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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: Proposed Rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat inspection regulations to establish a 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 proposing several changes to the regulations that would affect all establishments that slaughter any swine, regardless of the inspection system under which they operate or the age, size, or class of swine. These proposed changes would allow all swine slaughter establishments to develop sampling plans that are more tailored to their specific operations, and thus be more effective in monitoring their specific process control. These

proposed changes also would ensure that before the start of slaughter operations, food-contact surfaces are sanitary and free of enteric pathogens.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: FSIS invites interested persons to submit comments on this rule. Comments may be submitted by one of the following methods:

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

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

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

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-0017. Comments received in response to this docket will be made available for public inspection and posted without change,

including any personal information, to
<http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

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

SUPPLEMENTARY INFORMATION:

Executive Summary

FSIS began experimenting with new approaches to slaughter inspection based on Hazard Analysis and Critical Control Point Systems (HACCP) principles shortly after publishing the Pathogen Reduction/HACCP rule in 1996. In 1997, the Agency developed the HACCP-Based Inspection Models Project (HIMP) study to determine whether applying new Government slaughter inspection procedures, along with new plant responsibilities, could promote innovation and provide at least the same food safety and consumer protection. FSIS initiated the HIMP 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 a new optional 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. The risk model employed to assess the potential impact of the NPIS modeled scenarios involving an increase in targeted inspection activities (specifically unscheduled offline inspection activities). The results of this model, constructed on the assumption that the number of offline procedures performed in poultry establishments under the NPIS would increase proportionally to the number observed in HIMP establishments, suggested that implementing the NPIS would likely result in public health benefits, in the form of fewer poultry-associated foodborne Salmonella illnesses per year. Consistent with the underlying assumptions of the model, it is reasonable to conclude that inspection systems in which Agency resources are used to continue core online inspection activities while enhancing the frequency and focus of unscheduled offline activities directly related to food safety, such as HIMP and the NPIS, would likely result in a lower prevalence of carcasses contaminated with Salmonella, which in turn would likely lead to fewer human illnesses.

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 plans, sanitation standard operating procedures (sanitation SOPs), or other prerequisite programs (hereafter referred to as 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.

FSIS is now proposing to amend the Federal meat inspection regulations to establish a new optional inspection system for market hog slaughter establishments, the New Swine Slaughter Inspection System (NSIS), informed by the Agency's experiences under HIMP. FSIS is proposing this new inspection system to facilitate pathogen reduction in pork products; improve compliance with the HMSA; improve the effectiveness of market hog slaughter inspection; make better use of the Agency's resources; and remove unnecessary regulatory obstacles to innovation by revoking maximum line speeds and allowing establishments flexibility to reconfigure evisceration lines. If

establishment personnel sorted and removed unfit animals before ante-mortem inspection and trimmed and identified defects on carcasses and parts before post-mortem inspection by FSIS inspectors, FSIS inspectors would be presented with healthier animals and carcasses that have fewer defects to inspect, which would allow inspectors to conduct a more efficient and effective inspection of each animal and each carcass. Such a system would allow FSIS inspectors to conduct a more efficient inspection. As a result, FSIS could assign fewer inspectors to online inspection, freeing up Agency resources to conduct more offline inspection activities that FSIS has determined are more effective in ensuring food safety, such as verifying compliance with sanitation, HACCP, and humane handling requirements.

Key elements of the proposed NSIS include: (1) requiring establishment personnel to sort and remove unfit animals before ante-mortem inspection by FSIS and to trim and identify defects on carcasses and parts before post-mortem inspection by FSIS; (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 immediately denature all major portions of the carcass on-site, and maintain records to document the total number of animals and carcasses sorted and removed per day; (3) requiring establishment personnel to immediately notify FSIS inspectors if

they suspect an animal or carcass with a reportable or foreign animal disease (e.g., African swine fever, classical swine fever, or Nipah virus encephalitis) while conducting sorting activities; (4) shifting Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which would allow for up to two offline verification inspectors per line per shift and would reduce the number of online inspectors to a maximum of three per line per shift; (5) requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the new proposed definition of Ready-to-cook (RTC) pork product, which would be defined as any slaughtered pork product 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 (6) 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 during the slaughter operation. FSIS projects that the new system is unlikely to result in a higher prevalence of Salmonella on market hog carcasses and may even result in a lower prevalence of Salmonella on market hog carcasses, which in turn may lead to fewer human illnesses. In addition, the new system should

improve animal welfare and compliance with the Humane Methods of Slaughter Act (HMSA) because more FSIS resources will be available to verify humane handling as an offline activity.

