that the Hog HIMP Report did not indicate which inspection tasks were scheduled or unscheduled. The same commenter stated that FSIS did not demonstrate that the increased offline verification tasks in HIMP establishments were statistically significant, as opposed to a product of chance.

Response: The Agency uses PHIS to assign scheduled or ''routine'' inspection tasks. Inspectors in large, high-volume market hog slaughter establishments receive the same number of routine inspection tasks in both HIMP and traditional establishments. Unscheduled or ''directed'' inspection tasks are initiated by the inspector or their supervisor.

The Hog HIMP Report was not generated to evaluate the benefits of performing more scheduled versus unscheduled offline inspection verification tasks. The risk assessment discussed above evaluated, among other things, the effect of increased offline inspection verification tasks in swine slaughter establishments. The objective of the Hog HIMP Report was to determine whether the HIMP inspection system performs *as well as* the traditional inspection system in terms of product safety and wholesomeness, and overall consumer protection. As FSIS explained in the proposed rule (83 FR 4780, 4790), the Hog HIMP Report found that inspectors at HIMP market hog establishments are performing more off-line food safety related inspection verification tasks than inspectors at traditional market hog establishments, including an increased level of Sanitation SOP and HACCP inspection verification tasks. The Hog HIMP Report also found that HIMP market hog establishments have higher compliance rates with Sanitation SOP and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella* verification testing positive rates, and lower levels of violative chemical residues, as compared to traditional non-HIMP market hog establishments.

FSIS disagrees that the Agency needed to indicate which offline inspection verification tasks were scheduled and unscheduled or demonstrate that the increased number of offline verification tasks in HIMP establishments were statistically significant and could therefore be used to evaluate whether HIMP market hog establishments performed as well as traditional market hog establishments. FSIS explained in the Hog HIMP Report that inspectors conducted more offline inspection tasks in HIMP establishments largely due to the increased inspection for visible fecal material, ingesta, and milk contamination under 9 CFR 310.18. FSIS inspectors at hog HIMP establishments inspect a sample of 24 carcasses when they perform a Zero Tolerance verification task specifically for 9 CFR 310.18, whereas FSIS inspectors at traditional market hog establishments inspect a sample of 11 carcasses. These Zero Tolerance verification tasks are required every shift.

Tables 3–2 and 3–3 in the Hog HIMP Report show the number of times that FSIS inspectors verified compliance with a regulation. These tables do not necessarily show the number of times a task was performed. FSIS inspectors verify whether establishments meet requirements in 9 CFR part 417 when they conduct HACCP tasks; whether establishments meet requirements in 9 CFR 416.1–6 when they conduct sanitation performance standards (SPS) tasks; and whether establishments meet requirements in 9 CFR 416.11–17 when they conduct Sanitation SOP tasks. And, while inspectors receive the same routine tasks, not every regulation in tables 3–2 and 3–3 needs to be verified in every establishment. For example, FSIS inspectors would only verify whether establishments meet requirements in 9 CFR 416.16(b) if the establishment maintains records on a computer. In addition, inspectors would only check 9 CFR 417.3(a)–(c) in PHIS if they were verifying whether establishments met corrective action requirements after a deviation. So, the fact that table 3–2 and 3–3 show that FSIS inspectors verified fewer 9 CFR part 417 regulations in HIMP establishments does not mean that FSIS performed fewer HACCP inspection verification tasks in CY2012 and CY2013. Rather, it could mean that inspectors found fewer deviations that required the subsequent verification of corrective actions. Therefore, tables 3–2 and 3–3 do not support the commenter's argument that FSIS conducted fewer tasks in HIMP establishments, which they claimed could be detrimental to food safety.

As FSIS explained in the proposed rule (83 FR 4789) and above, the PHR list is relevant because it consists of regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement

[16] The Hargis Report is available at *https://www.fsis.usda.gov/OPPDE/nacmpi/Nov2002/Papers/NAFS97.pdf.*

action. The PHR list allows FSIS to focus on specific health related provisions of regulations that may be the most informative for prioritizing PHREs and FSAs. FSIS compared the number of verifications of PHR regulations in HIMP and traditional establishments because non-compliance with these regulations was determined by OPARM to be an important indicator of subsequent food safety issues and loss of process control.

Comment: One consumer advocacy group argued that the increased offline regulation verifications under HIMP are probably the result of greater reporting, rather than an actual increase in verifications. The commenter stated that they have received information that inspectors find that entering data into PHIS is cumbersome, so they do not enter data for unscheduled tasks unless they find problems. According to the commenter, there has been a significant drop in the number of verification tasks performed since the implementation of PHIS.

Response: FSIS inspectors in both HIMP and non-HIMP establishments use PHIS. FSIS provides instructions on how to use PHIS in its directives and notices. As FSIS explained above, an inspector at a large, high-volume slaughter establishment operating under HIMP would receive the same tasks as an inspector at a large, high-volume slaughter establishment operating under traditional inspection, except that the inspector in the HIMP establishment is instructed to schedule more carcass verification tasks. The documentation requirements for inspectors are also the same for HIMP and non-HIMP establishments. The key difference is that FSIS inspectors in HIMP establishments routinely document fewer condemned animals, carcasses, and parts because establishments conduct sorting procedures before FSIS inspection. Additionally, comments on inspectors not wanting to document completion of tasks in PHIS are outside the scope of these regulations.

Comment: A few consumer advocacy groups stated that they found 32 instances in which establishments were cited for violating 9 CFR 311.16(a)—Carcasses So Infected that Consumption of the Meat May Cause Food Poisoning. According to the commenters, these instances occurred in HIMP establishments rather than establishments operating under traditional inspection because establishment sorters on the slaughter line presented carcasses to FSIS that were unfit for processing. The commenters argued that the Hog HIMP Report should have compared NRs for 9 CFR 311.16(a) in HIMP and traditional establishments.

One consumer advocacy group noted that the Hog HIMP Report shows that there were statistically significant differences in the weighted, health-related Sanitation SOP and HACCP NRs for the five Hog HIMP establishments as compared to those establishments operating under traditional inspection for a combined four years. The commenter noted that while the Agency indicated in tables 3–9 and 3–10 that the total NRs for Sanitation SOP and HACCP PHRs were lower in CY2012 and CY2013 for the 5 HIMP establishments, these establishments had more NRs for non-compliance with other regulations. The commenter argued that for certain regulations like 9 CFR 417.3(a)(2), the five HIMP establishments had higher and statistically significant NRs compared to the 21 comparable non-HIMP traditional establishments. The commenter stated that the five HIMP establishments had an 11-fold and three-fold higher rate of violating 9 CFR 417.3(a)(2) in CY2012 and CY2013, respectively. The commenter noted that 9 CFR 417.3(a)(2) is a measure of whether an establishment is maintaining control over a critical control point. The commenter argued that because the five HIMP establishments received more NRs for this regulation, they were not adhering to their HACCP plans, and were out of control more frequently than the 21 comparable non-HIMP traditional establishments.

The same consumer advocacy group stated that they conducted their own analysis of NRs issued in the five HIMP establishments and five comparably-sized non-HIMP traditional establishments from CY2012 to CY2016. The commenter noted that, based on their own analysis, the five HIMP establishments had more NRs for non-compliance with 9 CFR 310.18, 416.3–416.5, 416.13, and 417.2. The commenter highlighted an NR that was issued to a HIMP establishment in 2017 because an establishment sorter did not identify a carcass with a food safety defect. The commenter also noted that OIG found that from FY 2008 to 2011, three of the 10 swine slaughter establishments cited with the most noncompliance records (NRs) were HIMP establishments. The commenter argued that these NRs demonstrate that the HIMP inspection system is not as effective as the traditional inspection system.

Response: FSIS disagrees that these NRs prove that HIMP establishments lose process control more often than traditional establishments. In Table 3–9 in the Hog HIMP Report,[17] PHR noncompliance rates in CY2012 at the five HIMP market hog establishments were statistically significantly higher for four regulations, statistically significantly lower for five regulations, and not statistically significantly different for eighteen regulations. Overall, the CY2012 PHR noncompliance rate for Sanitation SOP and HACCP regulations (9 CFR parts 416 and 417) in the five HIMP market hog establishments was statistically significantly lower than that for the 21 comparison non-HIMP market hog establishments. In Table 3–10 in the Hog HIMP Report, PHR noncompliance rates in CY2013 at HIMP market hog establishments were statistically significantly higher for three regulations, statistically significantly lower for five regulations, and not statistically significantly different for nineteen regulations. Overall, the PHR noncompliance rate in CY2013 for Sanitation SOP and HACCP regulations in the five HIMP market hog establishments was statistically significantly lower than that for the 21 comparison non-HIMP market hog establishments. The Sanitation SOP and HACCP regulations are among the regulations most strongly related to public health.

Under HIMP, if an establishment does not adequately sort for carcasses showing signs of septicemia or pyemia, FSIS issues an NR for 9 CFR 311.16(a). FSIS does not issue NRs for this regulation under traditional inspection because FSIS inspectors are responsible for identifying and removing food safety and non-food safety defects.

As is explained above, under HIMP, FSIS inspectors inspect a sample of 24 carcasses when they perform a Zero Tolerance verification task as opposed to inspecting a sample of 11 carcasses under traditional inspection. In addition, the Agency's offline inspectors in HIMP establishments perform more offline inspection activities that FSIS has concluded are more effective in ensuring food safety than offline FSIS inspectors perform in non-HIMP establishments operating under the traditional inspection system. Therefore, FSIS inspectors in HIMP establishments have more opportunities for detecting noncompliance with regulatory requirements that are directly related to public health than inspectors do in non-HIMP traditional establishments.

Comment: Several commenters argued that until FSIS can compare and

[17] *https://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AJPERES.*

evaluate HIMP and non-HIMP establishment performance using compatible data, the same data reporting period, and an equal number of establishments, and show a marked superiority of HIMP establishment performance, FSIS must not finalize the proposed rule.

Response: FSIS maintains that the data collected during the HIMP pilot study was valuable for evaluating whether the HIMP inspection system performs as well as the traditional inspection system. As stated above, FSIS did compare data from the same reporting periods and compared establishments with similar HACCP size and production volume. As stated in the Hargis 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.'' FSIS disagrees that the Agency needs to show that the HIMP system is superior to the traditional inspection system before it can finalize the proposed rule.

C. Risk Assessment

Comment: The risk assessment used FSIS microbiological testing and inspection data from 2010–2011 and data from the HIMP pilot study. A few consumer advocacy organizations and public health organizations argued that the data has the following problems: (1) The data is generated through regulatory programs designed to verify process control within a given establishment at a specific point in time; (2) the data is at least seven years old and may not be representative of current industry practices, and (3) there were only five market hog slaughter establishments that volunteered and agreed to meet the additional requirements in the HIMP pilot study, resulting in a biased sample and results that are not generalizable to all non-HIMP market hog slaughter establishments.

Response: For purposes of the risk assessment, data from HIMP establishments were combined with data from traditional establishments to get a more complete picture of the possible combinations of establishment characteristics, inspection procedures, and *Salmonella* prevalence. The assessment produced estimates of *Salmonella* illnesses under scenarios where inspectors perform more offline food safety activities as compared to traditional inspection. As FSIS explained above, the data FSIS used in the Hog HIMP Report and risk assessment are still useful, despite the passage of time, because the HIMP inspection model has not changed since 2013 and FSIS is still conducting the same inspection procedures. FSIS also explained above that the Agency does not believe that the results are biased because there is evidence that the volunteer establishments participating in the HIMP pilot study are typical of the broader industry.

Comment: One public health organization stated that the model predicts that maximum reduction in the percentage of *Salmonella* positive samples and market hog-attributable salmonellosis cases occurs when the average numbers of offline inspection procedures performed (Scheduled and Performed (SP) and Unscheduled (U)) increase 25 percent and the numbers of Scheduled but Not Performed (SNP) and NR inspection procedures decrease 50 percent and 46.67 percent, respectively. The commenter also stated that FSIS concluded that all establishments under NSIS are expected to achieve greater process control in response to increases in FSIS offline inspection tasks in addition to industry-wide commercial and technological innovation that will likely occur over time. According to the commenter, these results assume that resources will be re-allocated within an establishment in such a way that the FSIS offline inspection resources increase by 25 percent and the number of scheduled but not performed FSIS tasks decreases by 50 percent. The commenter questioned if this is achievable given FSIS's current inspection resources. The commenter stated that if inspection resources are lost, through attrition or budget cuts, these assumptions may not be realistic.

Response: The predicted increase in offline inspection resources and decrease in scheduled but not performed activities are achievable with FSIS's current inspection resources. In fact, NSIS will allow FSIS to better use its inspection resources. FSIS discusses the impact of attrition and budget in more detail in section ''I. Potential Budgetary Impacts on the Agency.''

Comment: One consumer advocacy organization stated that the risk assessment shows that the five HIMP establishments had higher NRs (9.4-times more, when weighted by volume) than the non-HIMP traditional establishments. According to the commenter, the risk assessment also shows that NRs are the strongest and a statistically significant indicator of human illnesses related to consuming contaminated pork.

The same commenter stated that decreasing NRs in all market hog establishments would have the effect of reducing illnesses by 3,893, or 4.7 percent. The commenter argued that this reduction would be 1.5 times greater than the reduction FSIS expects will be possible (2,533) by increasing offline verification tasks under NSIS. According to this organization's analysis, FSIS would reduce more illnesses by decreasing NRs, compared to redeploying inspection resources under NSIS.

Response: As FSIS explained in the risk assessment, NRs were included in this assessment for theoretical evaluation only as a possible decision variable because of inclusion in the NPIS risk assessment. For this assessment, the variables associated with offline inspection tasks represent the sum of each type of category across the various inspection procedure codes in an establishment on each day that a *Salmonella* sample was collected. Unlike SP, SNP, and U, NRs depend on noncompliance by establishments and are strictly not an FSIS decision variable. Historic occurrences of establishment non-compliance may help explain variability in pathogen performance that already has been observed. However, because future NR rates depend on the behavior of establishments, it is not feasible to assume that the NR rates can be varied (like SP, SNP, and U) solely by reallocating Agency inspection resources. Therefore, FSIS considers implementation scenarios that simulate future changes in the NR variable infeasible, but the theoretical examination of NRs offers potential risk management insights.

Comment: A consumer advocacy organization asked, if conducting more offline procedures at HIMP establishments reduces *Salmonella* contamination, why didn't FSIS find a statistically significant reduction in *Salmonella* in HIMP establishments as compared to non-HIMP traditional establishments? The commenter noted that from CY2006 through CY2009 the *Salmonella* percent positive for market hogs was lower in HIMP establishments than in non-HIMP establishments, but it was higher in the HIMP establishments in CY2010. According to the commenter, data from a baseline *Salmonella* study from August 2010 through August 2011 found that the *Salmonella* percent positive for carcasses in the HIMP establishments was almost one-half the value of the rate in comparable non-HIMP

establishments—0.69 percent and 1.35 percent, respectively—but the difference was not statistically significant. According to the commenter, FSIS did not explain why the *Salmonella* percent positive for carcasses are sometimes higher in HIMP establishments and sometimes lower as compared to non-HIMP establishments.

Response: The risk assessment was not conducted as a comparison between HIMP and non-HIMP establishments operating under traditional inspection. It was a regression analysis that looked at the numbers of FSIS inspection procedures conducted and *Salmonella* prevalence at all swine slaughter establishments together. The risk assessment did show a statistically significant relationship between increased offline inspection procedures and reduced *Salmonella* contamination for carcasses. In contrast, the Hog HIMP Report compared the average *Salmonella* percent positive between the five HIMP establishments and twenty-one non-HIMP comparison establishments. The latter analysis did not detect statistically significant differences between these two establishment groups across years, and this is likely attributable to the small sample size (number of HIMP and non-HIMP establishments) relative to the low number of *Salmonella* percent positives at the post-chill carcass sampling point.

Comment: A few consumer advocacy organizations and public health organizations noted that the risk assessment that informed the modernization of poultry slaughter inspection final rule also predicted that conducting more offline tasks would likely result in food safety benefits. According to the commenters, microbial sampling conducted since NPIS's implementation has not supported this prediction. A few commenters noted that in a preliminary assessment of NPIS provided to stakeholders last fall, FSIS indicated that *Salmonella* and *Campylobacter* percent positives were similar between large establishments that volunteered to operate under NPIS and large establishments that decided not to change their inspection systems. One consumer advocacy organization argued that recent data reveal that NPIS establishments are more likely to fail FSIS *Salmonella* performance standards than establishments that have not converted to NPIS. The commenters argued that like NPIS, NSIS will not have food safety benefits.

Response: As noted by the commenters, in a preliminary assessment of NPIS, FSIS found that carcass *Salmonella* and *Campylobacter* percent positives for the group of establishments that had converted to NPIS were comparable to those for similar establishments that had not converted to NPIS.[18] This assessment included all establishments that had converted to NPIS at that point in time, including the former HIMP establishments. The assessment also found that the former HIMP establishments had lower carcass *Salmonella* percent positives than both non-NPIS establishments and non-HIMP NPIS establishments, suggesting that carcass *Salmonella* percent positives are lower in establishments with more experience operating under HIMP and NPIS inspection systems. The Agency will continue to track FSIS carcass *Salmonella* percent positives as more establishments convert to NPIS.

The October 2017 preliminary analysis mentioned by the commenters compared 39 large NPIS establishments, 23 of which were former HIMP establishments, to 126 large non-HIMP and non-NPIS establishments. Poultry establishments continue to convert to NPIS, allowing for a more meaningful comparison between NPIS and non-NPIS establishments. FSIS analyzed the data and found no statistically significant difference in the proportion of establishments that fail to meet carcass *Salmonella* performance standards between those operating under NPIS and those operating under the traditional inspection system. Considering uncertainty, the 95 percent confidence interval for the difference in proportions includes zero. This provides supporting empirical evidence independent of the risk assessment model that in practice the NPIS provides an equivalent level of food safety protection compared to traditional inspection. FSIS disagrees that the current data shows that there will be no food safety benefits related to NPIS, and therefore, there will be no food safety benefits related to NSIS. Especially since the October 2017 preliminary analysis found that FSIS inspectors are performing approximately four times more offline verification tasks for visible contamination in NPIS establishments than in non-NPIS establishments. FSIS will continue to evaluate the public health impact associated with NPIS as more establishments convert and experience is gained with operating under NPIS.

[18] Update on Preliminary Analysis of Modernization of Poultry Slaughter, October 2017 available at: *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/himp-study-plans-resources/poultry-slaughter-inspection.*

Comment: One consumer advocacy organization noted that FSIS's uncertainty analysis indicated that there is a 12.5 percent chance that there will be increased illnesses simply by increasing the number of scheduled-performed verification tasks. The commenter argued that FSIS should not finalize a rule that would not improve public health.

Response: The risk assessment analyzed data on specific types of inspection activities and the prevalence of *Salmonella* in market hog slaughter establishments. The results suggest that, because inspection personnel assigned to NSIS will conduct more of the type of inspection activities that were correlated with lower *Salmonella* prevalence, NSIS will potentially result in fewer human illnesses than would be expected if not implemented. Therefore, FSIS needs to publish and implement this rule to be able to shift resources and realize the predicted benefits. In addition to the estimated values, the analysis provides the statistical uncertainty of the estimated number of averted illnesses by reporting the upper and lower confidence bounds around the estimates to acknowledge that uncertainty always will exist in such models.

Comment: One public health organization stated that FSIS did not assess the public health impact of increasing establishments' line speeds in the proposed rule. The same commenter stated that FSIS should explore the public health impact of increasing line speeds before finalizing the proposed rule.

Response: While the relationship between line speed and *Salmonella* prevalence was not incorporated into the risk assessment model, FSIS did consider the impact of line speed on HIMP establishment performance in the Hog HIMP Report. The Hog HIMP Report estimated that in CY2013, line speeds at the 5 HIMP market hog establishments varied from 885 to 1,295 head per hour (hph), with an estimated average line speed of 1,099 hph. The 21 non-HIMP comparison establishments had estimated line speeds of 571 to 1,149 hph, with an estimated average line speed of 977 hph. The Hog HIMP Report found that even with slightly faster line speeds, HIMP market hog establishments had higher compliance with Sanitation SOP and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella* verification testing positive rates than the 21 traditional non-HIMP comparison market hog establishments, and lower levels of violative chemical residues.

Comment: A few commenters urged the Agency to redo the risk analysis model using data from FSIS's *Salmonella* pork cuts and comminuted pork exploratory testing after that project has been finalized.

Response: Data from the Agency's pork cuts and comminuted pork exploratory testing project would not improve the risk assessment. While the pork parts data may prove useful for monitoring and evaluating process control during further processing, it will not be useful for measuring process control during slaughter operations. Processing establishments purchase primals from multiple slaughter establishments. Because establishments comingle primals during processing, they may become contaminated during processing. As a result, the *Salmonella* percent positives during processing would not be reflective of *Salmonella* percent positives or pathogen contamination at the end of slaughter operations.

Comment: One animal welfare group argued that the risk assessment and peer review were too narrow in scope. The commenter argued that the risk assessment should not have been limited to *Salmonella* risk but should have included every potential food safety and public health risk. The commenter was especially concerned about the risk of *Yersinia enterocolitica* and influenza.

Response: FSIS selected *Salmonella* because it is the most common cause of foodborne illness associated with pork products and interventions targeted at reducing *Salmonella* have been shown to be effective at reducing contamination by other enteric pathogens, such as *Yersinia enterocolitica.* FSIS did not include swine influenza in the Agency's risk assessment because swine influenza has not been shown to be transmissible to people through eating pork products.

Comment: One consumer advocacy organization commented that FSIS had not adequately considered the peer review comments and cited Reviewer E's comment about whether using simulated data is ''a statistically legitimate approach.''

Response: After additional internal review, FSIS has decided to add language to the risk assessment to highlight the results of the modeling without simulated data (*see* Table 13 in the risk assessment). FSIS is confident that it has addressed reviewers' comments on the risk assessment.

D. NSIS

Comment: Comments from swine slaughter establishments, trade associations representing the pork industry, and a few private citizens supported the proposed rule. These comments stated that NSIS will enhance FSIS inspection procedures and increase industry efficiency while ensuring safeguards are in place to promote worker safety and animal welfare.

However, comments from consumer advocacy organizations, labor unions, public health organizations, animal welfare advocacy organizations, worker rights advocacy organizations, and private citizens objected to NSIS for various reasons. Many of these commenters objected to NSIS because they view NSIS as a system that ''privatizes'' inspection by replacing FSIS inspectors with establishment employees.

Response: FSIS is not privatizing swine slaughter inspection. The new inspection system will not eliminate FSIS inspection. NSIS simply requires establishments to take additional steps *before* FSIS inspection to ensure that their products are safe and wholesome.

As FSIS explained in the proposed rule, most market hog establishments under traditional inspection already voluntarily conduct sorting activities before FSIS ante-mortem inspection (83 FR 4780, 4783). Under NSIS, because establishment employees are responsible for identifying and removing market hogs that are not fit for slaughter before FSIS ante-mortem inspection, FSIS inspectors are presented with healthier animals that are more likely to pass inspection. Under NSIS, FSIS will continue to conduct ante-mortem inspection. The key difference is that establishment sorting activities will be mandatory.

Under traditional inspection, establishments conduct no post-mortem carcass sorting to identify which carcasses and parts appear eligible to bear the mark of inspection, which carcasses and parts contain removable defects correctable through trimming, and which carcasses and parts should be submitted to FSIS for condemnation because of generalized diseases or conditions. Rather, under traditional inspection, establishments are required to assign competent assistants to take such actions as directed by FSIS online inspectors after the inspectors have conducted the initial inspection activities (see 9 CFR 307.2(g)). Therefore, under traditional inspection, establishments rely on FSIS online inspectors to effectively control and direct their processing.

Under NSIS, FSIS inspectors will still be stationed on the evisceration line and these inspectors will continue to inspect every head, viscera, and carcass as required by the FMIA. FSIS offline inspectors will also continue to conduct food safety related inspection activities and evaluate establishment process controls. However, FSIS will require establishments operating under NSIS to take a more proactive role in removing contamination and identifying defects before FSIS post-mortem inspection.

Comment: A few consumer advocacy groups argued that the proposed rule's ante-mortem condemnation provisions violate the FMIA. One consumer advocacy group stated that 21 U.S.C. 603 and 9 CFR 301.9(a) require FSIS inspectors to examine and inspect each animal before it can be slaughtered for human food. The consumer advocacy group argued that FSIS completely disregards this requirement by allowing establishment employees to ''bypass'' antemortem inspection for 90 to 95 percent of all moving animals not deemed suspect by the establishment.

Several commenters noted that a former chief veterinarian for FSIS spoke out against the ante-mortem portion of the proposal, suggesting that it would increase the risk that FSIS veterinarians could miss the early signs of a large-scale animal disease outbreak. The commenters stated that an outbreak could impact food safety while having devastating economic consequences for U.S. animal producers. According to the commenters, a large outbreak of Foot and Mouth Disease (FMD) has the potential to shut off all foreign markets to U.S. beef and pork, costing American producers an estimated $128 billion over a 10-year period.

Two foreign countries requested clarification on the role of the FSIS Public Health Veterinarian (PHV) and inspectors in the context of ante-mortem activities under the NSIS. The commenters questioned if FSIS inspectors or veterinarians will inspect all animals or carcasses removed by the establishment sorters.

Response: As FSIS explained in the proposed rule, animal sorting procedures under HIMP and NSIS are virtually the same as animal segregation procedures used voluntarily by most market hog establishments under traditional inspection. FSIS has allowed establishments operating under traditional inspection to voluntarily implement animal segregation procedures since at least the 1980s without adverse economic consequences.

Most establishments under traditional inspection that slaughter only market hogs voluntarily segregate animals that show signs of diseases or conditions from healthy animals before the Agency

performs ante-mortem inspection.[19] Therefore, market hog establishment personnel segregate animals that appear to be normal and healthy from abnormal or unhealthy animals that appear to have condemnable diseases or conditions (*e.g.,* animals exhibiting signs of neurologic conditions, pyrexia, or severe lameness) into ''subject'' pens, where they undergo additional FSIS inspection. FSIS requires these establishments to document their segregation procedures in their HACCP plans or prerequisite programs.[20] FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion.[21]

FSIS disagrees that this inspection scheme violates the FMIA. FSIS inspectors still conduct 100 percent ante-mortem inspection.[22] If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the ''U.S. Suspect'' pens for final disposition by the FSIS PHV. The FSIS PHV examines all animals in the ''subject'' and ''U.S. Suspect'' pens. FSIS inspectors observe establishment employees performing animal segregation procedures at least once per month.

As mentioned above, the key difference, as compared to traditional inspection, is that sorting procedures are mandatory under NSIS. All establishments operating under the NSIS must address, as part of their HACCP system, procedures for sorting animals showing signs of diseases or abnormalities from healthy animals. These procedures must cover establishment sorting activities for dead and moribund swine and swine suspected of having central nervous system (CNS) conditions or pyrexia. Establishments under NSIS that do not adequately sort for these food safety defects before FSIS ante-mortem inspection will receive an NR for noncompliance with 9 CFR 309.19.

Regarding the questions from the foreign countries, FSIS inspectors inspect every market hog offered for slaughter. However, an establishment may decide to divert hogs that do not meet its market specifications to another slaughter facility, where they will receive 100 percent ante-mortem inspection by an FSIS inspector. This is not a change in policy. Establishments operating under traditional inspection may also divert hogs to other establishments operating under traditional inspection. If establishments decide to divert hogs, they are required to follow the Animal and Plant Health Inspection Service's (APHIS's) regulations governing the movement of live animals.

Under the NSIS, FSIS inspectors will observe establishment employees performing sorting procedures. During this time, FSIS inspectors will verify that animals that are intended to be disposed of are humanely euthanized and that animals that are intended to be diverted to another official establishment are eligible for transport.

Comment: Several comments asserted that revoking maximum line speeds conflicts with the purposes or provisions of the FMIA because faster line speeds will make it more difficult for FSIS inspectors to effectively conduct online inspection. A consumer advocacy organization stated that the FSIS inspectors must provide a ''critical appraisal'' of all carcasses (*AFGE* v. *Glickman,* 215 F.3d 7, 11 (D.C. Cir. 2000)). According to the comments, revoking maximum line speeds will make it extremely difficult, if not impossible, for FSIS to conduct a critical appraisal of each hog.

Comments from consumer advocacy organizations and an animal welfare organization further argued that FSIS does not have the statutory authority to conduct rulemaking to increase efficiencies for the government and industry.

Response: Based on FSIS's experiences under HIMP, online inspectors in HIMP establishments can conduct an effective online inspection of the head, viscera, and carcass of each hog when operating at faster line speeds. To ensure that online inspectors will be able to conduct effective online inspections, FSIS PHVs in all NSIS establishments are authorized to direct establishments to operate at reduced line speeds when, in the PHV's judgment, a carcass-by-carcass inspection cannot be performed within the time available due to the way that the hogs are presented to online inspectors, or because the establishment is not maintaining process control (9 CFR 310.26).

FSIS has the authority to change its regulations to conduct more efficient inspections and to reduce unnecessary regulatory burdens on industry. As FSIS explained in the proposed rule (83 FR 4780, 4782), 21 U.S.C. 621 provides that the Secretary shall make such rules and regulations as are necessary for the efficient execution of the provisions of the FMIA. In addition, this rulemaking is consistent with E.O. 13563, which directs Federal agencies to review existing rules that may be burdensome, unnecessary, and outdated and to modify, streamline, expand, or repeal them accordingly.

Comment: Several comments from consumer advocacy organizations, public health organizations, worker advocacy organizations, labor unions, and private citizens objected to FSIS's requirement that establishment employees sort carcasses and parts before they are presented for FSIS inspection because the commenters believe that establishment employees will miss many food safety and OCP defects. A few commenters referenced affidavits from three FSIS inspectors who worked in HIMP establishments who stated that because of excessive line speeds and lack of training, establishment sorters routinely miss many food safety and wholesomeness defects. The commenters argued that FSIS must more thoroughly evaluate the proposal to allow establishment employees to perform preliminary sorting before the Agency implements NSIS.

Response: The Hog HIMP Report found that the overall performance of HIMP establishments was as good as non-HIMP establishments. Results from offline inspections in HIMP establishments, which are conducted after establishment employees have completed the initial sorting of carcasses and parts, show that the rates of carcasses with food safety defects (*e.g.,* septicemia, toxemia, pyemia, and cysticercosis) and visible contamination from visible fecal material, ingesta, and milk in HIMP establishments were very low, well below the levels set by the HIMP performance standards. In addition, as explained in the proposed rule, OCP defect rates identified on carcasses and parts in HIMP establishments average about half the corresponding OCP HIMP performance standard. Therefore, the data from the HIMP pilot study show that establishment employees do effectively sort carcasses, trim defects, and identify

[19] *See* FSIS Directive 6100.1, *Ante-mortem Livestock Inspection* available at *http://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b593-7dc5a0263504/6100.1.pdf?MOD=AJPERES.*

[20] See FSIS Directive 6100.1, Ante-mortem Livestock Inspection available at *http://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b593-7dc5a0263504/6100.1.pdf?MOD=AJPERES.*

[21] See FSIS Directive 6100.1, Ante-mortem Livestock Inspection available at *http://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b593-7dc5a0263504/6100.1.pdf?MOD=AJPERES.*

[22] *See* FSIS Directive 6100.1, *Ante-mortem Livestock Inspection* available at *http://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b593-7dc5a0263504/6100.1.pdf?MOD=AJPERES.*

carcasses for disposal before FSIS post mortem inspection.

Comment: Several consumer advocacy groups and a public health organization recommended that FSIS establish training for establishment employees performing sorting activities and require sorters to prove proficiency in performing their duties.

Members of industry stated that establishments operating under HIMP have been successful at training employees to sort for food safety and non-food safety defects. These commenters commended the Agency for creating its sorter guide. The commenters stated that the sorter guide is comprehensive and consistent with current practices under HIMP. However, the commenters stated that the sorter guide could be improved by defining several pathological conditions and veterinary terms not well-known to industry personnel, as well as updating photos and diagrams.

Response: FSIS is not prescribing specific sorter training or certification. FSIS made some editorial changes to its sorter guide to simplify the guideline. The Agency did not make any significant changes to its sorter guide in response to comments. FSIS did not think it was necessary to add the pathological conditions, veterinary terms, or pictures mentioned in the comments because they are not commonly found or used. However, FSIS PHVs will be available to discuss conditions and terms if an establishment has any questions. The guide is available on the FSIS website at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/compliance-guides-index.* As FSIS explained in the proposed rule, the guide that the Agency has developed is based on the training that FSIS provides to its online inspection personnel that are responsible for sorting carcasses under the existing inspection systems.

Comment: Members of the pork industry and a trade association representing members of the pork industry requested that FSIS clarify when NRs will be issued by offline inspectors for carcasses contaminated with visible fecal material, ingesta and milk. The commenters noted that the proposed rule stated that FSIS will issue NRs for every carcass contaminated with fecal material, ingesta, and milk. According to the commenters, this policy is not consistent with FSIS Directive 6420.2, which instructs inspection personnel to issue NRs based on a specific sampling procedure during carcass verification checks.

Response: FSIS is clarifying that, consistent with FSIS Directive 6420.2, only offline inspectors will issue NRs for fecal material, ingesta, or milk contamination if they observe the contamination on sampled carcasses when performing the Livestock Zero Tolerance Verification task. FSIS online inspectors will not issue NRs if they observe fecal material, ingesta, or milk contamination on the carcasses. Rather, online inspectors will stop the slaughter line to allow for trimming of the carcass by establishment personnel and reinspection of the carcass by the inspector, unless the establishment has provided a rail-out loop. FSIS did not intend to change these inspection procedures with the implementation of this rule.

Comment: Members of the pork industry and trade associations representing the pork industry stated that the proposed requirement to immediately denature carcasses that have been sorted and removed from slaughter is overly burdensome and unnecessary. One trade association stated that imposing specific denaturing requirements may discourage establishments from adopting NSIS. That commenter suggested that FSIS amend the proposed 9 CFR 309.19(c) to read ''the establishment must dispose of the carcass according to 9 CFR part 314.'' A HIMP establishment recommended FSIS require that establishments maintain procedures to control and isolate carcasses and parts removed from slaughter and demonstrate that they do not enter the human food chain or immediately denature in accordance with 9 CFR part 314.

Response: FSIS has considered these comments and believes they have merit. Therefore, FSIS has revised its proposed disposal requirements and will instead require establishments to develop, implement, and maintain written procedures to ensure that animals and carcasses that have been sorted and removed for disposal do not enter the human food supply and are properly disposed of according to 9 CFR part 314.

Comment: Members of the pork industry and trade associations representing members of the pork industry noted that APHIS uses FSIS animal disposition data, collected and maintained through PHIS, to monitor animal disease rates and identify trends. These commenters all agreed that these data are useful and should not be lost in the transition to NSIS. According to these commenters, it would not be overly burdensome for establishments to keep records of the specific reasons why hogs are removed from slaughter because they already produce similar records. The commenters recommended that FSIS work with establishments on a procedure to transfer disposition information to APHIS on a regular schedule to ensure the ongoing utility of APHIS's swine health surveillance programs.

Response: In response to these comments, FSIS has amended its proposed record keeping regulations to require swine slaughter establishments to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal. FSIS has created a form to collect disposition data from establishments. Establishments may provide the same information as requested on the form electronically if it is submitted in a format approved by FSIS; FSIS will provide further instructions on submitting this data electronically via PHIS later. FSIS will need establishments to submit their electronic data in a format that is compatible with PHIS so that the Agency can quickly analyze the data and share it with APHIS. FSIS has updated its Paperwork Reduction Act analysis to account for this new requirement.

Comment: Members of the pork industry, trade associations representing the pork industry, and a foreign country urged the Agency to allow establishments the discretion to incise lymph nodes when conducting carcass sorting activities based on their own hazard analysis. One member of the pork industry stated that they have demonstrated through testing and a supplier risk assessment that there is no value in incising lymph nodes to identify pathological conditions.

The foreign country noted that this approach aligns with the visual-only inspection methodology already implemented by other World Trade Organization (WTO) members. According to the foreign country, on-farm practices (husbandry, biosecurity, etc.) have evolved and improved to a point that disease transmission risks can be greatly reduced through effective on-farm controls. The foreign country stated that palpating and incising the mandibular lymph nodes has been shown to contribute to cross contamination of pork products by food safety hazards such as *Salmonella* and *Yersinia.* Therefore, the foreign country argued that moving to a routine visual-only inspection, supported by supply-chain information from primary production facilities, would improve food safety systems.

One trade association stated that the administrative hassle involved in collecting, organizing, and presenting

supply-chain information to FSIS to demonstrate that animal diseases like *M. avium* are not reasonably likely to occur would be unnecessarily arduous and not worth the benefits related to not incising lymph nodes.

Response: This final rule requires that establishment sorters incise mandibular lymph nodes and palpate viscera to detect the presence of animal diseases as part of their sorting activities, as was proposed (9 CFR 310.26(b)). However, establishments that operate under NSIS may seek waivers (9 CFR 303.1(h)) under the SIP to 9 CFR 310.26(b). Establishments would need to submit documentation supporting that the presence of animal diseases like *M. Avium* is not reasonably likely to occur. Should FSIS grant these waivers, establishments would be permitted to decide, on a lot-by-lot basis, whether to incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases. The Agency has decided to grant waivers, when appropriate, to gather more information on the public health impact of such sorting activities to support potential future rulemaking.

Comment: A foreign country requested clarification on the requirement (9 CFR 310.26(a)) for establishments with fewer than three inspection stations to have a mirror at the carcass inspection station. The commenter questioned whether all NSIS establishments will have to have mirrors at the carcass inspection station. The foreign country was concerned that this requirement will be more burdensome than necessary, particularly for small establishments operating at slower line speeds.

Response: FSIS is requiring all NSIS establishments to provide a mirror so that FSIS can adequately inspect carcasses. Large, high-volume market hog slaughter establishments under traditional inspection are already required to provide mirrors to assist FSIS inspection (*see* 9 CFR 310.1(b)(3) and 307.2(m)(6)).

As FSIS explained in the proposed rule, the Agency does not expect very small establishments to convert to NSIS because of the costs of hiring and training establishment sorters.

E. Line Speed

Comment: Members of the pork industry and trade associations representing members of the pork industry supported FSIS's proposal to revoke maximum line speed limits for establishments operating under NSIS. Some of these commenters noted that line speeds were originally established to define the number of FSIS online inspectors required to inspect carcasses based on the number of carcasses an individual could reasonably evaluate in a given period. According to the commenters, when these limits were set, animal disease prevalence was much higher, so inspectors needed more time to complete inspection. The commenters agreed with FSIS's conclusions that innovations in animal housing, genetics, and processing have been implemented and have improved livestock conditions at slaughter; therefore, the current line speed limits are outdated and unnecessary.

Members of the pork industry and trade associations representing the pork industry also stated that revoking maximum line speeds will allow establishments to better adapt their line speeds to slaughter conditions. These commenters argued that line speeds can be adjusted to optimize efficiencies without jeopardizing worker safety, animal welfare, food safety, or quality. These commenters noted that the Hog HIMP Report found that HIMP establishments do not operate at line speeds that are significantly faster than the current maximum line speed for market hogs.

Response: This final rule revokes the maximum line speeds for establishments operating under NSIS. The maximum line speed under the existing regulations for market hogs is 1,106 head per hour (hph) with seven online inspectors. Experience from the HIMP pilot study shows that HIMP establishments operate with an estimated average line speed of 1,099 hph, and that the line speeds varied from 885 hph to 1,295 hph (under a waiver). Thus, although they are authorized to do so, market hog HIMP establishments do not operate at line speeds that are significantly faster than the current maximum line speeds for market hog establishments operating under traditional inspection.

NSIS is informed by the Agency's experiences under HIMP, and establishments operating under HIMP have demonstrated that they are capable of consistently producing safe, wholesome, and unadulterated pork products while operating at line speeds above the current maximum line speeds (for market hogs under traditional inspection). HIMP establishments also have consistently met pathogen reduction and other performance standards when operating without prescribed maximum line speeds. Moreover, NSIS incorporates additional measures that will apply to all swine slaughter establishments. These measures, which include carcass testing for microbial organisms at pre-evisceration and post-chill (or for hot-boned product, pre-evisceration and after the final wash), are designed to ensure that establishments maintain process control. As a result, FSIS has decided that line speed limits are not necessary for establishments operating under NSIS.

Comments: Members of the pork industry and trade associations representing the pork industry stated that increased line speeds will not present greater risks for worker safety. One company that owns a HIMP establishment commented that they have not found a correlation between line speeds and worker safety issues in their establishment. According to this commenter, their company's Total Recordable Incident Rate (an OSHA reporting category) has shown a significant decline in recordable injuries since they started operating under their line speed waiver. The commenter also stated that their findings were consistent with the proposed rule's comparative analysis of injuries, which found that HIMP establishments had lower mean injury rates than non-HIMP establishments.

Members of the pork industry and trade associations representing the pork industry stated that establishments continuously evaluate worker safety. According to the commenters, establishments actively work to reduce injuries by implementing ergonomic programs, modifying processes, and creating additional job positions to distribute manual tasks among workers.

However, comments from worker advocacy organizations, labor unions, consumer advocacy organizations, an environmental advocacy organization, and private citizens asserted that revoking maximum line speeds will increase risks to worker health and safety in establishments that operate under NSIS. The comments referenced studies, reports, and other data on work-related injuries in the meat processing industry. The most commonly referenced information sources included:

- Documents published by OSHA that state that musculoskeletal injuries and disorders are prevalent in the meatpacking industry. In the documents, OSHA recommends that establishments should reduce line speeds and production rates to decrease injury rates.
- 2016 BLS data showing that employer reported injury rates for meat establishment workers who were injured or made ill at work are 2.4 times the rate of workers in other private-sector industries.

• Reports published by the GAO that concluded, among other things, that injury rates in the meat slaughter industry continue to be higher than the rates for others in the manufacturing industry, that meat workers may under-report illnesses and injuries because they fear losing their jobs, and that employers may underreport worker injuries because of concerns about potential costs.

• Various reports from worker advocacy organizations on worker safety in meat processing establishments. These reports include statements from slaughter establishment workers that have suffered illnesses and injury from the fast-paced repetitive tasks associated with the current line speeds.

The comments stated that the available studies, reports, and data contradict FSIS's analysis of worker illness and injury in the proposed rule.

Response: While FSIS agrees that safe working conditions in swine slaughter establishments are important, the Agency has neither the authority nor the expertise to regulate issues related to establishment worker safety. FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture under the FMIA, the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA; 21 U.S.C 1301 *et seq.*) (the Acts). Under these Acts, FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. The Acts authorize FSIS to administer and enforce laws and regulations solely to protect the health and welfare of consumers.

The Department of Labor's OSHA was created by the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) to assure safe and healthful working conditions for men and women by setting and enforcing standards and by providing training, outreach, education, and assistance. OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health. FSIS's authority with respect to working conditions in slaughter establishments extends only to FSIS inspection personnel.

FSIS has worked with OSHA to develop a poster that establishments must display providing information on the signs and symptoms of occupational injuries and illnesses experienced by market hog slaughter workers, and about workers' rights to report these conditions without fear of retaliation (see 9 CFR 310.27). This final rule also requires establishments operating under NSIS to submit on an annual basis an 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 of establishment workers (9 CFR 310.27). Because OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health, FSIS will forward these annual attestations to OSHA for use in its own enforcement program. FSIS employees, however, will not be responsible for determining the merit of the content of the attestation or for enforcement of non-compliance with the attestation provision. OSHA and FSIS will continue to partner through a Memorandum of Understanding,[23] to strengthen collaboration between FSIS inspectors and OSHA enforcement staff and ensure identification and reporting of safety hazards impacting working conditions of FSIS inspectors and those of establishment employees.

Comments: Comments from animal welfare advocacy organizations and private citizens concerned about animal welfare asserted that revoking maximum line speeds for establishments that operate under NSIS will have adverse effects on the humane handling of swine. The comments expressed concern that faster line speeds would increase the potential for workers to force animals to move faster than normal walking speeds and for ineffective stunning. Most of these comments referenced an undercover video that was taken at a HIMP establishment in 2015. According to the commenters, the video showed hogs that were beaten and electrically prodded to move to keep up with the slaughter line speed. The commenters claimed that the video showed hogs that were conscious when they entered the scalding tank because they were improperly stunned.

Several animal welfare groups also claimed that establishment employees are pressured by establishment management to never slow the slaughter line. A few commenters stated that they found a Memorandum of Interview (MOI) issued in 2017 to a HIMP establishment that stated that an FSIS inspector observed that hog handlers were driving animals too fast and with more excitement than necessary, in violation of 9 CFR 313.2. According to the commenters, the MOI also stated that the inspector's concerns had been raised at least twice at weekly meetings with establishment management. The commenters argued that the MOI shows that hogs are routinely forced to move too fast in HIMP establishments.

One commenter supported FSIS's decision to add a second offline inspector to conduct additional offline activities such as monitoring compliance with the HMSA. However, the commenter opposed FSIS's decision to decrease the total number of FSIS in-plant personnel.

Response: FSIS disagrees that revoking line speeds will have a negative effect on animal welfare. As the Agency explained in the proposed rule, FSIS was able to conduct more offline humane handling verification tasks under HIMP as compared to traditional inspection. As is the case under HIMP, more inspection resources will be available to verify whether establishments meet humane handling requirements as an offline activity under NSIS.

Regarding the undercover video, multiple FSIS experts—including trained veterinarians and humane handling experts—reviewed the video and determined that there was unacceptable rough handling and inappropriate use of a rattle paddle to drive animals. FSIS took immediate regulatory action against the establishment and required it to respond with acceptable corrective actions to prevent a recurrence.

While a person in the video suggests that animals were conscious after stunning, FSIS found that the animals appeared properly stunned and insensible to pain, as required by Federal law. The video was reviewed by a professor of animal science, who reached the same conclusion.

FSIS reviewed the 2017 MOI that stated that an FSIS inspector observed that hog handlers were driving animals too fast and with more excitement than necessary. FSIS has instructed its inspection personnel to properly document noncompliance in NRs and not MOIs.

Comment: One animal welfare organization noted that they submitted a petition in 2014 requesting that the Agency require all swine slaughter establishments to immediately and humanely euthanize non-ambulatory disabled (NAD) pigs. According to the petition, prohibiting the slaughter of NAD pigs would improve inspection efficiency and compliance with the HMSA, as well as reduce *Salmonella* risks. The animal welfare organization argued that FSIS must respond to their petition before finalizing the proposed rule.

Response: After carefully considering the issues raised in the petition, along

[23] The MOU is available at: *https://www.osha.gov/laws-regs/mou/1994-02-04.*

with the referenced information and other letters received in support of the petition, FSIS has concluded that its existing regulations and inspection procedures are sufficient and effective in ensuring that NAD pigs are handled humanely at slaughter and in preventing diseased animals from entering the human food supply. Consequently, the Agency is denying the petition. The Agency's final petition response is available at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions.* FSIS denied a similar petition in 2013 requesting that the Agency prohibit the slaughter of all NAD livestock. That petition response is also available at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions.*

F. Ready-to-Cook

Comment: Members of the pork industry and trade associations representing members of the pork industry generally support the proposed RTC pork product standard. However, the commenters requested that FSIS amend the definition to include language such as ''reasonably free,'' or ''sufficiently free,'' to clarify that the RTC standard is a standard for non-food safety defects and not a zero-tolerance standard.

These same commenters recommended that the Agency allow establishments to apply the RTC standard at any appropriate location at or before the point of packaging or to clarify that the Agency intends this type of flexibility if that is the case. One trade association said that because an establishment may apply processes targeting RTC criteria and other quality issues at various locations after the cooler, FSIS should not inspect for RTC criteria before the cooler. The commenter argued that there is no food safety concern associated with carcasses and parts that may not yet meet the RTC standard entering the cooler.

Members of the pork industry, trade associations, and a foreign country asked FSIS to clarify when FSIS inspectors can slow or stop the evisceration line because of non-food safety defects in establishments operating under NSIS. These commenters also asked FSIS to clarify how the Agency will document noncompliance with RTC standards. According to the commenters, online inspectors should be instructed to stop the line only to remove food safety defects after the establishment's final control, and NRs should only be given after offline personnel assess and confirm a loss of process control.

A trade association noted that several processing defects covered in the RTC definition are listed under 9 CFR 310.18(a), which applies to all swine establishments and is typically enforced as a zero-tolerance standard. The commenter also noted that 310.18(a) is regularly categorized as a PHR. The commenter was concerned that if an NSIS establishment receives an NR for 9 CFR 310.18(a) for failure to meet RTC standards, it will unjustly influence the establishment's PHR rate. Rather than cite 9 CFR 310.18(a), the commenter suggested that inspectors should cite 9 CFR 310.26(d)(1) for products not meeting RTC standards at NSIS establishments to delineate NRs for non-food safety issues from NRs for food safety issues.

Response: Under NSIS, 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 RTC pork product definition. The records will be subject to review and evaluation by FSIS offline inspectors (9 CFR 310.26(d)(1)).

FSIS has decided to amend the definition of RTC pork product to clarify that it is not a zero-tolerance standard. RTC pork product will now be defined as ''any slaughtered pork product *sufficiently* free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor, which is suitable for cooking without need of further processing.''

FSIS also is clarifying that the RTC definition applies to pork products at the end of the slaughter process and before carcasses and parts enter the cooler. This is consistent with the Agency's requirements under HIMP and NPIS.

FSIS will issue instructions to its inspectors on how to verify the RTC pork product requirements using the routine and directed PHIS Swine RTC task. When conducting the routine task, FSIS offline inspectors will verify that an establishment maintains records as required by 9 CFR 310.26(d)(1). FSIS will issue an NR for 9 CFR 310.26(d)(1) if an establishment does not have records to document that the products resulting from its slaughter operation meet the definition of RTC pork product.

If FSIS online inspectors believe that the presentation of persistent unattended trim or processing defects indicates a lack of process control, they will notify the PHV. The PHV may then tell an offline inspector to conduct a directed PHIS Swine RTC task. FSIS offline inspectors will follow the same method and apply the same criteria that the establishment uses to check that they are meeting the RTC standard. FSIS will issue an NR for 9 CFR 310.26(d)(1) if the results exceed the criteria set by the establishment or if the establishment did not take the necessary corrective actions to restore process control when the evaluation criteria was exceeded.

If the PHV determines that the presentation of persistent unattended trim or processing defects indicates a loss of process control that affects the online inspectors' ability to adequately conduct a carcass-by-carcass inspection, the PHV will direct the establishment to reduce its line speeds. The PHV will then issue an NR citing 9 CFR 310.26(d)(1).

FSIS inspectors will use PHIS to link all NRs that are issued for the failure to meet the RTC pork product standard and associated documentation requirements. If establishment management is unwilling or unable to take the necessary steps to re-establish control of its process to meet RTC regulatory requirements, FSIS inspectors will discuss the issue with their supervisor and the DO. The DO will notify the establishment in writing that repeated NRs may lead the Agency to take a regulatory control action (9 CFR 500.2).

In the rare case that FSIS online inspectors identify a carcass so affected with non-food safety defects (*e.g.,* malignant lymphoma, icterus, or uremia) that the entire carcass must be condemned, they will stop the line for carcass condemnation unless the establishment provides a rail-out loop to rail carcasses offline for reexamination and condemnation.

G. Implementation

Comment: One member of the pork industry supported the NSIS implementation strategy suggested in the proposed rule. However, the pork producer requested more information on whether two shift operations must convert both shifts to NSIS at the same time. The same commenter also requested more information on what would happen if an establishment that converted to NSIS decided it wants to move back to traditional inspection.

A trade association noted that FSIS's implementation plan for NPIS was phased in with close coordination with DOs and establishments. The commenter stated that FSIS should follow a similar implementation plan for NSIS, with an initial notification period for establishments that want to adopt NSIS and an algorithm to

determine transition order. This commenter also suggested a phased-in approach for the mandatory provisions for all swine establishments based on establishment size.

The same trade association stated that establishments should submit for approval unique transition plans to the DO when providing notification that they intend to adopt NSIS. The trade association suggested that FSIS identify and provide acceptable examples of transition plan elements. According to the commenter, pre-approved elements should include transitioning single inspection stations in succession, one shift at a time, one inspection focus area (*i.e.,* head inspection) at a time, RTC monitoring before transitioning inspection activities, and others.

Consumer advocacy organizations stated that only establishments that have their HACCP plans approved by FSIS should be allowed to implement NSIS. The commenters suggested that FSIS should review every establishment's HACCP plans to determine if their tailored microbiological testing programs are valid before allowing them to convert to NSIS.

Response: All market hog establishments will initially have six months to notify their DO of their intent to operate under NSIS. Establishments that do not notify their DO of their intent to transition during this time will be deemed to have chosen to continue to operate under traditional inspection. Market hog establishments that decide that they would like to convert to NSIS after the initial notification date may notify their DO of their intent at any time after that date. The Agency will implement NSIS in the additional establishments that intend to convert on a schedule consistent with the availability of Agency resources and establishment readiness. The Agency intends to implement NSIS in all market hog establishments that choose to operate under this new inspection system, regardless of when the establishment notifies FSIS of its intent to transition to NSIS. However, the initial implementation wave will only include those establishments that submit their intent to convert to NSIS within the initial notification period.

Because there are fewer market hog establishments than poultry establishments, the Agency does not think it will be necessary to use an algorithm to determine transition order. FSIS also does not think it is necessary to require establishments to develop formal transition plans. Establishments will need to transition all shifts and inspection stations to NSIS at one time. However, FSIS DOs will work with establishments to ensure a smooth transition from traditional inspection to NSIS. And, if necessary, FSIS DOs will work with establishments to ensure a smooth transition from NSIS back to traditional inspection.

FSIS does not think it is necessary to review HACCP plans before establishments convert to NSIS. FSIS already has inspection tasks in place to verify that establishments are properly implementing their HACCP systems in accordance with 9 CFR part 417.

The Agency is establishing separate applicability dates for large, small, and very small establishments to comply with the regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process in 9 CFR 310.18(c), and the regulations that prescribe recordkeeping requirements in 9 CFR 310.18(d). The applicability dates will provide additional time for small and very small establishments to comply with these provisions.

H. Environmental Assessment

Comments: Comments from an animal welfare advocacy organization and an environmental advocacy organization stated that before FSIS can finalize the proposed rule, the Agency must prepare an Environmental Impact Statement (EIS), as required under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) because, according to these commenters, allowing market hog slaughter establishments to increase line speeds will result in significant environmental impacts. The commenters stated that faster line speeds would mean more hogs slaughtered per shift. According to the commenters, more hogs slaughtered would mean more waste and more water use. The commenters asserted that these are all significant environmental impacts, with both individual and cumulative effects at the local, state, and national levels. The commenters also stated that FSIS cannot claim the categorical exclusion from the preparation of an Environmental Assessment (EA) or an EIS under 7 CFR part 1b of the USDA regulations.

Response: FSIS maintains that this rulemaking is categorically excluded from NEPA requirements. Federal agencies may identify classes of actions that normally do not require the preparation of either an EA or EIS because such actions do not have a significant effect on the human environment, either individually or cumulatively (40 CFR 1507.3(b)(2)). Such classes of actions are ''categorically excluded'' from NEPA requirements (40 CFR 1508.4). Under 7 CFR 1b.4, all FSIS actions, including inspection functions, are categorically excluded from preparation of an EA or EIS unless the Agency head determines that a particular action may have a significant environmental effect. Accordingly, FSIS is not required to prepare an EA or EIS unless it anticipates that this rule may have a significant environmental effect.

The Agency does not anticipate that its decision to revoke maximum line speeds for establishments that operate under NSIS will have individual or cumulative effects on the environment. As FSIS explained in the proposed rule, expected sales of pork products to consumers will determine the total number of hogs that an establishment slaughters, not the maximum line speed under which it operates. The Agency has no authority to determine an establishment's production levels. An establishment may decide to increase production hours to slaughter more hogs in response to market demand, regardless of its maximum line speed. Revoking maximum line speeds allow establishments to slaughter hogs more efficiently but will not directly affect consumer demand for the establishment's pork products. In some instances, an establishment operating under NSIS may be able to reduce its hours of operation while maintaining production at a rate necessary to meet market demand for its meat products. Thus, revoking line speeds is not expected to determine the number of hogs slaughtered or result in more waste or more water use, as suggested by the commenters.

In addition, all slaughter establishments, regardless of line speed, are required to meet all local, State, and Federal environmental requirements.

Sampling

Comments: Comments from consumer advocacy organizations and public health organizations supported FSIS's decision to require establishments to develop written procedures to prevent and mitigate microbial contamination of carcasses throughout the entire slaughter and dressing operations and incorporate the intervention strategies into their HACCP systems. These same commenters stated that sampling at pre-evisceration and post-chill will make it easier for establishments to see if their process control system is working. According to the commenters, microbial testing at the end of the process encourages industry to focus primarily on post-slaughter interventions, while the new approach encourages them to focus on prevention and mitigation of

microbial contamination throughout the slaughter process.

Response: FSIS agrees that requiring establishments to keep 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 actions to prevent further product contamination.

Comments: Comments from members of industry stated that FSIS should revise the proposed rule to remove sampling schemes based on establishment size. According to the commenters, basing sampling frequency on the size of the establishment is not supportable from a statistical sampling point of view. The commenters suggested that FSIS propose a minimum sampling frequency for all establishments based on the number of head slaughtered, over a certain time period.

Response: FSIS changed its proposed sampling frequency to remove the exception for very small establishments. Under this final rule, very small establishments will need to sample carcasses at pre-evisceration and post-chill (for hot-boned product, carcasses sampled at pre-evisceration and after the final wash) at a frequency of one per 1,000 carcasses. However, FSIS has decided to keep the exception for very low-volume establishments. This change makes the sampling requirements for swine slaughter establishments more consistent with the sampling requirements for poultry slaughter establishments. Additionally, if FSIS adopted a sample frequency of one per 1,000 carcasses for very low-volume establishments, many of these establishments would not have to sample at all.

Comment: Several consumer advocacy organizations and one public health organization objected to FSIS's proposal to allow establishments to develop their own sampling and testing protocols and to use alternate sampling locations and frequencies. These same commenters argued that it would be too difficult for FSIS inspectors to verify sampling plans that use alternate sampling locations and frequencies. Two consumer advocacy organizations argued that FSIS's *Salmonella* performance standards remain a core element of HACCP and should not be eliminated under the proposed rule. One consumer advocacy organization argued that FSIS must not move forward with proposed inspection changes without maintaining a pathogen-specific performance standard. The commenter argued that modernized, HACCP-based inspection cannot function adequately without such a performance standard. The commenter further stated that uniform microbial testing is necessary to evaluate the impact of FSIS's planned inspection changes, as the Agency will not be able to verify trends in pathogen rates caused by the inspection changes without an effective national testing program.

One consumer advocacy organization argued that FSIS should maintain the current generic *E. coli* testing standard. Although the commenter did not oppose substitution of another indicator organism for generic *E. coli,* they argued that FSIS must ensure that any newly permitted testing program is evidence-based and equal or superior to the prior generic *E. coli* standard for fecal contamination detection. The commenter recommended that FSIS require establishments who seek to use an alternative testing program to the generic *E. coli* standard to apply for a regulatory waiver, which would allow for pre-implementation Agency review.

Response: The purpose of the 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, ingesta, and milk on an ongoing basis. It is not intended to generate data to compare establishment performance across the industry.

However, FSIS has determined that it may be too difficult for inspectors to review and verify sampling plans that use alternate sampling frequencies and locations. As a result, FSIS is withdrawing the proposal to allow establishments to use alternate sampling frequencies and locations. Establishments that still wish to use alternate sampling frequencies and locations may submit a SIP waiver request to FSIS for review.[24] As is noted above, FSIS will provide information about waiver criteria in a future **Federal Register** document.

As FSIS explained in the proposed rule, FSIS discontinued its *Salmonella* verification sampling program for market hogs (carcasses) in 2011 to make better use of its resources. Because verifying the codified performance standards for market hogs was not a good use of Agency resources, and the standards have not been used since 2011, FSIS is removing the carcass *Salmonella* performance standards for market hogs. With that said, FSIS is currently testing pork cuts and comminuted pork products for *Salmonella* and expects to decide in 2019 whether to develop new pathogen performance standards for these products or take other actions to address *Salmonella* in these products.[25] FSIS pathogen test results for pork products are posted quarterly on the FSIS website: *https://www.fsis.usda.gov/wps/wcm/connect/df529ce7-575a-43e7-9219-48be29c80fa5/Sampling-Project-Results-Data.xlsx?MOD=AJPERES.*

Establishments may continue to sample for generic *E. coli.* FSIS considers the requirements under the former regulations for generic *E. coli* to be a scientifically validated ''safe harbor'' for monitoring process control, specifically for fecal contamination. FSIS previously granted waivers under the SIP to the generic *E. coli* testing regulations for establishments that want to test for other indicator organisms. Establishments operating under these waivers have demonstrated that they are able to effectively maintain process control based on their SIP sampling data.

Comments: Several members of industry, trade associations, and a State Department of Agriculture objected to the proposed pre-operational environmental sampling requirements. One HIMP establishment stated that environmental sampling would be an expensive change with little value. The commenter argued that current HIMP establishments have not been required to conduct environmental sampling beyond those tests that may also meet the Sanitation SOP requirements, and these establishments have shown consistent or better performance controlling for *Salmonella.*

A few public health organizations stated that requiring facilities to monitor and assess food contact surfaces for enteric pathogens is a reasonable measure given that recent investigations of *Salmonella* foodborne illness outbreaks revealed food contact surfaces to be contaminated with the outbreak strain. The commenters stated that requiring pre-operational environmental sampling should help ensure that

[24] See FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols available at *https://www.fsis.usda.gov/wps/wcm/connect/c64d8f3b-56aa-49c9-91f3-daf0caaba6bd/New-Technology-Protocols-042015.pdf?MOD=AJPERES.*

[25] See U.S. Govt. Accountability Office, GAO–18–272, Food Safety: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products (March 2018). *https://www.gao.gov/assets/700/690709.pdf.*

surfaces are sanitary and free of enteric pathogens.

Response: This final rule does not require swine slaughter establishments to develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens. In response to concerns about the regulatory burden, FSIS has decided to withdraw this part of the proposal until it considers options and timing for gathering more data on enteric pathogen contamination in the pre-operational environment. FSIS agrees that current HIMP establishments have shown consistent performance controlling for *Salmonella.*

Comments: Several members of industry, industry trade associations, and private individuals objected to certain content in the sampling guide. These commenters argued that the language in the sampling guide is prescriptive in both tone and language and implies mandatory requirements. The commenters stated that the sampling guide includes unhelpful and problematic sampling methods, techniques, and analysis, as these depend on individual establishments' sampling programs. For example, several commenters argued that, absent codified standards, Table 4 in the sampling guide would be a de facto performance standard, contrary to the objectives in the proposed rule. The commenters stated that the sampling guide should be revised to promote sampling programs tailored to each establishment. One industry commenter further argued that the word ''compliance'' should be removed from the document title to be consistent with recent changes to other FSIS guidance documents and because the document provides best practice recommendations and not regulatory requirements.

Response: FSIS guidance documents are intended to provide best practices and, in some cases, safe harbors based on the most current science available to Agency stakeholders to help them comply with regulatory requirements, and when applicable, meet performance standards. The sampling guide explains that FSIS considers the requirements under the former regulations for generic *E. coli* to be a scientifically validated ''safe harbor'' for monitoring process control for very low-volume establishments. The sampling guide also includes recommendations to assist small and very small establishments to meet regulatory requirements, and recommendations to develop a custom approach that are not dependent on establishments' available resources. For example, the sampling guide provides baseline information for those establishments that may need a starting place from which to calculate their own control limits. However, control limits change over time as establishment-specific data is collected and analyzed. FSIS has removed Table 4 and replaced it with a new table (Table 2) to provide better guidance for establishments that may want to use data from the 2010–2011 market hog baseline survey as an initial starting point from which to set their upper control limits. Therefore, the information provided in the document is not a performance standard.

In response to the comments, FSIS has revised the sampling guide to, in part, further clarify the purpose of the document, which is to assist small and very small establishments to comply with the new microbial organism sampling requirements that apply to all swine slaughter establishments under this final rule. The sampling guide has also been revised to include additional information on the intended use of provided methods, techniques, and analyses; and to remove the word ''compliance'' from the document title and clarify that the document does not constitute regulatory requirements. Additionally, the Agency moved the example control charts from the sampling guide from the sampling guide to Appendix 2 of the guideline and clarified how establishments can use control charts. The Agency did not recommend a specific control chart format. Finally, the Agency removed all references to pre-operational environmental sampling. The updated sampling guide is available at *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.*

Comments: Several commenters objected to certain information provided in the sampling guide related to indicator organism sampling and testing. One industry commenter stated that both the proposed rule and the sampling guide, as written, could mandate a shift from analyzing market hog carcasses for enteric pathogens of concern, such as *Salmonella,* to monitoring a surrogate, such as Aerobic Plate Count (APC). The commenter argued that this process control approach is too singular, and FSIS should clarify in the sampling guide that establishments will maintain the flexibility to select for one or more indicator organisms. In addition, several commenters argued that FSIS should revise the sampling guide to remove sampling schemes based on establishment size. They stated that, from a statistical sampling viewpoint, establishing sampling frequency based on the size of the establishment is not supportable. These commenters also stated that generic *E. coli* testing should not remain a ''safe harbor,'' even for small and very small establishments, because no scientific correlation exists between microorganism presence/growth and facility size. Finally, one industry commenter noted that the sampling guide does not summarize all known control points for *Salmonella,* as the document claims it does.

Response: The sampling guide provides flexibility and monitoring options for establishments, and it makes clear that establishments may select one or more indicator organisms to monitor.

To address the comment about the singular process control approach, the sampling guide provides a link to the December 2013 FSIS guideline for controlling *Salmonella* in market hogs, which describes potential control points for *Salmonella* in the pre- and post-harvest production process. The potential control points described in that 2013 guideline may or may not be applicable to a specific establishment's process.

Comments: Several commenters expressed concerns with information provided in reference and example charts throughout the sampling guide. One member of the pork industry and one trade association representing the pork industry argued that establishments should not compare process control results to a nationwide geometric mean displayed in one chart. The commenters argued that market hog data is an inappropriate basis for developing upper control limits, as it is not applicable to all swine establishments. Further, they stated that these data from 2011 are outdated. One commenter stated that ''under NSIS'' should be removed from one table column heading, as the information would apply to all swine establishments.

Response: FSIS revised the sampling guide to remove the table that provided averages that represented the 80th percentile limits for each indicator organism included in FSIS's 2010–2011 market hog baseline survey. The Agency also removed the ''under NSIS'' language from the table that provides information for all swine establishments

In cases where an establishment does not have the resources or capacity to initially develop its own statistical control limits or analytical procedures, an establishment can utilize the aggregated data from the FSIS Nationwide Market Hog Microbiological Baseline Survey. The 2010–2011 baseline survey provides a wealth of microbiological data specific to swine

carcass sampling; these data are meant to provide a starting point for an establishment to develop its own control limit parameters over time. During the survey, FSIS collected two carcass samples at pre-evisceration and post chill.

Comment: One member of the pork industry and one trade association representing the pork industry recommended that FSIS remove from the sampling guide information related to finished product standard (FPS) waivers, as the subject is unrelated to the sampling guide.

Response: FSIS has removed the FPS waiver information from the sampling guideline.

I. Economic Assessment

Comment: One company that owns a HIMP establishment said that the cost of additional employees has been their most significant cost from the HIMP pilot study, and that they have had to hire and train up to 11 employees per shift to staff and maintain the inspection process.

Response: FSIS incorporated information from this comment into section III.G.1.a by revising the upper bound estimate from 10 employees to 11 in the description of additional establishment workers likely to be required by establishments that adopt the NSIS.

Comment: One industry commenter estimated that a full-time position, per slaughter shift, would be required to collect, record, and analyze data required to verify that an establishment's products meet the definition of RTC.

Response: While establishments are free to design their own process control monitoring systems, FSIS finds the estimated time and labor requirement provided in this comment to be inconsistent with FSIS's observations of HIMP establishments verifying OCP performance standards. FSIS explained in the proposed rule that pork carcasses that meet the HIMP OCP performance standards would meet the RTC pork product definition. Large swine establishments can verify OCP performance standards by taking 24 carcass samples per shift, requiring roughly one hour to collect, record, and analyze the data.

Comments: Several comments from members of the pork industry stated that they own establishments that operate under SIP waivers and conduct process control sampling at alternate frequencies.

Response: FSIS incorporated the information from these comments into section III.G.2.b of the final rule and used it to revise the cost estimate associated with changes to requirements for microbial organism process control sampling and analysis. This revision caused a slight decrease in potential industry savings. Under the SIP, 11 large swine establishments currently sample at an alternative frequency and the Agency assumes that these establishments will continue to do so when the applicability dates for this final rule arrive. As such, these establishments are not expected to change their process control sampling and will not experience a change in associated costs.

Comment: One member of the pork industry claimed that process control sampling requirements would increase cost.

Response: As is detailed in section III.G.2.b of the final rule, overall, the changes in process control sampling requirements were estimated to reduce industry wide sampling costs by about $0.57 million annualized over 10 years, applying a three percent discount rate.

Comment: One member of the pork industry reported that all six of their company's facilities have written sanitary dressing plans.

Response: FSIS incorporated information from this comment into section III.G.2.a of the final rule to reduce the cost estimate associated with developing, composing, training, monitoring, recording, and verifying written sanitary dressing plans to reflect that six establishments already have written sanitary dressing plans.

Comment: One company stated that many small and very small establishments are unlikely to adopt the NSIS due to the program's costs.

Response: FSIS agrees that many small and very small establishments are unlikely to adopt the NSIS. The Agency's cost benefit analysis assumes that very small establishments that exclusively slaughter market hogs do not have a high enough production volume to justify incurring the costs of converting to the NSIS.

Comment: One company participating in HIMP stated that it invested in capital expenditure projects to add or relocate inspection stations and reconfigure lines.

Response: The NSIS may require a minor capital improvement if the establishment does not already provide a mirror at the carcass inspection station. All the large high-volume establishments are already required to provide mirrors under existing regulations. Providing a mirror is a minor potential cost for a limited number of establishments.[26] If an establishment believes that additional capital expenditures will result in a benefit, they may voluntarily reconfigure or update their facilities to fully capture all the potential production efficiencies offered through participation in NSIS. Examples of such changes include line reconfiguration, which can cost between $10,000 and $250,000 and the creation of an inspection station, which can cost between $5,000 and $6,000. Establishments may reduce these costs by coordinating these facility updates with previously planned establishment renovations.

Comment: A few consumer advocacy organizations claimed that the Agency's cost benefit analysis understated training costs because the industry has a high turnover rate, necessitating that training take place more frequently than once per year.

Response: FSIS used BLS' industry turnover rate for non-durable manufactured goods to estimate annual training costs. Section III.G.1.a of the final rule provides additional details on how the cost benefit analysis estimates industry's training costs, which includes training new employees given the industry's turnover rate.

Comments: Several commenters stated that the Agency's guidance documents will likely need to be translated into additional languages. One commenter claimed that industry would be forced to hire translators to translate the Agency's guidance documents, the cost of which was not included in the cost benefit analysis.

Response: The Agency plans to make translated guidance documents publicly available as the need arises at no cost to industry. The cost of translating these documents is already within the Agency's budget. As such, the cost is not expected to increase the Agency's budgetary needs and is therefore not included in the rule's cost analysis.

III. Executive Orders (E.O.s) 12866 and 13563

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts,

[26] The cost was estimated to be very small because all 22 large high-volume establishments and potentially several of the 13 small high-volume establishments are already required to provide mirrors. As such, any new expense would be negligible compared to the industry costs included in the cost-benefit analysis.

and equity). E.O. 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 E.O. 12866. Accordingly, the rule has been reviewed by the OMB under E.O. 12866.

A. Updates to the Regulatory Impact Analysis (RIA)

FSIS updated the proposed rule's RIA to reflect the changes made in the final rule in response to public comments. The changes to the costs and benefits sections incorporate the following factors:

- The Agency removed the mandatory pre-operational environmental sampling requirement.
- Establishments currently operating under SIP waivers conduct process control sampling at an alternative frequency and the Agency assumes that they will continue to do so when the applicability dates for this final rule arrive. Therefore, these establishments have been removed from the cost estimate associated with changes to requirements for microbial organism process control sampling and analysis.
- Additional information from the risk assessment that more transparently demonstrates the potential uncertainty, is now reflected in the cost-benefit analysis. However, the anticipated net benefit did not change.
- One company reported that all 6 of its establishments already have written sanitary dressing plans. As such, the annual cost estimate associated with developing, composing, training, monitoring, recording, and verifying written sanitary dressing plans has been revised down by approximately $87,000.
- The highest number of establishment employees to be hired to meet the needs of NSIS has been revised up to 11, based on an industry comment.
- The per head margin has been updated to rely on the North American Meat Institute's (NAMI's) 2017 Meat and Poultry Facts.[27]

B. Need for the Rule

The swine slaughter industry in the United States has evolved since Congress enacted the Wholesome Meat Act in 1967. Many of today's producers have invested in farm to table quality and food safety controls that effectively address health risks and consumer quality issues.[28] For these producers, the prescriptive nature of some FSIS regulations inhibits efficient production and the adoption of improved production methods and restricts their ability to adopt new technologies. Further, at large and high-volume establishments that exclusively slaughter market hogs, the current regulations that require FSIS to focus on non-food safety issues prevent FSIS from efficiently allocating resources, which inhibits food safety improvements and humane handling hazard prevention. Therefore, while traditional inspection is generally sufficient for low-volume establishments and for establishments that slaughter classes of swine other than market hogs, a modernized swine slaughter inspection system is needed, one that is less prescriptive, creates incentives for establishments to develop and invest in advancements in food safety and quality controls and procedures, and allows FSIS to improve inspection methods.

Baseline

C. Overview of the Market

U.S. pork production has increased at a moderate pace as seen in Table 2. Much of the additional growth in domestic production has been used to satisfy increasing export demands, which increased 43 percent between 2009 and 2018.[29] According to the Food and Agricultural Organization (FAO), pork is consistently ranked as the top meat in per-capita consumption worldwide[30] and is ranked third in the United States.[31]

TABLE 2—U.S. PORK SUPPLY AND DEMAND

[Carcass weight, million pounds]

Year	U.S. production	Imports	Exports	Consumption	
				Domestic	Per capita *
2009	22,999	834	4,094	19,869	65
2010	22,437	859	4,223	19,077	62
2011	22,758	803	5,196	18,382	59
2012	23,253	802	5,379	18,607	59
2013	23,187	880	4,986	19,104	60
2014	22,843	1,011	5,092	18,836	59
2015	24,501	1,116	5,010	20,592	64
2016	24,941	1,091	5,239	20,892	65
2017	25,584	1,116	5,632	21,034	65
2018	26,315	1,042	5,870	21,497	66

* Measured in carcass weight, pounds.

Source: Livestock and Meat Domestic Data, All supply and disappearance, Historical, WASDE Pork-Full. USDA ERS Livestock and Meat Domestic Data. <*https://www.ers.usda.gov/data-products/livestock-meat-domestic-data/livestock-meat-domestic-data/#All%20meat%20statistics*> accessed on 6/12/2019. Last updated on 5/29/19.

In 2016, there were approximately 612 swine slaughter establishments under Federal inspection, Table 3.[32] Combined, these establishments process roughly 118 million hogs annually. FSIS divides swine into the following

[27] Nalivka, J.S., The 2017 Meat and Poultry Facts, NAMI August 2018.

[28] Key, Nigel and William McBride. 2007. The Changing Economics of U.S. Hog Production. USDA Economic Research Service (ERS.). Report No. 52.

[29] Livestock and Meat Domestic Data, All supply and disappearance, Historical, WASDE Pork-Full. USDA ERS Livestock and Meat Domestic Data. <*https://www.ers.usda.gov/data-products/livestock-meat-domestic-data/livestock-meat-domestic-data/#All%20meat%20statistics*> accessed on 6/12/2019. Last updated on 5/29/19.

[30] FAO Livestock commodities. <*http://www.fao.org/docrep/005/y4252e/y4252e05b.htm*> Accessed on 11/29/16.

[31] Livestock and Meat Domestic Data, All supply and disappearance, Historical. USDA ERS Livestock and Meat Domestic Data. <*https://www.ers.usda.gov/data-products/livestock-meat-domestic-data/livestock-meat-domestic-data/#All%20meat%20statistics*> accessed on 6/12/2019. Last updated on 5/29/19.

[32] USDA, FSIS, Public Health Information System (PHIS).

production categories for data collection purposes: Roaster swine, market hog, sow, and boar/stag. Today, the majority (97%) of the pork products available in the market are derived from market hogs.[33]

TABLE 3—NUMBER OF SWINE SLAUGHTER ESTABLISHMENTS BY SIZE, 2016

HACCP processing size	Number of establishments	Total swine slaughter (head count)	Total market hog slaughter (head count)	Percent market hog
Large	28	105,678,519	105,321,950	99.66
Small	105	11,862,341	8,497,891	71.64
Very Small *	479	903,009	625,863	69.31
Total	612	118,443,869	114,445,704	96.62

Source: Public Health Information System (PHIS).
* Two establishments classified as N/A were included in the category total for Very Small establishments.

As shown below in Table 4, many establishments now exclusively slaughter market hogs, a species sub class which, because of technological and animal management improvements, such as improved genetics, nutrition, and medical services, generally presents fewer food safety and quality issues.[34]

D. Overview of the Final Rule's NSIS

Several of the final rule's provisions apply to only those establishments that choose to participate in the optional NSIS. Meeting these provisions will likely increase an establishment's labor and training costs. Only market hog slaughter establishments are eligible to participate in the NSIS. Due to the economic constraints, FSIS expects that only large and small high-volume establishments that exclusively slaughter market hogs will choose to participate in the optional NSIS. In 2016,[35] there were 40 high-volume establishments that exclusively slaughtered market hogs: 27[36] large[37] (5 HIMP + 22 non-HIMP)[38] and 13 small establishments, Table 4. These establishments account for 93 percent of total swine slaughter annually, Table 4. Given their large share of the market and the ability to slaughter a sufficient number of market hogs to justify the likely costs associated with the NSIS, these 40 market hog establishments are expected to choose to implement the optional NSIS. Therefore, this analysis calculates the costs and benefits associated with the NSIS provisions for these 40 market hog establishments. However, because the 5 HIMP establishments already meet NSIS requirements, they are not expected to incur any additional new costs nor contribute to any increase in quantified benefits associated with adopting the NSIS.

TABLE 4—HEAD COUNT DISTRIBUTION ACROSS TYPES OF ESTABLISHMENTS, 2016

Type of establishment	HACCP size	Number of establishments	Total swine slaughter (head count)	Percent of total head count
High-Volume Market Hog Only	Large—HIMP	5	17,517,254	14.79
	Large—Non-HIMP	22	87,746,770	74.08
	Small	13	4,617,680	3.90
Low-Volume Market Hog Only	Very Small	71	32,360	0.03
Mix of Species and Swine Sub Classes	Large/Small	93	7,659,156	6.47
	Very Small	408	870,649	0.74
Grand Totals		612	118,443,869	

* HACCP sizes were combined so as to not reveal proprietary information.
Source: PHIS.

E. Overview of the Final Rule's Mandatory Components

All swine slaughter establishments will need to comply with the two mandatory provisions of the final rule discussed below.

1. Written Sanitary Dressing Plans

FSIS is amending 9 CFR 310.18 to require swine slaughter establishments to develop, implement, and maintain as part of their HACCP systems, written procedures to ensure that no visible fecal material, ingesta, or milk is present by the point of FSIS post-mortem inspection of swine carcasses. This requirement will address a weakness of the current traditional inspection system, which is that verification checks performed at the end of the slaughter and chilling process encourage industry to focus its activities on post-process interventions to reduce contamination rather than prevention throughout the slaughter process. Prevention throughout the slaughter process is preferred because it promotes containing contamination close to its origin, which reduces cross contamination of multiple carcasses. The existing regulations require that establishments prevent swine carcasses contaminated with visible fecal material

[33] Source: PHIS.

[34] Key, Nigel and William McBride. 2007. The Changing Economics of U.S. Hog Production. USDA ERS. Report No. 52.

[35] Establishment level data from 2016 was used in both the Preliminary Regulatory Impact Analysis (RIA) and the Final RIA.

[36] In 2016 there was 1 large establishment that did not exclusively slaughter market hogs. As such, this analysis assumed they would not choose to participate in the optional NSIS and were excluded from the relevant sections in the analysis.

[37] HACCP size: Very Small Establishment = Less than 10 employees or less than $2.5 million in annual sales; Small Establishment = 10–499 employees; Large Establishment = 500 or more employees.

[38] In 2016, there was 1 large establishment that did not exclusively slaughter market hogs.

from entering the cooler. While preventing swine carcasses contaminated with visible fecal material from entering the cooler is an important safeguard for reducing the prevalence of pathogens on swine 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 control procedures for preventive measures. 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 allows 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. In addition, it will allow the establishment to implement corrective actions that could include the addition of preventive control measures to prevent recurrence of similar product contamination events or insanitary conditions.

Based on public comment, the final rule assumes all but six establishments will need to develop written sanitary dressing plans.

2. Process Control Sampling and Analysis for Microbial Organisms

Under this final rule, instead of following a prescribed microbiological testing program, each establishment will be responsible for developing and implementing its own microbiological sampling plan. Each establishment, except very low-volume establishments, is required to include carcass sampling at pre-evisceration and post-chill (*i.e.,* the point in the slaughter process after the carcass has chilled in the cooler and after all slaughter interventions are completed) or for hot-boned products, carcass sampling at pre-evisceration and after the final wash.

The microbiological standards prior to the final rule prescribed that all establishments monitor process control by sampling for generic *E. coli.* High-volume establishments were required to take one sample per 1,000 carcasses or request an alternative frequency. Very low-volume establishments were required to take 1 sample per week of operation up to 13 times a year. Several commenters from industry reported that each of their establishments operating under SIP conduct process control sampling at an alternative frequency. In addition, an industry survey found that many establishments elect to perform other microbiological tests in addition to testing for generic *E. coli.*[39]

F. Overview of the Impact of the Final Rule on the Agency

This analysis, in part, takes into consideration potential impacts to the Agency's budget. FSIS's budget is expected to be impacted by changes in staffing and training requirements for those establishments that choose to operate under the NSIS. Under traditional inspection, each slaughter line requires up to 11 full-time positions. Generally, these positions include both a supervisory and non-supervisory Public Health Veterinarian, (PHV) (OPM Veterinary Medical Science Series, 0701); a supervisory and non-supervisory consumer safety inspector, (CSI) (OPM Consumer Safety Inspection Series, 1862); and up to 7 Food Inspectors, (FI) (OPM Food Inspection Series, 1863). There are currently 418 full-time equivalent units (FTE) assigned to slaughter inspection at the 22 large non-HIMP (27 large—5 HIMP) and 13 small swine slaughter establishments expected to convert to the NSIS, Table 5. When these establishments convert to the NSIS, Agency personnel will require NSIS training. Additionally, the number of Agency personnel required to inspect the slaughter process will likely be reduced. See Agency Staffing section for details.

TABLE 5—CURRENT FSIS SLAUGHTER LINE POSITIONS AT NON-HIMP ESTABLISHMENTS THAT SLAUGHTER EXCLUSIVELY MARKET HOGS

OPM job code	Number of positions
1862 (CSI)	120
1863 (FI)	245
0701 (PHV)	53
Total	418

Source: PHIS.

G. Potential Costs of the Final Rule

1. Costs Associated With the NSIS Components of the Rule

This analysis estimates the costs associated with the final rule's NSIS components. The 35 establishments that the Agency assumes will adopt the NSIS portion of the rule have similar characteristics to the 5 HIMP establishments, such as volume and sub species slaughtered. Given the successful participation of the 5 HIMP establishments in the pilot program and industry's continued interest in increasing the number of establishments participating in the HIMP pilot study, the potential benefits from adopting NSIS are expected to outweigh the potential costs. This analysis assumes that very small establishments that exclusively slaughter market hogs do not have a high enough production volume to justify incurring the costs of converting to the NSIS. While the 5 HIMP establishments are expected to adopt the NSIS, they have already implemented the changes associated with the NSIS by their participation in the HIMP pilot study and are not expected to incur any new or additional expenses. As such, they are not included in the group of establishments expected to incur an increase in costs associated with NSIS. The following analysis also excludes further consideration of the costs of submitting an attestation of work-related conditions due to its small estimated cost.[40] Costs examined generally fall under three categories: Labor, capital expenses, and developing written procedures.

In the following sections, this analysis presents the costs and benefits generated over a range of assumptions with respect to how much of the industry chooses to adopt the NSIS within five years. As was done with the NPIS, this analysis assumes a 5-year adoption period with roughly consistent annual adoption rates. These estimates are scaled for an illustrative calculation and assume that 35 of the 40 establishments that are likely to adopt the NSIS will incur additional costs associated with adoption. Using this illustrative calculation was supported by one public comment, which suggested that adoption timing and rate are difficult to estimate without a final rule. As is stated above, the 5 HIMP establishments are not expected to incur any additional costs associated with adopting the NSIS and are therefore excluded when calculating potential costs of the NSIS components of this final rule.

[39] Viator, C. et al. 2015. Meat Industry Survey in Support of Public Health Risk-Based Inspection. P5–42. Question 3.1.

[40] It was estimated that submitting such an attestation would require a Quality Control Technician with a labor compensation rate of $68.52 per hour, 2 minutes per year. Combined, submitting an annual attestation would cost all 27 large and 13 small establishments likely to adopt the NSIS approximately $91.36 annually (2 minutes * $68.52 per hour * 40).

TABLE 6—NSIS ADOPTION RATE

Year	Total number of establishments adopted		Percent adopted
	Large	Small	
1	4	2	17
2	8	4	34
3	12	7	54
4	17	10	77
5	22	13	100

a. Costs of Additional Establishment Workers

This analysis expects establishments operating under the NSIS to experience an increase in labor costs. Under the NSIS, establishments will be required to dedicate labor to sort and remove unfit animals before ante-mortem inspection; trim and identify defects, such as dressing defects, contamination, and pathology defects, on carcasses and parts before post-mortem inspection; identify animals or carcasses that they have sorted and removed for disposal before FSIS inspection with a unique tag, tattoo, or similar device, and to develop, implement, and maintain written procedures to ensure that animals and carcasses that have been sorted and removed for disposal do not enter the human food supply and are properly disposed of; maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal; while conducting sorting activities, notify Agency inspectors if they suspect that an animal or carcass has a reportable or foreign animal disease; and maintain records documenting that products resulting from their slaughter operations meet the new definition of RTC pork product. Based on observations [41] of HIMP establishments and a comment from industry,[42] this increase in work is expected to require an increase in labor demand ranging from 6–11 additional workers per line per shift at large establishments. This analysis assumes each large establishment that converts to the NSIS will require 9 additional workers per line per shift. Due to data limitations, this analysis assumes small establishments that convert to the NSIS will require 1 additional worker per line per shift. Costs associated with this labor fall into 3 categories: Wages and benefits, training, and continuing education.

Establishment Labor Wage Increases

Many of the 22 large and 13 small non-HIMP market hog establishments that are assumed to adopt the NSIS operate multiple lines and shifts. Taking these multiple lines and shifts into consideration, the number of industry positions is estimated to increase by 383 if all high-volume establishments that have a history of exclusively slaughtering market hogs, adopt NSIS. The majority of these, 369, are attributable to the large establishments (41 (number of lines) × 9),[43] Table 7. The remaining 14 positions are attributable to the small establishments (14 (number of lines) × 1),[44] Table 7. According to the BLS, the estimated hourly wage for a Slaughterer and Meat Packer occupation (''production employee'') is $13.00.[45] A benefits and overhead factor of two was then used to estimate the total labor costs. The total hourly labor costs to industry for a production employee including benefits and overhead, is $26.00 per hour ($13.00 × 2 [46]). Based on data obtained through PHIS, the average large establishment slaughters swine 269 days annually. Assuming workers work 8-hour shifts, the total annual remuneration cost to these 22 large establishments is approximately $20.65 million, (369 × $26.00 × 269 × 8), Table 7. The average small establishment slaughters 244 days annually. Again, assuming workers work 8-hour shifts, the total annual remuneration cost to these 13 small establishments is approximately $0.71 million, (14 × $26.00 × 244 × 8), Table 7. These cost estimates take into consideration the fact that some establishments operate multiple lines and multiple shifts.

Costs for Training Online Sorters and Carcass-Inspection Helpers

Establishments are expected to incur costs associated with initially training employees to fill online sorter and carcass-inspection helper positions, annual replacement training, and continuing education training. This analysis assumes the cost to train online sorters and carcass-inspection helpers are similar to the costs of training production employees in HACCP, which range from $274 to $823 with a midpoint average of $549 per new employee.[47] To ensure a conservative estimate and account for employee rotation patterns as well as leave, FSIS assumes that establishments will train 4 employees for each new position. Under these assumptions, large establishments will need to train approximately 1,476 (369 × 4) employees, while small establishments will need to train approximately 56 (14 × 4) employees. The cost of this training ranges from $419,768 to $1,260,836, with a midpoint estimate of $0.84 million (1,532 × $549), Table 7.

To account for estimated turnover of establishment employees, FSIS projects that establishments will have to train approximately 452 (1,532 × 0.295) replacement employees annually, 435 at the large and 17 at the small establishments.[48] The additional annual training cost for new employees was estimated to also be similar to the costs of HACCP training. Therefore, FSIS estimates the combined annual training costs due to turnover to be approximately $0.25 million (452 ×

[41] Observations were obtained through a survey conducted, in February 2016, through the *Salmonella* Initiative Program and conversations with industry at a meeting, which took place in February 2016, with the North American Meat Institute.

[42] One corporation reported in a comment to the proposed rule that they hired and trained up to 11 employees per shift.

[43] Source: PHIS.

[44] Source: PHIS.

[45] BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2016. 51–3023 Slaughterers and Meat Packers *https://www.bls.gov/news.release/archives/ocwage_03312017.pdf* Accessed on 12/04/18. Last modified 3/31/17.

[46] To be consistent with analyses done by the Department of Health and Human Services, this analysis accounts for fringe benefits and overhead by multiplying wages by a factor of 2.

[47] Viator, C. et al. 2015. Costs of Food Safety Investments. Table 4–4. Training Costs for Management and Production Employees.

[48] This estimate was rounded up. This analysis uses the industry turnover rate for non-durable manufactured goods to estimate separations. Source: BLS Economic News Release Table 16. Annual total separations rates by industry and region, not seasonally adjusted. *https://www.bls.gov/news.release/archives/jolts_03162017.htm* Accessed on 12/04/18. Last updated on 3/16/17.

$549), with large establishments accounting for approximately $0.24 million (435 × $549) and small establishments accounting for approximately $9,333 (17 × $549), Table 7.

FSIS assumes that 1,080 (1,532 × 0.705) retained employees, 1,041 at the large and 39 at the small establishments, will require annual continuing education. This analysis assumes annual continuing education costs to be similar to annual HACCP refresher training costs, which range from $12 to $36 per employee, with a mid-point of $24.[49] Using the mid-point value, this analysis estimates the combined average recurring cost for continuing education is $25,920 (1,080 × $24), with large establishments accounting for approximately $24,984 (1,041 × $24) and small establishments accounting for approximately $936 (39 × 24).

Under the assumed adoption rate as set forth in Table 6, annualized wages and training cost to industry for staffing additional online personnel is approximately $16.61 million, applying a 3 percent discount rate[50] over 10 years, Table 7. The majority of this cost is attributed to wages and benefits, Table 7.

TABLE 7—ESTABLISHMENT LABOR COSTS

[M$]

Type of establishment	Type of expense	Number of personnel	One-time cost	Recurring cost
Large	Wages	369		$20.65
	Initial Training	1,476	$0.81	
	Training Due to Labor Turnover	435		0.24
	Continuing Education	1,041		0.02
Small	Wages	14		0.71
	Initial Training	56	0.03	
	Training Due to Labor Turnover	17		0.009
	Continuing Education	39		0.001

Totals

One-Time	0.84
Recurring Cost	21.63
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	16.61
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	15.97

b. Costs of Capital Improvements

The NSIS may require a minor capital improvement if the establishment does not already provide a mirror at the carcass inspection station. All the large high-volume establishments are already required to provide mirrors under existing regulations. The following analysis excludes further consideration of the costs of requiring a mirror due to its minor potential cost for a limited number of establishments.[51] If an establishment believes that additional capital expenditures will result in a benefit, they may voluntarily reconfigure or update their facilities to fully capture all the potential production efficiencies offered through participation in the NSIS. Examples of such changes include line reconfiguration, which can cost between $10,000 to $250,000[52] and the creation of an inspection station, which can cost between $5,000 and $6,000.[53] Establishments may reduce these costs by coordinating these facility updates with previously planned establishment renovations.

c. Costs of Developing Ante-Mortem Written Procedures

Under the final rule, establishments operating under the NSIS are required to develop and maintain in their HACCP systems (HACCP plans, sanitation SOPs, or other prerequisite programs) written procedures for the segregation, identification, and disposition of animals suspected of having one of the condemnable generalized diseases or conditions listed in 9 CFR 309. This analysis assumes establishments will coordinate this work and costs with the development of written procedures to prevent the contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk throughout the entire slaughter and dressing operation, a mandatory component of the final rule. Details of these costs can be found in the sanitary dressing costs section III.G.2.a.

d. Costs Associated With Ready-to-Cook Pork Standards

Under the final rule, establishments operating under the NSIS are required to collect, record, and analyze documentation to demonstrate that the products resulting from their slaughter operation meet the definition of RTC pork products. This analysis estimates the labor costs to collect, record and analyze such documentation under two assumptions. First, FSIS assumes that establishments will assign the task to a quality control (QC) technician, with an hourly compensation rate, which

[49] Viator, C. *et al.* 2015. Costs of Food Safety Investments. Table 4–4. Training Costs for Management and Production Employees.

[50] As is explained in Circular A–4, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. For regulatory analysis, net benefit estimates should be provided using a 3 percent and 7 percent discount rate. Source: Circular A–4, OMB, September 17, 2003, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

[51] The cost was estimated to be very small because all 22 large high-volume establishments and potentially several of the 13 small high-volume establishments are already required to provide mirrors. As such, any new expense would be negligible compared to the industry costs included in the analysis.

[52] In a May 2004 study, ERS estimated the cost of compliance per establishment with the PR/HACCP rule. Capital expenditures in Hog Slaughter establishments were estimated to be $251,800.

Ollinger, Moore, Chandran (2004). Meat and Poultry Establishments' Food Safety Investments. USDA, Economic Research Service.

[53] Modernization of Poultry Slaughter Inspection; Final Rule, 79 FR 49566 (2014).

includes wages, benefits, and overhead, of $68.52.[54] [55] Second, FSIS assumes that this work will take 1 hour at a large establishment and ½ hour at a small establishment per day. As is explained in the Draft Market Hogs HIMP paper,[56] large swine establishments can verify they meet OCP performance standards by taking 24 unit samples, requiring roughly 1 hour to collect, record, and analyze the data. Based on information obtained through PHIS, the average large swine establishment operates 269 days per year. This equates to an annual cost of approximately $18,432 (269 × 1 × $68.52), or approximately $0.41 million for all 22 non-HIMP establishments ($18,432 × 22). Similarly, the cost to an average small establishment, which based on data obtained through PHIS operates 244 days a year, is approximately $8,359 (244 × 0.5 × $68.52), or approximately $0.11 million for all 13 small establishments ($8,359 × 13). Combined, under the assumed adoption rate as set forth in Table 6, these costs are expected to increase NSIS establishments' annual labor costs by approximately $0.39 million, applying a 3 percent discount rate over 10 years, Table 8.

TABLE 8—COST OF RTC REQUIREMENTS

[M$]

Type of market hog only establishment	Number of establishments	Recurring
		Labor
Large	22	$0.41
Small	13	0.11
Totals *		
Recurring Cost		0.51
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		0.39
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		0.38

* Note, some of the totals may not equal the sum due to rounding.

2. Costs Associated With Requirements for All Swine Slaughter Establishments

The mandatory costs of the final rule will apply to all 612 swine slaughter establishments and begin on the effective date for these requirements. These costs are associated with (a) written procedures to prevent visible fecal material, ingesta, and milk contamination; and (b) sampling and analysis for microbial organisms to monitor process control for enteric pathogens.

a. Costs of Developing, Composing, Training, Monitoring, Recording, and Verifying Written Sanitary Dressing Plans

Under the mandatory portion of the final rule affecting all Federally inspected establishments that slaughter swine, FSIS is requiring that all official swine slaughter establishments develop, implement, and maintain in their HACCP systems written procedures to prevent the contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk throughout the entire slaughter and dressing operation. This cost component for establishments includes: (1) Developing and incorporating these procedures into their food safety system, (2) training, and (3) monitoring, recordkeeping, and verification. This analysis assumes 606 swine establishments will incur these costs.[57]

Costs for Developing and Composing a Written Sanitary Dressing Plan

FSIS assumes incorporating written sanitary dressing plans into an establishment's HACCP system will result in a one-time HACCP plan reassessment cost. According to RTI's Costs of Food Safety Investments report,[58] the mid-point costs of a HACCP plan reassessment for large establishments is $730, the mid-point costs for small and very small establishments is $365.[59] The cost to large establishments is approximately $16,060 (22 × $730), small establishments is approximately $38,325 (105 × $365), and very small establishments is approximately $174,835 (479 × $365). The annualized costs to industry with a 3 percent discount rate for all 606 swine slaughter establishments is approximately $0.03 million, Table 9.

[54] BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2016. 19–1021 Food Scientist and Technologist. <*https://www.bls.gov/news.release/archives/ocwage_03312017.pdf*>. Accessed on 12/04/18. Last Modified 3/31/2017.

[55] To be consistent with analyses done by the Department of Health and Human Services, this analysis accounts for fringe benefits and overhead by multiplying wages by a factor of 2.

[56] Draft Market Hogs HIMP (HACCP-Bases Inspection Models Project). Draft 6/21/05. <*https://www.fsis.usda.gov/wps/wcm/connect/d6ccbad7-59e0-43f5-bf54-1987152ccfe8/HIMP_Market_Hog.pdf?MOD=AJPERES.*>.

[57] One corporation has informed FSIS, through public comment, that all six of its swine harvest facilities have written sanitary dressing plans. As such, they were not included in this portion of the cost analysis, which reduced annual costs by roughly $87,000 as compared to the proposed rule.

[58] Viator, C. et al. 2015. RTI International collected data on the cost of food safety investments for the production of meat and poultry products at the pre-harvest and slaughter and processing stages. This data was provided to FSIS in a final report titled 'Costs of Food Safety Investments' and was prepared by Catherine L. Viator, Mary K. Muth, and Jenna E. Brophy. The contract number is No. AG–3A94–B–3–0003. The order number is AG–3A94–K–14–0056.

[59] Viator, C. et al. 2015. Table 4–1. Costs of HACCP Plan Development, Validation and Reassessment per HACCP.

TABLE 9—WRITTEN SANITARY DRESSING PLAN DEVELOPMENT

[M$]

HACCP size	Number of establishments	One-time cost
Large	22	$0.02
Small	105	0.04
Very Small	479	0.17
Totals		
One-Time Cost		0.23
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		0.03
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		0.03

Costs for Training Establishment Personnel on Executing a Written Sanitary Dressing Plan

FSIS assumes training programs will be utilized to ensure that establishment personnel understand and can execute the sanitary dressing plan. This training includes a one-time initial training cost to the establishment, a recurring cost of training new hires due to separations, and the cost of conducting annual refresher training. This portion of the model is informed by the RTI Costs of Food Safety Investments report.[60] As is noted in the RTI report, these costs are based on the amount of time a panel of experts recommends establishments spend on training, which may exceed the amount of time establishments spend on training. Due to data limitations, this analysis assumes the number of establishment employees conducting sanitary dressing tasks at swine establishments is equal to the number of employees conducting sanitary dressing tasks at beef slaughter establishments.[61] This is likely an overestimate because unlike beef, the majority of swine are scalded, de-haired, and polished prior to opening the carcass, which decreases the need for employees to conduct sanitary dressing tasks.

As seen in Table 10, costs are shared across HACCP sizes, with large establishments incurring higher costs. The rate of new hires, 29.5 percent, is derived from the BLS, 2016 Turnover Rate for Non-Durable Manufacturing Goods.[62] Likewise, the retention rate for the refresher training is one minus the turnover rate. The total one-time cost to train the employees for all 606 establishments is roughly $1.00 million, while the total recurring costs is roughly $0.44 million, Table 10. The annualized costs with a 3 percent discount rate over 10 years for Sanitary Dressing task related training is $0.55 million, Table 10.

TABLE 10—SANITARY DRESSING TRAINING COSTS

[M$]

HACCP size	Number of establishments	Average number of employees	Training costs		
			One-time	Recurring	
			Initial	New hires	Refresher
Large	22	179	$0.48	$0.14	$0.07
Small	105	25	0.32	0.09	0.04
Very Small	479	3	0.20	0.06	0.03
Totals *					
One-Time Cost					1.00
Recurring Cost					0.44
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years					0.55
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years					0.57

* Note, some of the totals may not equal the sum due to rounding.

[60] Viator, C. et al. 2015.

[61] The Survey is at: *http://www.fsis.usda.gov/wps/wcm/connect/184a3baa-2f73-4651-8aba-68124580f4e0/Pathogen_Controls_in_Beef_Operations_Survey.pdf?MOD=AJPERES.* The survey report is at: *http://www.fsis.usda.gov/wps/wcm/connect/6d37a1fc-a3e1-40b6-90cc-719bdb391522/STEC_Survey_Comments_Summary.pdf?MOD=AJPERES.*

[62] Source: BLS Economic News Release Table 16. Annual total separations rates by industry and region, not seasonally adjusted. <*https://www.bls.gov/news.release/archives/jolts_03162017.htm*> Accessed on 12/04/18. Last updated on 3/16/17.

Cost of Monitoring, Recordkeeping, and Verification Associated With the Written Sanitary Dressing Plan

This analysis also estimates the annual monitoring, recordkeeping and verification costs associated with maintaining sanitary dressing procedures. This analysis assumes it will take a production employee 5 minutes to monitor and 5 minutes to maintain records for the sanitary dressing procedures, for a total of 10 minutes. Establishments are required to verify the plan each day of production. In addition, this analysis assumes it will take a QC manager 15 minutes to perform a verification task and that such task will be completed each week that slaughter takes place. Combined, these tasks are estimated to cost the entire industry roughly $0.84 million annually, applying a 3 percent discount rate over 10 years, Table 11.

TABLE 11—MONITORING, RECORDKEEPING AND VERIFICATION COSTS

[M$]

Recurring costs				
HACCP size	Monitoring	Recordkeeping	Verification	Combined
Large	$0.01	$0.01	$0.03	$0.05
Small	0.04	0.04	0.12	0.20
Very Small	0.07	0.07	0.44	0.58
Totals *				
Recurring Cost				0.84
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				0.84
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				0.84

* Note, some of the totals may not equal the sum due to rounding.

Summary Costs of Written Sanitary Dressing Procedures

Table 12 provides an overview of the one-time and recurring costs associated with requiring all establishments to develop written sanitary dressing procedures. Combined, these tasks are expected to cost the industry $1.41 million annualized, assuming a 3 percent discount rate over 10 years, Table 12.

TABLE 12—SUMMARY OF COSTS ASSOCIATED WITH REQUIRING WRITTEN SANITARY DRESSING PROCEDURES

[M$]

HACCP size	Number of establishments	One-time costs		Recurring costs	
		Development	Initial training	Training	Monitoring, recording, validating
Large	22	$0.02	$0.48	$0.21	$0.05
Small	105	0.04	0.32	0.14	0.20
Very Small	479	0.17	0.20	0.09	0.58
Totals *					
One-Time Cost					1.23
Recurring Cost					1.27
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years					1.41
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years					1.44

* Note, some of the totals may not equal the sum due to rounding.

b. Cost of Carcass Sampling and Analysis for Microbial Organisms

This section reviews the potential changes in costs associated with the alterations to microorganism testing. These costs are limited to the changes associated with removing the requirement that swine establishments test carcasses for generic *E. coli* and replacing it with new testing requirements described above. While the final rule also removes the codified *Salmonella* pathogen reduction performance standards for swine, because the codified standards are already no longer in use, there are no potential costs or benefits to industry. Such changes fall under four categories: Sampling plan reassessment, transferring from prescriptive to process testing requirements, sampling rates, and sample recordkeeping. This analysis uses results from the RTI International Meat Industry Survey in Support of Public Health Risk-Based Inspection report [63] and Costs of Food

[63] Viator, C. et al. 2015. (a) RTI International designed and conducted surveys on industry practices to control pathogens and promote food safety. The sample design, administration procedures, analysis and results were provided to FSIS in a final report titled 'Meat Industry Survey

Safety Investments report.[64] Each of these categories is explained in detail below. Based on industry comment on the proposed rule, this analysis excludes the 11 large swine establishments that were participating in the SIP program when data for this analysis was collected. Under SIP, these establishments currently sample at an alternative frequency and we assume that they will continue to do so. As such, these 11 SIP swine slaughter establishments are not expected to change their process control sampling and will not experience a change in associated costs.

Cost of Process Control Sampling Plan Reassessment

This analysis assumes establishments will incur one-time costs of conducting a process control sample plan reassessment under the final 9 CFR 310.25(a)(2)(i). The RTI Costs of Food Safety Investments report estimates the costs of reassessing a microbiological sampling plan. For large establishments, these costs include labor, consultant fees, and travel expenses, which combined range from $27,320 to $81,960, with a midpoint of $54,640 per establishment. Costs to small and very small establishments are limited to labor expenses and range from $122 to $365, with a midpoint of $243 per establishment.[65] The annualized reassessment cost to industry is roughly $0.12 million, assuming a 3 percent discount rate over 10 years, Table 13.

TABLE 13—COST OF PROCESS CONTROL SAMPLING PLAN REASSESSMENT

[M$]

HACCP size	Number of establishments	Per establishment (mid-point estimate) *	Total one-time costs
Large	17	$0.05	$0.93
Small	105	243	0.03
Very Small	479	243	0.12
Totals **			
One-Time Cost			1.07
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			0.12
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			0.14

* The values for Small and Very Small Establishments are in dollars.
** Note, some of the totals may not equal the sum due to rounding.

Cost of Transferring From Prescriptive To Process Specific Microbiological Testing Requirements

Prior to the final rule, regulations prescribed that each slaughter establishment test for generic *E. coli*.[66] In addition to mandated generic *E. coli* testing, many establishments voluntarily conduct additional microbiological testing to verify process control. Common microbiologic tests include APC, total plate count (TPC), and total coliforms. Based on the meat slaughter survey conducted by RTI, roughly 71 percent of very small, 80 percent of small, and 100 percent of large establishments conduct microbiological testing in addition to testing for generic *E. coli*.[67] Establishments voluntarily conducting additional testing are an indication that the generic *E. coli* testing is not the best means to verify process control in their respective establishments.

This analysis assumes that, if permitted to choose a microbiological test to ensure process control, establishments will select the single best test that demonstrates process control at their establishment. Under these assumptions, establishments that currently test for generic *E. coli* and conduct at least one other type of microbiological test will stop testing for generic *E. coli.* As a result, the 17 large (17 × 1.00), 41 small high-volume (51 × .80), 43 small low-volume (54 × .80), 4 very small high-volume[68] (6 × .714), and 338 very small (473 × .714) establishments that currently test for generic *E. coli* and at least one other microbial or pathogen indicator[69] will experience a cost reduction. Given the similarity in laboratory testing costs and costs associated with switching sampling programs, this analysis assumes the remaining 158 establishments that exclusively test for generic *E. coli* will continue to do so.

Calculating the cost reductions is a function of estimating the testing rate and testing costs. This analysis assumes all large, small, and very small high-volume,[70] establishments conduct 1 test, every 1,000 carcasses, and all low-volume establishments conduct 13 tests annually.[71] To calculate testing costs, this analysis estimates the associated labor expenses, laboratory fees, and shipping costs. The mean cost to an establishment to test a single generic *E. coli* sample in house is $25.97.[72] To have the sample tested at a contracted

in Support of Public Health Risk-Based Inspection' and was prepared by Catherine Viator, Sheri C. Cates, Shawn A. Karns, Peter Siegel, Ariana Napier, and Mary K. Muth. The contract number is No. AG–3A94–B–13–0003. The order No. is AG–3A94–K–13–0053.

[64] Viator, C. et al. 2015. (b).

[65] The report classifies establishments as either large or small. Given this data limitation, this analysis assumes very small and small establishments have similar reassessment costs.

[66] 9 CFR 310.25 (2018).

[67] Viator, C. *et al.* 2015. (a) P5–42. Question 3.1.

[68] Very small high-volume establishments slaughter more than 20,000 swine, or a combination of swine and other livestock exceeding 6,000 cattle and 20,000 total of all livestock.

[69] Question 3.1 from the Meat Industry Survey in Support of Public Health Risk-Based Inspection Report asks ''In addition to the generic *E. coli* testing of carcasses and Listeria testing of ready-to-eat (RTE) products required by FSIS regulation, does this establishment conduct microbiological testing? ''; 28.6% of very small, 20% of small, and 0% of large establishments responded no, meaning 71.4% of very small, 80% of small and 100% of large establishments conduct additional testing.

[70] Note that the 11 large establishments participating in SIP have been excluded from this analysis because they have an alternative sampling frequency.

[71] 9 CFR 310.25(a)(2)(iii)(B). The current regulation (9 CFR 310.25(a)(2)(v)) defines very low-volume swine slaughter establishments as slaughtering 20,000 head annually or fewer. For the purposes of this analysis, FSIS has labeled swine establishments that annually slaughter more than 20,000 head per year as high volume.

[72] Viator, C. et al. 2015. (b) Table 5–1.

lab, the cost is $49.81.[73] Based on survey results, this analysis assumes 79 percent of large, 28 percent of small and 5 percent of very small establishments test in house.[74] For these 443 establishments, the combined reduction in testing costs of no longer being required to test for generic *E. coli* was estimated to reduce annual testing costs by approximately $2.69 million, assuming a 3 percent discount rate over 10 years, Table 14.

TABLE 14—RECURRING COSTS (SAVINGS) FROM NO LONGER REQUIRING GENERIC *E. coli* TESTING

[M$]

HACCP size	Number of establishments	(Savings)
Large	17	($2.04)
Small High-Volume	41	(0.40)
Small Low-Volume	43	(0.02)
Very Small High-Volume	4	(0.01)
Very Small Low-Volume	338	(0.21)
Totals		
Recurring Cost		(2.69)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(2.69)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(2.69)

* Note, some of the totals may not equal the sum due to rounding.

Process Control Sampling Rates

The final rule requires large, small, and very small high-volume establishments to take carcass samples at pre-evisceration and post-chill (for hot-boned products carcass samples must be taken pre-evisceration and after the final wash), which will increase the number of samples taken from 1 sample per 1,000 carcasses to 2 samples per 1,000 carcasses for large, small, and very small high-volume establishments. The final rule does not require low-volume establishments to increase their sampling rates. Under the final regulations, large establishments' annual process control sampling costs were estimated to increase by roughly $1.46 million, which is roughly $85,745 per establishment ($1.46 million/17),[75] Table 15. Small high-volume establishments' annual process control sampling costs were estimated to increase by roughly $0.30 million, which is roughly $5,974 ($0.30 million/51) per establishment, Table 15. Very small high-volume establishments' annual process control sampling costs were estimated to increase by roughly $8,890, which is roughly $1,482 ($8,890/6) per establishment, Table 15.

Cost of Process Control Sample Recordkeeping

This analysis takes into consideration the increase in recordkeeping costs associated with an increase in the sampling rate from 1 to 2 samples per 1,000 head. According to PHIS data, the average large non-SIP establishment slaughters approximately 3.87 million swine per year. As such, this analysis estimates that a large non-SIP establishment currently takes approximately 3,869 samples annually (3,869,276/1,000). The average small high-volume swine establishment slaughters 0.23 million swine per year and requires approximately 229 samples (228,784/1,000) annually. While the average very small high-volume establishment slaughters 51,925 swine per year and requires approximately 52 samples (51,925/1,000) annually. Assuming it takes 2.5 minutes to record the results of each sample, the average large establishment currently requires 9,673 minutes (2.5 × 3,869) per year; the average small high-volume establishment currently requires 573 minutes (2.5 × 229) per year; and the average very small high-volume establishment currently requires 130 minutes (2.5 × 52) per year. Requiring establishments to increase their sampling rates from 1 to 2 samples per 1,000 head will increase the average large non-SIP establishment's annual number of samples to 7,738 samples annually (3,869,276/1,000 × 2), which will require approximately 19,346 minutes (2.5 × 7,738)[76] annually. The same requirement will increase a small high-volume establishment's annual sampling to 458 (228,784/1,000 × 2), which will require approximately 1,145 minutes (2.5 × 458) annually. Likewise, a very small high-volume establishment's annual sampling will increase to 104 (51,925/1,000 × 2), which will require approximately 260 minutes (2.5 × 104) annually. As such, the estimated additional time required for recordkeeping is approximately 9,673 minutes (19,346 − 9,673) for large non-SIP establishments; 572 minutes (1,145 − 573) for small high-volume establishments; and 130 minutes (260 − 130) for very small high-volume establishments. Assuming a quality control technician with a compensation rate of $68.52 per hour[77][78] conducts this work, the additional costs to the average large non-SIP establishment is approximately $11,046 (9,673/60 × $68.52). Similarly, the additional cost to the average small high-volume and very small high-volume establishment is approximately $653 (572/60 × $68.52) and $148 (130/60 × $68.52, respectively). Scaling this up to all impacted establishments, the total increase in costs to all large non-SIP establishments is approximately $0.19 million ($11,046 × 17); $0.03 million ($654 × 51) for small high-volume establishments; and $888 ($148 × 6) for very small high-volume establishments, Table 15.

[73] Viator, C. et al. 2015. (b) Table 5–1.

[74] Viator, C. et al. 2015. (b).

[75] Values in text may differ because of rounding.

[76] Values in text may differ because of rounding.

[77] BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2016. 19–1021 Food Scientist and Technologist. *https://www.bls.gov/news.release/archives/ocwage_03312017.pdf* Accessed on 12/04/18. Last Modified 3/31/2017.

[78] To be consistent with analyses done by the Department of Health and Human Services, this analysis accounts for benefits and overhead by multiplying wages by a factor of 2.

The combined annualized sampling and recordkeeping cost to all large non-SIP, small, and very small high-volume establishments is roughly $1.99 million, applying a 3 percent discount rate over 10 years. Large establishments will potentially incur the majority of this cost, Table 15.

TABLE 15—COSTS CHANGES ASSOCIATED WITH INCREASE SAMPLING RATES

[M$]

	Number of establishments	Costs		
		Sampling	Recordkeeping	Combined *
Large non-SIP	17	$1.46	$0.19	$1.65
Small High-Volume	51	0.30	0.03	0.34
Very Small High-Volume (Dollars)	6	8,890	888	9,778
Totals				
Recurring Cost				1.99
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				1.99
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				1.99

* Note, some of the totals may not equal the sum due to rounding.

Summary of Process Control Sampling Cost Changes

Overall, the changes in sampling requirements under the final rule were estimated to reduce industry wide sampling costs by about $0.57 million annualized over 10 years, applying a 3 percent discount rate, Table 16. However, only the 443 establishments that currently conduct multiple types of microbiological tests will potentially experience a reduction in cost. The remaining establishments, roughly 158 small and very small establishments, will potentially incur a portion of the one-time costs associated with plan reassessment, Table 16. Cost increases associated with testing and recordkeeping will be exclusively borne by large, small, and very small high-volume establishments.

TABLE 16—SUMMARY OF CHANGES TO PROCESS CONTROL SAMPLING

[M$]

Type of change	Cost (savings)	
	One-time	Recurring
Plan Reassessment	$1.07	.....
Converting to Process Control Sampling	.....	($2.69)
Testing Costs	.....	1.77
Recordkeeping	.....	0.22
Totals *		
One-Time Cost		1.07
Recurring Cost		(0.70)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(0.57)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(0.55)

* Note, some of the totals may not equal the sum due to rounding.

Summary of Voluntary and Mandatory Costs for Final Rule

The total annualized value of all costs to industry, under the assumed five-year adoption rate as shown in Table 6, is roughly $17.83 million, assuming a 10-year annualization and a 3 percent discount rate, Table 17. Large establishments that voluntarily switch to the NSIS incur the majority of costs. For example, the recurring labor costs associated with the NSIS is the single largest recurring cost to industry and is mostly incurred by large establishments. It should be noted that the five HIMP pilot study establishments have already incurred these costs, suggesting for those five establishments, the benefits of the NSIS outweigh the costs. It also suggests that the benefits of adopting the NSIS outweigh the costs for other establishments as well. Training staff accounts for the bulk of the costs associated with written sanitary dressing procedures. Sampling costs will potentially decrease for those establishments that currently conduct microbiological tests in addition to generic *E. coli.*

TABLE 17—COMBINED COSTS TO INDUSTRY

[M$]

Type of cost	Number of establishments	Total costs	
		One-time	Recurring
Voluntary:			
Establishment Labor	35	$0.84	$21.63
Ready to Cook	35		0.51
Mandatory:			
Written Sanitary Dressing Procedures	606	1.23	1.27
Process Control Sampling	601	1.07	(0.70)
Totals *			
Number of Establishments **			612
One Time Cost			3.14
Recurring Cost			22.72
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			17.83
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			17.23
Totals Mandatory *			
Number of Establishments **			612
One-Time Cost			2.30
Recurring Cost			0.58
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			0.84
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			0.88
Totals Voluntary *			
Number of Establishments			35
One-Time Cost			0.84
Recurring Cost			22.15
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			17.0
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			16.35

* Note, some of the totals may not equal the sum due to rounding.

** Note, 612 includes all swine slaughter establishments, including the 11 SIP establishments that were excluded from the process control sampling costs and the 6 establishments that were excluded from the written sanitary dressing plans costs.

H. Potential Benefits of the Final Rule

1. Potential Benefits Associated With Public Health

Switching existing FSIS inspection program personnel (IPP) activities toward more offline verification activities (*e.g.,* sanitation performance standards, sampling, fecal inspections, and other inspection requirements) is unlikely to result in a higher prevalence of *Salmonella* on market hog carcasses and is estimated to result in a lower prevalence of *Salmonella* on market hog carcasses, which in turn may lead to fewer human illnesses. This conclusion is supported by a two-part risk assessment which compares typical FSIS market swine inspection outcomes with the outcomes observed in a small subset of establishments that participated in the HIMP pilot study (referred to in the risk assessment as HIMP plants).

Stage 1 of the risk assessment consists of a multiple regression analysis to identify the relationships between establishment characteristics (including HIMP status) and carcass contamination prevalence. FSIS presents two different models for estimating the potential for avoiding illnesses in the risk assessment one using only empirical data and one using additional simulated data, see Tables 13 and 14 in the risk assessment and accompanying text. The results of the modeling with simulated data, had less uncertainty around the estimated change in illnesses—are not used in support of the final rule. The modeling without simulated data is carried through in this section. As a result, the uncertainty around estimated illnesses avoided is greater; however, the most likely estimated illnesses avoided are not affected. Stage 2 of the risk assessment consists of multiple scenario models in which combinations of plausible changes to inspection procedures are inserted into equations created using the coefficients computed in Stage 1. These scenarios produce estimates of changes in carcass contamination prevalence under the inspection procedures of NSIS.

Changes in estimated numbers of *Salmonella* illness are estimated based on a proportional relationship between carcass contamination prevalence and illnesses that has been published in the

peer-reviewed literature.[79] [80] This relationship was also validated internally in the risk assessment, with an analysis of variance (ANOVA) test indicating that carcasses slaughtered in establishments with relatively low prevalence of *Salmonella* did not show significantly different contamination load (measured by enumeration of *Salmonella* colony-forming units per gram) when compared with establishments with relatively high prevalence of *Salmonella.* In other words, the proportion of contaminated carcasses is more predictive of *Salmonella* illnesses than the contamination load of each contaminated carcass; thus, if the proportion of carcasses with no detectable *Salmonella* contamination increases with implementation of the NSIS, illnesses caused by consumers' exposure to these carcasses were estimated to decrease proportionally.

As with any risk assessment, FSIS's risk assessment relies on a number of assumptions. FSIS assumed that the differences between the process of slaughtering hogs and slaughtering poultry do not alter the relationship between the presence of *Salmonella* contamination post-slaughter and human illness.

FSIS also assumed, for the purpose of this risk assessment, that the relationship between *Salmonella* contamination of hog carcasses and downstream products such as pork parts (*e.g.,* pork chops) and ground pork closely mirrors that of the established relationship between *Salmonella* contamination of poultry (*e.g.,* chicken) carcasses and downstream products such as chicken parts and ground chicken. While FSIS did not conduct any specific analyses to examine this assumption, the Agency has conducted numerous peer-reviewed analyses of the relationship between *Salmonella* contamination frequency on chicken carcasses and chicken parts.[81] These analyses indicate that the prevalence of *Salmonella* contamination on downstream products (*e.g.,* parts) often exceeds that for the prevalence of Salmonella contamination in upstream products (*e.g.,* carcasses). The higher prevalence is logical given that samples of downstream products contain primals from multiple carcasses, increasing the likelihood of a single sample being contaminated.

The market hog *Salmonella* illness risk model estimates that the prevalence of *Salmonella* detected in carcasses may decline on average from an initial prevalence of 0.9407% to a final prevalence of 0.9066% if the 35 identified establishments adopt the new inspection system. This decrease in prevalence should correspond to an average decrease in illnesses due to market hog product consumption by an average of 2,533 annual cases.[82]

More specifically, CDC applies 14 empirical, population-adjusted, and Pert uncertainty distributions multiplicatively modeled as Monte Carlo distributions with repeated sampling and Bayesian characteristics to the data collected at their surveillance sites. CDC states that the illness estimates are robust but likely underestimates due to extrapolation from surveillance and outbreak data with underreporting not captured in the CDC uncertainty estimates based ultimately on laboratory confirmed cases. CDC's modeling approach used to estimate total uncertainty of illnesses is designed to capture multiple sources of uncertainty that were not explicitly modeled, that is, the uncertainty in CDC illness estimates captures components of consumer behavior, cross contamination and *Salmonella* inactivation and growth between production and consumption.[83] The uncertainty surrounding illness estimates is the largest contributor to overall uncertainty in the NSIS risk model. The total uncertainty in the case rate is estimated to be bounded at the 10th and 90th percentiles by a potential increase of 1,719 and a potential decrease of 6,685 cases, respectively. The total case uncertainty distribution is dependent on the uncertainty in the change in *Salmonella* prevalence in market hogs.

The prevalence estimates are modeled with data variability and robust uncertainty components taken from sampling data and model parameter estimates. Additional, unquantified uncertainty includes the possibility that differences between HIMP plants and non-HIMP plants that adopt NSIS not accounted for in the risk assessment could affect *Salmonella* prevalence. A number of potential differences, however, are taken into account in the risk assessment. The variability and uncertainty in the market hog proportion of illnesses is modeled from FSIS market hog slaughter data and Bayesian uncertainty. As demonstrated in the 2010–2011 Market Hog Baseline Study, the market hog slaughter process resulted in 2,390,482 carcasses produced per year and a weighted *Salmonella* contamination prevalence rate of 1.66%; the 10th percentile estimate for this value is 2,218,169 carcasses and the 90th percentile estimate is 2,561,973 carcasses. This uncertainty in the carcass prevalence rate in market hogs according to the peer reviewed prevalence model corresponds to the overall uncertainty in consumer *Salmonella* cases of illnesses from market hogs with an average of 69,857 cases and 10th and 90th percentiles of 40,778 and 104,333 cases respectively, under traditional inspection. With adoption of the new inspection system, the average number of cases is likely to decrease to 67,324.

[79] Williams M.S., Ebel, E.D., Vose, D. 2011. Framework for Microbial Food-Safety Risk Assessments Amenable to Bayesian Modeling. *Risk Analysis* 31(4):548–565.

[80] Ebel, E.E., *et al.* 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. *Food Control* 28(2): pp. 250 257.

[81] Ebel, E.D., Williams, M.S., Tameru, B. (2019) Relatedness of Salmonella contamination frequency on chicken carcasses and parts when processed in the same establishment. *Food Control* 100: 198–203.

[82] The relationship between carcass contamination prevalence and human illnesses modeled as in Williams *et al.,* 2010, Estimating changes in public health following implementation of hazard analysis and critical control point in the United States broiler slaughter industry, Foodborne Pathogens and Disease, 9 and Ebel *et al.,* 2012, Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments, Food Control, 28.

[83] CDC's surveillance and outbreak attribution data are available in Scallan, E., *et al.* 2011. Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases* 17(1): 7–15.

The market hog risk assessment estimates that if the 35 establishments expected to convert to the NSIS over 5 years do so, the number of human illnesses attributed to products derived from market hogs could reduce by an average of 2,533 *Salmonella* illnesses. The combined robust model estimate of quantified uncertainty in the case rate based on CDC *Salmonella* illness and FSIS market hog contamination data is estimated to be bounded at the 10th and 90th percentiles by an increase of 1,719 and a decrease of 6,685 cases, respectively. It is worth noting, however, that there is an approximately 80% likelihood of a decrease in illnesses.[84] The ERS estimates of the annual per case cost of foodborne illnesses for *Salmonella* range from roughly $321 to $5,820, with a mean of roughly $3,682.[85] These estimates factor in the costs of physician office, emergency room, and outpatient clinic visits, as well as hospitalizations, productivity loss, and deaths. Assuming approximately 2,533 averted cases of *Salmonella,* potential savings range from roughly $0.81 million to $14.74 million, with a midpoint of $9.33 million, Table 18. Health costs would increase by roughly $6.33 million if cases increased by 1,719, which corresponds to the 10th percentile, and each case cost $3,682, Table 18. Alternatively, health costs would decrease by roughly $24.62 million if 6,685 cases were averted, which corresponds to the 90th percentile, and each case cost $3,682, Table 18. Using the midpoint estimate of $9.33 million cost decrease and applying a five-year adoption rate, the annualized value is approximately $7.09 million, at a 3 percent discount rate, Table 18. These estimated benefits may underestimate total benefits because they do not include pain and suffering costs. They may also overestimate benefits and cost savings given the uncertainty between the number of illnesses and the number of carcasses with detectable *Salmonella.*

TABLE 18—POTENTIAL BENEFITS FROM AVERTED CASES OF SALMONELLA

Percentile	Change in illnesses by scenario	Cost per illness *		
		Low	Mid	High
		$321	$3,682	$5,820
		Scenario Costs, $M		
10th	1,719	$0.55	$6.33	$10.01
Mean	(2,533)	(0.81)	(9.33)	(14.74)
90th	(6,685)	(2.15)	(24.62)	(38.91)
Comparison of Mean Recurring Costs (M$)				
Low				
Recurring Cost				6.33
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				4.81
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				4.62
Mid				
Recurring Cost				(9.33)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				(7.09)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				(6.81)
High				
Recurring Cost				(24.62)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				(18.71)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				($17.97)

* Source: USDA ERS, 2014, Cost Estimates of foodborne illnesses. *http://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx#48446* Accessed on 9/9/2011. Last updated on 11/12/2014.
Note, some of the totals may not equal the sum due to rounding.

[84] The primary conclusion for the purposes of this regulatory change, however, is that the NSIS is unlikely to result in a higher prevalence of *Salmonella* on market hog carcasses and may result in a lower prevalence of *Salmonella* on market hog carcasses, which in turn may lead to fewer human illnesses. As such, public health benefits are characterized as ''potential'' rather than ''expected'' benefits.

[85] USDA ERS, 2014, Cost Estimates of foodborne illnesses. *http://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx#48446* Accessed on 9/9/2011. Last Updated on 11/12/2014.

2. Other Benefits Associated With Modernizing Existing Regulations

The final rule will potentially reduce the regulatory burden on establishments by shifting from prescriptive to performance-based regulation. Based on the Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs Report, the five HIMP establishments' average line speed was approximately 12.49 percent faster than comparable establishments.[86] This increase in line speed is synonymous with an increase in industrial efficiency. To quantify the benefit associated with this efficiency gain, this analysis used the North American Meat Institutes' (NAMI's) average pork packer margins for 2013–2017, which was reported to be $15.20[87] per head in NAMI's 2017 Meat and Poultry Facts.[88] The pork packer margin is the price the packer receives less the cost of the hog and production costs, making it an estimate for accounting profits. However, economic profit may be more precisely associated with producer surplus. Economic profit is equal to the establishment's revenues minus its implicit and explicit costs. Implicit costs are costs establishments do not spend money on, such as opportunity costs, while explicit costs are costs establishments spend money on, such as labor or hogs. Accounting profits can be larger than economic profits because they exclude some implicit costs. FSIS requested, but did not receive, comment on refining this estimate so as to distinguish between accounting profit and economic profit.

By using accounting profits to estimate producer surplus, this analysis multiplied the change in quantity produced by half the per head margin, which is $7.60 ($15.20/2). This approach assumes that marginal costs increases as a function of quantity produced and that the marginal cost curve is linear, in which case the profit margin reaches zero for the last unit produced.

Assuming establishments increase their production by 12.49 percent and that this increased production has an average packer margin of $7.60 per head, an average large establishment's surplus could increase by approximately $3.78 million, while an average small high-volume establishment's surplus could increase by $0.34 million, all else being equal. Combined, such an increase in efficiency at all 35 establishments will increase producer surplus by roughly $87.64 million[89] (22 × $3.78 million + 13 × $0.34 million), which has an annualized benefit of roughly $66.93 million, assuming a 3 percent discount rate over 10 years, Table 19. This estimate takes into consideration the assumed five-year adoption rate. However, this increase in surplus may be an overestimate given that an increase in line speeds may change market hog prices, establishment production costs, retail prices, and export volumes. Additionally, this analysis does not account for a change in consumer surplus, which will be conditional on how an increase in line speed affects retail prices. The Agency sought, but did not receive, comment on the extent to which such an increase in line speeds will affect market hog prices, establishment hours of production, consumer prices, and export volumes.

TABLE 19—INDUSTRIAL EFFICIENCY, (BENEFITS)

[M$]

Type of establishment	Number of establishments	Change in producer surplus	
		Per establishment	Combined
Large	22	($3.78)	($83.26)
Small	13	(0.34)	(4.38)
Combined *	35		(87.64)
Totals *			
Recurring Cost			(87.64)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			(66.93)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			(64.32)

* Note, some of the totals may not equal the sum due to rounding.

[86] USDA FSIS Evaluations—HACCP Inspection Models Project (HIMP) for Market Hogs *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/evaluations-+himpAccessedon1/6/2017.* Last updated on 11/14/2014.

[87] Note that the increase in benefits as compared to the proposed rule is due to updating the margin used from NAMI's 2015 Meat and Poultry Facts to NAMI's 2017 Meat and Poultry Facts. The proposed rule used a five-year average of $4.10 (2010–2014) per head, with a low of a $2.85 (2012) per head loss to a $11.49 (2010) per head gain. While the Final Rule uses a five-year average of $15.20 (2013–2017) per head, with a low of a $4.50 (2013) per head gain to a $25.26 (2017) per head gain.

[88] Nalivka, J.S., The 2017 Meat and Poultry Facts, *NAMI* August 2018.

[89] Note, some of the totals may not equal the sum due to rounding.

The five HIMP establishments have demonstrated that establishments operating under the NSIS are able to increase their compliance with sanitation SOPs and HACCP regulations, lower their level of non-food safety defects, achieve equivalent or better *Salmonella* verification testing rates, and lower the level of violative chemical residues.[90] The five establishments that participated in the HIMP pilot study account for 15 percent of total swine production.

Additionally, the NSIS increases the Agency's ability to conduct more process and product verification and to increase monitoring of humane handling procedures, which is expected to improve animal welfare. FSIS inspectors devoted approximately 5.33 hours per shift to verifying humane handling activities for the Humane Activity Tracking System, HATS, categories in HIMP market hog establishments compared to approximately 4.29 hours per shift in the 21 non-HIMP market hog comparison establishments.[91] Under the NSIS, establishments sort, remove, and identify swine unfit for slaughter before FSIS ante-mortem inspection. More FSIS resources can be devoted to offline inspection activities because initial sorting and tagging functions are performed by establishment personnel. This change will provide Agency personnel with more time to conduct offline inspection activities.

I. Potential Budgetary Impacts on the Agency

Under the final rule, FSIS will shift Agency resources from online to offline activities. This analysis estimates how such a shift will reduce labor expenses by approximately $6.67 million annually, Table 20. However, Agency personnel at NSIS establishments will require additional training, the annualized cost of which is estimated to be approximately $0.30 million. Both annualized estimates apply a 3 percent discount rate over 10 years and takes into consideration the assumed five-year adoption period. The Agency will also update PHIS to allow establishments to enter information on animals removed from the slaughter process. This modernization process will likely cost FSIS approximately $300,000 but will be paid for using existing Agency funds. Details of these costs are provided below.

1. Agency Staffing

The following section discusses the impact on the Agency's budget due to reassignment of the inspection staff. As discussed in section F of this document, under traditional inspection, a single slaughter line at a large establishment requires up to 11 FTEs, while a small market hog establishment requires up to 2 FTEs. Under NSIS, a single slaughter line at a large establishment will potentially require 6 FTEs, while a small market hog establishment will potentially to require 3 FTEs. Under NSIS, large establishments with 2 slaughter lines will potentially require 10 FTEs,[92] while a small market hog establishment with 2 slaughter lines will potentially require 4 FTEs.

This analysis considers likely staffing changes at the 22 large and 13 small establishments which will potentially convert to NSIS over a course of five years. Combined, these establishments operate 46 shifts and 55 lines.[93] This analysis uses PHIS data provided by the Office of Field Operations (OFO) to calculate the number of FTEs assigned to each slaughter line. The FSIS Office of the Chief Financial Officer (OCFO) provided the wage and benefit data for each of these positions. This data was used to model the staffing changes in terms of both full- time positions and monetary value. Based on this data, to conduct traditional inspection, the Agency requires a combined 365 (334 at large and 31 at small establishments) FTE food or consumer safety inspectors at an annual cost of approximately $30.43 million, Table 20. If all 22 large non-HIMP and 13 small high-volume market hog only establishments convert to the NSIS, the Agency will require 218 (187 at large and 31 at small establishments) FTE food or consumer safety inspectors. This number was arrived at by assuming that under NSIS each of the 41 lines at the large establishments will have up to 3 FTEs assigned to them and each of the 32 shifts at the large establishments will have up 2 FTEs assigned to them ((41 lines × 3 FTEs) + (32 shifts × 2 FTEs) = 187 FTEs). Likewise, under NSIS, the 13 small establishments will each require between 2–3 FTEs, based on configuration, for a total of 31 FTEs. These staffing levels are based on FSIS's experience at HIMP establishments. The combined labor costs for NSIS is approximately $21.70 million, Table 20. This cost estimate includes estimated grade increases associated with converting to the NSIS. As is shown in Table 20, if all 22 large establishments convert to NSIS, this analysis estimates a net decrease of 147 (334 − 187) FTEs required for slaughter line inspection. The NSIS inspection program at these large establishments has a remuneration value of just over $18.58 million. A similar analysis of the 13 small high-volume establishments reveals no net change in the number of FTEs. However, because the NSIS requires all inspectors to be CSIs, many of the FTEs will likely be promoted from a FI to a CSI. Overall, if all 35 establishments converted to NSIS, the Agency will require 147 fewer FTEs for swine slaughter inspection, with potential annual decrease in costs of roughly $8.73 million, which is equal to roughly $6.67 million a year, assuming a 3 percent discount rate and the assumed five-year adoption period, Table 20.

[90] USDA FSIS Evaluations—HACCP Inspection Models Project (HIMP) for Market Hogs *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/evaluations-+himpAccessedon1/6/2017.* Last updated on 11/14/2014.

[91] USDA FSIS Evaluations—HACCP Inspection Models Project (HIMP) for Market Hogs *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/evaluations-+himpAccessedon1/6/2017.* Last updated on 11/14/2014.

[92] The difference in staffing between large establishments with 1 and 2 lines is because the Agency does not anticipate duplicating offline FTEs per line.

[93] The 22 large establishments operate 41 slaughter lines during 32 shifts, while the 13 small establishments operate 14 lines during 14 shifts, source PHIS.

TABLE 20—POTENTIAL CHANGES IN AGENCY STAFFING

[M$]

Type	Traditional		NSIS		Increases (reductions)	
	Number positions	Labor costs	Number positions	Labor costs	Number positions	Labor costs
Large	334	$27.56	187	$18.58	(147)	($8.98)
Small	31	$2.87	31	$3.12	0	0.25
Total	365	$30.43	218	$21.70	(147)	(8.73)

Totals

Recurring Cost	(8.73)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	(6.67)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	(6.42)

Since 2008, the Agency has annually lost, through attrition, 270 food inspectors on average. See Table 21 for details. The Agency plans to utilize all personnel made available as a result of conversion to NSIS to fill these vacant positions.

TABLE 21—ANNUAL TURNOVER OF FOOD INSPECTORS

Fiscal year	Number of positions
2008	307
2009	264
2010	231
2011	268
2012	266
2013	246
2014	273
2015	305

TABLE 21—ANNUAL TURNOVER OF FOOD INSPECTORS—Continued

Fiscal year	Number of positions
Average	270

Source: OFO.

2. Agency Training

a. Three Day NSIS Methods Course

If all 22 large and 13 small market hog establishments convert to NSIS over the course of five years, as set forth in Table 6, the Agency estimated training 266 personnel (218 CSIs and 48 PHVs), with pay grades ranging from GS–8 to GS–13, on NSIS methods. The majority of these personnel, 228, are associated with 22 large establishments, while the remaining 38 are associated with 13 small establishments, Table 22. The associated one-time cost of such training includes labor and travel expenses associated with the employees receiving training, as well as temporary replacement labor costs required to fulfill the work that would have been completed by the employees receiving training. Based on the HIMP pilot study, this analysis assumes NSIS methods training will take 3 days and replacement labor will be equivalent to GS–13 step 5. Under these assumptions, the total one-time cost of NSIS training is approximately $0.64 million ($0.56 million for all large establishments and $0.08 million for all small establishments), Table 22. This one-time cost equals approximately $0.07 million if it were annualized over 10 years under a 3 percent discount rate, Table 22.

TABLE 22—THREE DAY NSIS TRAINING COURSE

[M$]

Type of establishment	Cost of trainee		Replacement labor		Combined costs
	Number of inspectors requiring training	Costs of wages and benefits for trainees	Number of replacement inspectors required	Costs of wages and benefits for replacements	
Large	228	$0.21	228	$0.34	$0.56
Small	38	0.03	38	0.06	0.08

Totals *

One-Time Cost	0.64
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	0.07
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	0.07

* Note, some of the totals may not equal the sum due to rounding.

b. Fill an Increase Need for Consumer Safety Inspectors

Under the final rule, slaughter line inspectors at a NSIS establishment will work both on and off the slaughter line. As such, every inspection position will fall under the CSI position classification. To fill the increase in demand for CSIs, the Agency plans to train existing FIs. Training includes a four-week meat inspector course titled Inspection Methods (IM) and a one-day computer familiarization course. If all 22 large establishments convert to NSIS, the Agency will need an additional 82 CSIs. Likewise, if all 13 small market hog establishments convert, the Agency will need an additional 16 CSIs. Converting a FI into a CSI may result in a grade increase, the cost of which has been included in the Agency Staffing section above. The combined one-time cost for converting FIs into CSIs is roughly $2.16 million, Table 23. Nearly half of this cost stems from the need for replacement labor. Again, under the projected five-year adoption rate, as set forth in Table 6, and annualized over 10 years under a 3 percent discount rate, the cost for converting FIs to CSIs is approximately $0.23 million, Table 23.

TABLE 23—COST OF CONVERTING A FOOD INSPECTOR INTO A CONSUMER SAFETY INSPECTOR

[M$]

Training component	Labor		Travel, M&IE, and lodging	Combined costs
	Trainee	Replacement		
Four Week IM Course	$0.52	$0.98	$0.59	$2.09
One Day Computer Training	0.03	0.05		0.07
Totals *				
One-Time Cost				2.16
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				0.23
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				0.25

* Note, some of the totals may not equal the sum due to rounding.

Combined Estimated Budgetary Impacts

The Agency's budget will potentially be impacted both by changes to personnel and training requirements. First, on average, there will be fewer Agency inspection personnel per slaughter line operating under NSIS. If all 22 large and 13 small establishments convert to NSIS over the course of five years, the Agency will require approximately 147 fewer FTEs to inspect the 55 [94] slaughter lines operating at these establishments. The annual remuneration value of these 147 positions is roughly $8.73 million, Table 24. Second, the Agency will need to train approximately 266 personnel on NSIS methods at a one-time cost of approximately $0.64 million, Table 24. Third, the Agency plans to meet the increase in demand for CSIs by converting existing FIs into CSIs. The one-time cost of doing so is approximately $2.16 million, Table 24. The annualized value of the combined changes to the Agency's budget is a net reduction of roughly $6.38 million, over 10 years assuming a 3 percent discount rate, Table 24.

TABLE 24—COMBINED CHANGES TO FSIS'S BUDGET

[M$]

	Total costs	
	One-time	Recurring
Changes to Agency Staffing		($8.73)
Three Day NSIS Training	$0.64	
Converting Food Inspectors into Consumer Safety Inspectors	2.16	
Totals		
One-Time Cost		2.80
Recurring Cost		(8.73)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(6.38)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(6.09)

J. Net Benefits

Assuming all high-volume large and small exclusively market hog establishments convert to NSIS (5 HIMP, 22 large, and 13 small high-volume), the rule is anticipated to have a net benefit of approximately $62.56 million a year, annualized over 10 years assuming a 3 percent discount rate, Table 25. The majority of the costs will be incurred by the 35 non-HIMP establishments that will potentially voluntarily switch to the NSIS in the form of increased labor needs.

[94] Source: PHIS.

TABLE 25—NET COSTS AND (BENEFITS)

[M$]

	Number of establishments	One-time	Recurring
Costs to Industry		$3.14	$22.72
Voluntary *	** 40	0.84	22.15
Mandatory	612	2.30	0.58
Health Benefits ***			(9.33)
Industrial Efficiency			(87.64)
Impacts to Agency's Budget		2.80	(8.73)
Totals			
One-Time Cost		$5.94	
Recurring Cost		(82.98)	
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(62.56)	
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(60.00)	

* Further explanation and details on the NSIS adoption rate are provided in section G. Potential Cost of the Final Rule, Table 6: NSIS Adoption Rate and section J. Net Benefits, Table 26: Quantified Cost and (Benefits) of Various Adoption Rates

** Note, this includes 5 HIMP establishments, which were not estimated to incur any cost or benefits associated with the NSIS

*** Further explanation and details on the range of health benefits have been provided in section H. Potential Benefits of the Final Rule, Table 18: Health Benefits from Averted Cases of *Salmonella.* The value of health benefits ranges from a $6.33 million decrease to a $24.62 million increase in health benefits, with a mean increase in benefits of $9.33 million, assuming a cost per illness of $3,682.

**** Note, some of the totals may not equal the sum due to rounding.

Given the lack of data with which to make cost-benefit comparisons across the industry, Table 26 provides a range of possible adoption scenarios and their corresponding costs and benefits. Under scenario A, only the 5 HIMP establishments adopt the NSIS. Because these 5 establishments are already operating under NSIS practices, there will not be any additional voluntary costs or benefits associated with these 5 establishments adopting the NSIS. However, 606 establishments will incur costs associated with the final rule's mandatory components. As such, scenario A has a net cost. Scenario B assesses the net cost and benefits of just 6 establishments adopting the NSIS (5 HIMP and 1 large). This scenario reveals that the rule is net beneficial if just 1 large establishment adopts the NSIS in addition to the 5 HIMP establishments. Scenarios C, D, and E measure the net costs and benefits of 50, 75, and 100 percent of the 35 non-HIMP establishments converting to the NSIS, respectively. Each of these scenarios are net beneficial.

TABLE 26—QUANTIFIED COST AND (BENEFITS) OF VARIOUS ADOPTION RATES

[M$] ^

	Number to adopt *	Costs		(Benefits)			Net
		Mandatory @	NSIS	Health	Line speeds	Agency budget	
A	5	$0.84	$0.0	$0.0	$0.0	$0.0	$0.84
B	6	0.84	0.86	(0.27)	(3.78)	(0.38)	(2.73)
C	23	0.84	8.34	(3.59)	(33.34)	(3.14)	(30.90)
D	32	0.84	13.08	(5.52)	(51.51)	(4.88)	(47.99)
E	40	0.84	17.0	(7.09)	(66.93)	(6.38)	(62.56)

* These numbers include the 5 HIMP establishments. However, because these establishments are already conducting NSIS practices, they did not contribute to quantified NSIS costs, health benefits, or the impacts to the Agency's budget.

@ These costs are incurred by all 612 swine establishments.

^ Annualized Assuming a 3% Discount Rate Over 10 Years

* Note, some of the totals may not equal the sum due to rounding.

K. Alternatives

Table 27: Alternative Policy Options

Alternatives	Benefits	Costs	Net
A. No action (Baseline)	1. No additional costs to industry.	1. Potential for inefficient use of agency resources. 2. No potential increase in industrial efficiency. 3. Lack of incentive for establishments to innovate and improve their process controls. 4. No potential health benefits.	
B. Mandatory Portion of the Final Rule Only	1. In comparison to the baseline, potential $0.57M in Process Control Sampling cost savings.	1. In comparison to the baseline, potential $1.41M in Other Industry Costs.	Costs of $0.84M
C. Final Rule (40 Establishments Adopt NSIS)	1. Potential $7.09M in averted illnesses. 2. Potential $66.93M in Industrial Efficiency. 3. Potential $0.57M in Process Control Sampling cost savings. 4. Roughly $6.67M in Agency Labor Savings.	1. Potential $16.61M Increase in Industry Labor Costs 2. Potential $1.80M in Other Industry Costs 3. Roughly $0.30M in Agency Training Costs	Benefits of $62.56M
D. Require All 612 Establishments Adopt NSIS	1. Potentially more than $7.09M in averted illnesses.	1. Potential $25.9M Increase in Industry Labor	Benefits of $47.59M

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A—Taking No Action (Baseline)

FSIS considered maintaining the current inspection system for all 612 swine slaughter establishments. The Agency rejected this alternative because it would forgo the benefits provided by the NSIS. These benefits include the establishment's ability to innovate and develop process controls which increase foodborne hazard detection and more efficiently use all their resources. Taking no action would also forgo potential industrial efficiency increases.

Further, no action would result in the Agency continuing to dedicate resources to food quality issues, at the expense of increasing offline activities benefitting food safety. Last, taking no action would also forgo potential health benefits identified under the final rule.

B—The Mandatory Portion of the Final Rule

FSIS considered limiting the final rule to only include new requirements that affect all swine slaughter establishments. Under such a scenario, quantified benefits are limited to an estimated $0.57 million reduction in process control sampling costs. This cost reduction will potentially be off-set by a $1.41 million increase in other industry costs associated with requiring written sanitary dressing plans. In comparison to the baseline, this scenario has a net cost of roughly $0.84 million. Additionally, under such a scenario, the Agency's inspection staff would not be reassigned, and the Agency would continue to require the same number of inspectors. As such, the Agency's labor costs would not decrease by the estimated $6.67 million. However, because FIs would not be converted into CSIs nor will inspectors require additional training, the Agency would not incur the corresponding $0.30 million in training costs ($0.07 for NSIS training plus $0.23 in CSI training). As mentioned earlier, simultaneously increasing unscheduled and scheduled inspection procedures and decreasing scheduled but not performed procedures accrues most of the public health benefits. The unscheduled and scheduled tasks are currently not performed as a result of lack of offline personnel. In comparison to the final rule, this alternative would eliminate most of the public health benefits associated with the rule, which are estimated at $7.09 million annually. Additionally, line speed restrictions would remain in place, leading to an estimated loss of over $36.14 million in industrial efficiency gains. FSIS has rejected this alternative in light of its estimated net cost as compared to the baseline as well as the decrease in net benefits as compared to the final rule.

C—The Final Rule

Applying a 3 percent discount rate over 10 years the costs associated with the final rule includes $16.61 million in additional industry labor costs, $1.80 million in other industry costs including costs associated with meeting ready to cook standards and written sanitary dressing plans, as well as $0.30 million in Agency training costs. The quantified health benefits of the final rule are limited to reductions in *Salmonella* illnesses and have an estimated value of $7.09 million, assuming a 3 percent discount rate. Allowing establishments to set line speeds so long as they maintain process control will potentially increase their efficiency by $66.93 million, assuming a 3 percent discount rate. The final rule could potentially reduce industry costs associated with process control sampling by roughly $0.57 million, assuming a 3 percent discount rate. Additionally, the final rule could potentially reduce the Agency's labor costs by roughly $6.67 million, assuming a 3 percent discount rate. In comparison to the baseline, the final rule has an estimated net benefit of $62.56 million, assuming a 3 percent discount rate over 10 years, and as such, the Agency recommends the final rule.

D—Requiring All Federally Inspected Establishments Adopt the New Swine Inspection System

FSIS considered requiring all federally inspected swine slaughter establishments to convert to NSIS. This would expand NSIS from the 5 large HIMP, 22 large and 13 small high-volume non-HIMP establishments expected to convert under the final rule to include 572 additional establishments. This expansion would include low-volume establishments that slaughter all types of swine as well as other establishments that slaughter a mix of species.

In comparison to the baseline, the benefits of this alternative potentially include more than $7.09 million in averted illnesses, a $66.93 million increase in industrial efficiency, $0.57 million in industrial savings associated with process control sampling requirements, assuming a 3 percent discount rate over 10 years. While compared to the baseline, this alternative reduces Agency labor costs by $2.72 million, assuming a 3 percent discount rate over 10 years. However, this alternative's Agency labor costs savings are less than the final rule's Agency labor costs savings because this alternative would result in additional promotions and training in small and very small establishments. The production at these 572 additional establishments represents less than 8 percent of total production and, as such, is not expected to return substantial reductions in contamination prevalence or illnesses and falls outside of the current risk assessment. In particular, the uncertainty around measurement and model parameters that is already included in the health benefit calculations for the final rule likely produce wide enough estimates that the impact of adopting the NSIS in all establishments would have an effect within the uncertainty bounds. The increase in industrial efficiency remains similar to that of the final rule because these additional establishments are generally less automated and maintain slower line speeds to address higher rates of quality defects associated with non-market hogs.

In comparison to the baseline, the potential costs associated with this alternative include a $25.90 million increase in industrial labor, a $3.14 million increase in other industry costs, which include costs associated with RTC standards and written sanitary dressing plans, as well as roughly $0.68 million in Agency training costs. In comparison to the final rule, the additional increases in costs to industry are substantially higher and predominately fall on small and very small business. While this alternative has a net benefit of $47.59 million, assuming a 3 percent discount rate over 10 years, the Agency rejects it because its net benefit is less than the final rule.

IV. Regulatory Flexibility Act Assessment

The FSIS Administrator has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). FSIS used an establishment's HACCP processing size, which applies to an individual establishment, as a proxy for business size. HACCP processing sizes are the following: large establishments have 500 or more employees; small establishments have between 10 and 499 employees; very small establishments have fewer than 10 employees or annual sales of less than $2.5 million. Section III provides additional details on costs incurred by small businesses.

The final rule's mandatory requirements will affect approximately 584 small entities—105 small and 479 very small. First, the mandatory requirements include that all small and very small establishments create written sanitary dressing plans with cost components of development of the plan, training of employees, and recordkeeping, at an annualized cost of $1,869 per establishment, applying a 3 percent discount rate over 10 years. Second, the mandatory changes to process control sampling requirements could potentially decrease small establishments' sampling costs by roughly $984 per establishment annually, applying a 3 percent discount

rate over 10 years. In addition to this sampling cost reduction, the Agency will allow small and very small low-volume establishments to modify their sampling plans to collect samples less frequently once they have collected 13 consecutive weekly samples and can demonstrate that they are not exceeding their upper control limit and that they are effectively maintaining process control. FSIS is also allowing establishments to develop sampling plans that are more tailored to their specific operation, and thus more effective in monitoring their specific process control as compared to the current generic *E. coli* criteria. Therefore, the final rule's mandatory requirements could potentially increase small establishments' costs by roughly $885 ($1,869 − $984 = $885) per establishment annually, an amount that will potentially have little effect on small entities. To put this in perspective, the average small and very small establishment slaughters over 21,000 swine annually. Using the American Meat Institute's average pork packer dollars per head margins for 2013–2017, the average small and very small establishment's marginal revenue is $332 thousand (21,858 (heads slaughtered) × $15.20 (average margin per head)). The final rule also provides small and very small establishments with additional time to comply with the new requirements in 9 CFR 310.18(c) and (d). Additionally, the optional NSIS portion of the rule could potentially provide an overall cost savings for the 13 small high-volume establishments of roughly $288,731 per establishment that adopts the NSIS. This estimate takes into consideration the increase in labor cost ($42,025 per establishment), cost associated with meeting RTC standards ($6,300 per establishments) and cost savings from increased industrial efficiency ($337,056 per establishment). See section III for additional details.

V. Executive Order 13771

Consistent with E.O. 13771 (82 *FR* 9339, February 3, 2017), FSIS estimates that this final rule will yield cost savings. Assuming a 7 percent discount rate, a perpetual time horizon, and a starting year of 2019, the final rule is estimated to yield approximately $51.91 million (2016$) in annual cost savings, not including potential health benefits. Therefore, this rule is an E.O. 13771 deregulatory action.

VI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

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 12988, Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

IX. Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, Consultation and Coordination with Indian Tribal Governments. E.O. 13175 requires Federal agencies to consult and coordinate with Indian tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule has minimal tribal implications. If an Indian tribe requests consultation, FSIS will work with the OTR to ensure meaningful consultation is provided.

X. USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA must, 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.

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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).

XI. Environmental Impact

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

Establishments that operate under NSIS will be able to slaughter and process swine more efficiently than is possible under current regulations, leading to a reduction in production costs. FSIS expects that consumer demand for pork products will determine the number of swine slaughtered rather than production costs. Because of the efficiencies in the NSIS, the price of pork products may decrease. The predicted price reduction could lead to a slight increase in demand for pork products. With the slight increase in pork product sales, some establishments may choose to increase the number of swine slaughtered, which could result in an increase in the number of condemned carcasses and parts that must be disposed of. However, because the anticipated change in price and sales is very small, especially in comparison to changes in price and sales in response to other market forces, the Agency has determined that the change in the

number of swine slaughtered, as well as the number of condemned carcasses and parts to be disposed of, will be very small and thus will not have a significant individual or cumulative effect on the human environment. Therefore, this regulatory action is appropriately subject to the categorical exclusion from the preparation of an EA or EIS provided under 7 CFR 1b.4(b)(6) of the USDA regulations.

XII. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this final rule have been submitted by the Agency to OMB for approval which has not yet been received. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

Title: Swine Slaughter Inspection.

Type of Collection: New.

Abstract: FSIS updated the proposed rule's information collection assessment to reflect the changes made in the final rule in response to public comments and to better align it with the final cost estimates in section III. FSIS is also requiring a new information collection burden but has reduced the total annual burden estimate by 52,729.04 hours. The changes to the final burden estimates incorporate the following factors:

- FSIS is requiring a new information collection burden; specifically, the Agency is requiring market hog slaughter establishments operating under NSIS to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal.
- The proposed mandatory pre-operational environmental sampling was removed from the final rule. Therefore, these time estimates were removed from the final burden estimates.
- Establishments operating under SIP conduct process control sampling at an alternative frequency. Therefore, these 11 establishments have been removed from the final burden estimates.
- The final burden estimates only include the time to record the sample results for the new process control sampling requirements.
- The final burden estimates were updated so that the establishment and time estimates align with the final cost analysis in section III.

New Information Collection in This Final Rule

FSIS is requiring a new regulation that will create a new information collection burden, in that it will require market hog slaughter establishments operating under NSIS to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal. FSIS has created a form to collect disposition data from establishments. Establishments may provide the same information as requested on the form electronically if it is submitted in a format approved by FSIS. FSIS estimates this new requirement will take establishments operating under NSIS, 5 minutes per shift regardless of whether establishments complete the form or submit the information electronically. This is a new recordkeeping requirement that FSIS has submitted to OMB for approval.

Estimated Annual Recordkeeping Burden for Maintaining Records to Document the Total Number of Animals and Carcasses Sorted and Removed per Day and the Reasons for Their Removal

Respondents: Official market hog slaughter establishments that operate under NSIS.

Estimated maximum number of respondents: 40.

Estimated Average Annual Number of Responses per Respondent: Large establishments 352; small high-volume establishments 290.

Estimated Maximum Total Potential Annual Responses: 13,282.

Estimated Total Annual Recordkeeping Burden: 1,107 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	Animals and carcasses sorted and removed and their reasons.	27	352	9,504	5	792
Small high-volume establishments.	Animals and carcasses sorted and removed and their reasons.	13	290	3,770	5	314
Total Recordkeeping Burden for sorting and removing.	.....	40	332	13,274	5	1,106

Under this final rule, establishments also will have to maintain written procedures to ensure that animals and carcasses that have been sorted and removed for disposal do not enter the human food supply and are properly disposed of under 9 CFR part 314. The requirement that swine slaughter establishments have written procedures in their HACCP systems is already covered under an approved information collection system, Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (OMB control number 0583–0103). Therefore, this requirement of this final rule will create no new burden on establishments.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250; (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 method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, 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 FSIS, at the addresses 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 within 60 days of the publication date of this final rule.

Information Collections That Were Included in the Proposed Rule

Under this final rule, establishments operating under NSIS are required to (1) identify animals or carcasses that establishment personnel have sorted and removed for disposal before FSIS inspection with a unique tag, tattoo, or similar device, and to develop, implement, (2) maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal, and (3) maintain records documenting that products resulting from their slaughter operations meet the new definition of RTC pork product. Furthermore, each establishment operating under the NSIS 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.

In addition, each official swine slaughter establishment, regardless of the inspection system under which they operate, will need to maintain, as part of its HACCP system, written procedures for preventing, throughout the entire slaughter and dressing operation, contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk. These procedures must include sampling and analysis for microbial organisms to monitor process control for enteric pathogens, as well as written procedures to prevent visible fecal material, ingesta, and milk contamination.

As mentioned above, the requirement that swine slaughter establishments have written procedures in their HACCP systems is already covered under an approved information collection system. Therefore, this requirement of this final rule will create no new burden on establishments.

The requirement that swine slaughter establishments monitor their systems through microbial testing and recordkeeping will create a new information collection burden. For each sample on which a microbiological test is conducted, there is a ''response'' for the establishment to record the sample result. Under the final rule, large, small and very small high-volume establishments will test and record microbiological results for enteric pathogens, for carcass samples taken at both pre-evisceration and post-chill (for hot-boned products, carcass samples will be collected pre-evisceration and after the final wash), at a frequency of once per 1,000 carcasses; and small and very small low-volume establishments, 13 times a year. The small and very small low-volume establishments do not experience an increase in sampling under the final rule.

Estimated Annual Recordkeeping Burden: Swine Slaughter Inspection.

Respondents: Official high-volume swine establishments.

Estimated Number of Respondents: 74 (17 large, 51 small high-volume, and 6 very small high-volume).

Estimated Average Annual Number of Responses (samples) per Respondent: Large establishments 3,869; small high-volume establishments 229; and very small high-volume establishments 52.

Estimated Total Annual Responses: 77,764.

Estimated Total Annual Recordkeeping Burden: 3,240 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 recordkeeping ...	17	3,869	65,773	2.5	2,741
Small high-volume establishments.	Microbial testing data recordkeeping ...	51	229	11,679	2.5	487
Very small high-volume establishments.	Microbial testing data recordkeeping ...	6	52	312	2.5	13
Total Recordkeeping Burden for process control.	.....	74	1,051	77,764	2.5	3,240

FSIS is also requiring that market hog slaughter establishments operating under NSIS 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.

Estimated Annual Reporting Burden for Submitting an Annual Attestation on Work-Related Conditions to the FSIS Circuit. Safety Committee: Swine Slaughter Inspection.

Respondents: Official market hog slaughter establishments that operate under NSIS.

Estimated maximum number of respondents: 40.

Estimated Average Annual Number of Responses per Respondent: Large establishments 1; small high-volume establishments 1.

Estimated Maximum Total Potential Annual Responses: 40.

Estimated Total Annual Recordkeeping Burden: 1.33 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	Attestation on Work-Related Conditions.	27	1	27	2	.90
Small high-volume establishments.	Attestation on Work-Related Conditions.	13	1	13	2	.43
Total Reporting Burden	.....	40	1	40	2	1.33

SUMMARY OF BURDEN SWINE SLAUGHTER INSPECTION

[With the recordkeeping burden for maintaining records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal]

Total Number Respondents	84
Average Annual Number Responses per Respondent ..	1,084.33
Total Annual Responses	91,084
Average Hours per Response	0.05
Total Annual Burden Hours ..	4,347.33

SUMMARY OF BURDEN SWINE SLAUGHTER INSPECTION

[Without the recordkeeping burden for maintaining records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal]

Total Number Respondents	84
Average Annual Number Responses per Respondent ..	926.24
Total Annual Responses	77,804
Average Hours per Response	0.04
Total Annual Burden Hours ..	3,241.33

XIII. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to it 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 *Constituent Update* is available on the FSIS web page. Through 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/subscribe.* Options range from recalls, export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Final Regulatory Amendments

List of Subjects

9 CFR Part 301

Meat inspection.

9 CFR Part 309

Animal diseases, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 310

Animal diseases, Meat inspection.

For the reasons stated in the preamble, FSIS is amending 9 CFR chapter III as follows:

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

■ 1. The authority citation for part 301 is revised to read as follows:

Authority: 7 U.S.C. 138–138i, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

■ 2. Amend § 301.2 by adding the definition of ''Ready-to-cook (RTC) pork product'' in alphabetical order to read as follows:

§ 301.2 Definitions.

* * * * *

Ready-to-cook (RTC) pork product. Any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor, which is suitable for cooking without need of further processing.

* * * * *

PART 309—ANTE–MORTEM INSPECTION

■ 3. The authority citation for part 309 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 4. Add § 309.19 to read as follows:

§ 309.19 Market hog segregation under the new swine slaughter inspection system.

(a) The establishment must conduct market hog sorting activities before the animals are presented for ante-mortem inspection. Market hogs exhibiting signs of moribundity, central nervous system disorders, or pyrexia must be disposed of according to paragraph (c) of this section.

(b) The establishment must develop, implement, and maintain written procedures to ensure that market hogs exhibiting signs of moribundity, central nervous system disorders, or pyrexia do not enter the official establishment to be slaughtered. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOPs, or other prerequisite programs.

(c) The establishment must identify livestock that establishment employees have sorted and removed from slaughter with a unique tag, tattoo, or similar device. The establishment must develop, implement, and maintain written procedures to ensure that the animals sorted and removed from slaughter do not enter the human food supply and are disposed of according to 9 CFR part 314.

(d) The establishment must maintain records to document the number of animals disposed of per day because they were removed from slaughter by establishment sorters before ante-mortem inspection by FSIS inspectors and the reasons that the animals were removed. These records are subject to review and evaluation by FSIS personnel.

(e) The establishment must immediately notify FSIS inspectors if the establishment has reason to believe that market hogs may have a notifiable animal disease. Notifiable animal diseases are designated by World Animal Health Organization.

PART 310—POST-MORTEM INSPECTION

■ 5. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 6. Amend § 310.1 by revising paragraph (b)(3) to read as follows:

§ 310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

* * * * *

(b) * * *

(3) *Swine inspection.* There are two systems of post-mortem inspection: The New Swine Slaughter Inspection System (NSIS), which may be used for market hogs, and the traditional inspection system, which may be used for all swine.

(i) The NSIS may be used for market hogs if the official establishment requests to use it and meets or agrees to meet the requirements in 9 CFR 309.19 and § 310.26. The Administrator may permit establishments that slaughter classes of swine other than market hogs to use NSIS under a waiver from the provisions in 9 CFR 309.19 and § 310.26 as provided by 9 CFR 303.1(h). The Administrator also may permit establishments that slaughter both market hogs and other classes of swine to slaughter the market hogs under NSIS and slaughter the other classes of swine under traditional inspection.

(ii) Traditional inspection shall be used for swine when NSIS is not used. The following inspection staffing standards are applicable to swine slaughter configurations operating under traditional inspection when NSIS is not used. The inspection standards for all slaughter lines are based upon the observation rather than palpation, at the viscera inspection station, of the spleen, liver, heart, lungs, and mediastinal lymph nodes. In addition, for one- and two-inspector lines under traditional inspection, the standards are based upon the distance walked (in feet) by the inspector between work stations; and for three or more inspector slaughter lines, upon the use of a mirror, as described in § 307.2(m)(6) of this chapter, at the carcass inspection station. Although not required in a one- or two-inspector slaughter configuration, except in certain cases as determined by the inspection service, if a mirror is used, it must comply with the requirements of § 307.2(m)(6).

TABLE 1 TO PARAGRAPH (B)(3)—ONE INSPECTOR—STAFFING STANDARDS FOR SWINE

Distance walked [1] in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
0 to 5	140	150	131	143
6 to 10	134	144	126	137
11 to 15	129	137	122	132
16 to 20	124	132	117	127
21 to 35	120	127	113	122
26 to 30	116	122	110	118
31 to 35	112	118	106	114
36 to 40	108	114	103	110
41 to 45	105	110	100	106
46 to 50	101	107	97	103
51 to 55	98	103	94	100
56 to 60	96	100	91	97
61 to 65	93	97	89	94
66 to 70	90	95	87	92
71 to 75	88	92	85	89
76 to 80	86	89	82	87
81 to 85	84	87	80	85
86 to 90	82	85	79	83
91 to 95	80	83	77	81
96 to 100	78	81	75	79

[1] Distance walked is the total distance that the inspector will have to walk between work stations during one inspection cycle (*e.g.,* between viscera, carcass, head, and wash-basin).

TABLE 2 TO PARAGRAPH (B)(3)—TWO INSPECTORS—STAFFING STANDARDS FOR MARKET HOGS

Distance walked [1] in feet by inspector B is—	Maximum inspection rates (head per hour with heads attached or detached)		
	Line configuration		
	Carcass,[2] head viscera [3]	Viscera,[2] head carcass [3]	Head,[2] viscera carcass [3]
Without Mirror			
0 to 5	151–253	151–271	151–296
6 to 10	151–239	151–255	151–277
11 to 15	151–226	151–240	151–260
16 to 20	151–214	151–227	151–244
21 to 25	151–204	151–215	151–231

TABLE 2 TO PARAGRAPH (B)(3)—TWO INSPECTORS—STAFFING STANDARDS FOR MARKET HOGS—Continued

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour with heads attached or detached)		
	Line configuration		
	Carcass,[2] head viscera[3]	Viscera,[2] head carcass[3]	Head,[2] viscera carcass[3]
With Mirror			
0 to 5	151–253	151–303	151–318
6 to 10	151–239	151–283	151–304
11 to 15	151–226	151–265	151–289
16 to 20	151–214	151–249	151–270
21 to 25	151–204	151–235	151–254

[1]Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (*e.g.,* between viscera, carcass, and washbasin).
[2]Inspector A.
[3]Inspector B.
Note 1 to Table 2 to paragraph (b)(3): In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 3 TO PARAGRAPH (B)(3)—TWO INSPECTORS—STAFFING STANDARDS FOR SOWS AND BOARS

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour)			
	Line Configuration			
	Carcass,[2] head viscera,[3] heads detached	Viscera,[2] head carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads attached
Without Mirror				
0 to 5	144–248	144–254	144–267	144–267
6 to 10	144–235	144–240	144–253	144–253
11 to 15	144–222	144–227	144–239	144–239
16 to 20	144–211	144–215	144–226	144–226
21 to 25	144–201	144–205	144–214	144–214
With Mirror				
0 to 5	144–248	144–292	144–305	144–292
6 to 10	144–235	144–273	144–291	144–280
11 to 15	144–222	144–256	144–272	144–268
16 to 20	144–211	144–241	144–255	144–255
21 to 25	144–201	144–228	144–240	144–240

[1]Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (*e.g.,* between viscera, carcass, and washbasin).
[2]Inspector A.
[3]Inspector B.
Note 1 to table 3 to Paragraph (b)(3): In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 4 TO PARAGRAPH (B)(3)—THREE INSPECTORS OR MORE—STAFFING STANDARDS FOR SWINE

Maximum inspection rates (head per hour with heads attached)	Number of inspectors by station			
	Head	Viscera	Carcass	Total
Market hogs:				
319 to 506	1	1	1	3
507 to 540	1	2	1	4
541 to 859	2	2	1	5
860 to 1,022	2	3	1	6
1,023 to 1,106	3	3	1	7
Sows and boars:				
306 to 439	1	1	1	3
306 to 462[1]	1	1	1	3
440 to 475	2	1	1	4
476 to 752	2	2	1	5
753 to 895	3	2	1	6

TABLE 4 TO PARAGRAPH (B)(3)—THREE INSPECTORS OR MORE—STAFFING STANDARDS FOR SWINE—Continued

Maximum inspection rates (head per hour with heads attached)	Number of inspectors by station			
	Head	Viscera	Carcass	Total
896 to 964	3	3	1	7

[1]This rate applies if the heads of sows and boars are *detached* from the carcasses at the time of inspection.

Note 1 to table 4 to paragraph (b)(3): In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

■ 7. Amend § 310.18 by adding paragraphs (c) and (d) to read as follows:

§ 310.18 Contamination of carcasses, organs, or other parts.

* * * * *

(c) Official swine slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. These procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in paragraphs (c)(1) and (2) of this section to monitor their ability to maintain process control.

(1) *Sampling locations.* Official swine slaughter establishments, except for very low-volume establishments, must collect and analyze carcass samples for microbial organisms at the pre-evisceration and post-chill points in the process. Establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number. Establishments that bone their products before chilling (*i.e.,* hot-boned products) must collect and analyze samples at the pre-evisceration point in the process and after the final wash instead of at post-chill. Very low-volume establishments must collect and analyze samples for microbial organisms at the post-chill point in the process. All swine establishments must sponge or excise tissue from the ham, belly, and jowl areas.

(i) Very low-volume establishments annually slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock.

(ii) [Reserved]

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

(i) Establishments, except for very low-volume establishments as defined in paragraph (c)(1)(i) of this section, must collect and analyze samples at a frequency of once per 1,000 carcasses, but a minimum of once during each week of operation.

(ii) Very low-volume establishments as defined in paragraph (c)(1)(i) 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, very low-volume establishments can demonstrate that they are effectively maintaining process control, they may modify their sampling plans.

(iii) Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (d) of this section.

(d) Official swine slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under 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.

§ 310.25 [Amended]

■ 8. Amend § 310.25 as follows:

■ a. Remove paragraph (a)(2)(ii)(C);

■ b. Remove the undesignated sentence following paragraph (a)(2)(iii)(A);

■ c. Remove ''20,000 swine,'' in paragraph (a)(2)(v)(A);

■ d. In paragraph (a)(5):

■ i. Redesignate Table 1 as Table 1 to paragraph (a)(5); and

■ ii. In newly redesignated Table 1 to paragraph (a)(5), remove the entry for ''swine'';

■ e. In paragraph (b)(1):

■ i. Remove ''in Table 2'' and add ''in Table 1 to this paragraph'' in its place;

■ ii. Redesignate Table 2 as Table 1 to paragraph (b)(1); and

■ iii. In newly redesignated Table 1 to paragraph (b)(1), remove the entries for ''Hogs'' and ''fresh pork sausages'' and footnote (b).

■ 9. Add § 310.26 to read as follows:

§ 310.26 Establishment responsibilities under the new swine slaughter inspection system.

(a) *Facilities.* The establishment must comply with the facilities requirements in 9 CFR part 307. The establishment must provide a mirror at the carcass inspection station in accordance with 9 CFR 307.2(m)(6).

(b) *Carcass sorting and disposition.* The establishment must conduct carcass sorting activities and identify any condemnable conditions or defects before carcasses are presented to online inspectors. Establishment sorters must incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases as part of their sorting activities. The establishment must develop, implement, and maintain written procedures to ensure that market hog carcasses adulterated with septicemia, toxemia, pyemia, or cysticercosis are properly removed before the point of post-mortem inspection of carcasses. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOPs, or other prerequisite program. These procedures must cover the establishment sorting activities required under this section.

(c) *Line speed limits.* The line speed limits in § 310.1 do not apply to the establishment, provided it is able to maintain effective process control and prevent contamination of carcasses and parts by enteric pathogens and visible fecal material, ingesta, and milk. Establishments operating under the NSIS must reduce their line speed as directed by the Inspector-in-Charge (IIC). The IIC is authorized to direct an establishment 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 carcasses are presented to the online inspector, the health conditions of a particular herd, or factors that may indicate a loss of process control.

(d) *Records.* (1) The establishment must maintain records to document that

the products resulting from its slaughter operation meet the definition of Ready-to-cook pork product in § 301.2. These records are subject to review and evaluation by FSIS personnel.

(2) The establishment must maintain records to document the number of carcasses disposed of per day by establishment sorters before FSIS post-mortem inspection and the reasons that the carcasses were disposed of. These records are subject to review and evaluation by FSIS personnel.

■ 10. Add § 310.27 to read as follows:

§ 310.27 Attestation requirements.

Each establishment that participates in the NSIS must 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, injury and illness logs, as well as nurse or medical office logs, workers' compensation data, and any other injury or illness information available.

■ 11. Add § 310.28 to read as follows:

§ 310.28 Severability.

Should a court of competent jurisdiction hold any provision of § 310.27 to be invalid, such action will not affect any other provision of 9 CFR part 309 or this part.

Done in Washington, DC.

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019–20245 Filed 9–30–19; 8:45 am]

BILLING CODE 3410–DM–P