Under the proposed rule, market hog slaughter establishments that do not choose to operate under the NSIS may continue to operate under their existing inspection system (hereafter referred to as "traditional inspection"). As mentioned above, NSIS provides public health protection at least equivalent to traditional inspection. FSIS recognizes that some establishments may not be prepared to make the investment in facilities and labor needed to convert to NSIS. In addition, many small, very low volume establishments slaughter more than one type of livestock species and the facilities updates need to convert to the proposed NSIS may not accommodate the slaughter of livestock other than market hogs. Therefore, FSIS is proposing to give establishments the flexibility to operate under the system that is best suited to their operations.

FSIS is also proposing several changes that would affect all establishments that slaughter swine, regardless of the inspection system under which they operate. FSIS is proposing to require 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, 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.

FSIS is proposing to prescribe a minimum frequency with which establishments would be required to collect two samples, 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 small and very low volume establishments, a single post-chill sample. FSIS considers the microbial load of hog carcasses at pre-evisceration to be a valuable source of data about how well an establishment is taking into account the sanitary condition of live hogs coming to slaughter and the processing steps (i.e., washing, dehairing) they implement to reduce the external contamination of the carcass prior to evisceration. FSIS also considers the microbial characteristics of hog carcasses post-chill (after all processing steps have taken place) to be a valuable source of data about how well an establishment is minimizing contamination during chilling as well as the overall effectiveness of all process control interventions the establishment has chosen to apply throughout its production process. Because most establishments apply one or

more interventions between the pre-evisceration and post-chill sampling points to help control microbiological hazards, FSIS would expect that a reduction in microbiological contamination between these two sampling points to be an indication of the effectiveness of those controls.

Under the proposed rule, establishments, except for very small and very low volume establishments, would be required to collect pre-evisceration and post chill samples at a frequency of once per 1,000 carcasses. Very small and very low volume establishments would be required to collect at least one sample during each week of operation each year. If, after consecutively collecting 13 weekly samples, very small and very low volume establishments can demonstrate that they are effectively maintaining process control, they can modify their sampling plans to collect samples less frequently. FSIS is proposing to allow very small and very low volume establishments to collect and analyze samples for microbial organisms at the post-chill point in the process only because these establishments typically are less automated and run at slower line speeds than larger establishments. The lower level of automation and the slower line speeds require less complicated measures for maintaining and monitoring process control on an ongoing basis. These proposed frequencies reflect the frequencies prescribed under the existing regulations for generic Escherichia coli (E. coli)

testing. FSIS is proposing to remove the current requirement that swine establishments test carcasses for generic E. coli to monitor process control and to remove the codified Salmonella pathogen reduction performance standards for swine and replace them with the new testing requirements described above. The new testing requirements would allow establishments to develop sampling plans that are more tailored to the specific establishment, and thus more effective in monitoring their specific process control than the current generic E. coli criteria.

FSIS is proposing to allow establishments to substitute alternative sampling locations if they are able to demonstrate that the alternative sampling locations are able to provide a definite improvement in monitoring process control than at pre-evisceration and post-chill. FSIS interprets "definite improvement" to mean any improvement of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products. FSIS is also proposing to allow establishments to substitute alternative sampling frequencies if they are able to demonstrate that the alternative is an integral part of the establishments' verification procedures for their HACCP plans and are able to provide a definite improvement in monitoring process control than at the prescribed frequency. FSIS is

requesting comments on the proposed sampling requirements, particularly the incremental value (from both a process-improvement and public health standpoint) of pre-evisceration sampling over what is provided by post-chill sampling.

Finally, FSIS is proposing to require that all official swine slaughter establishments develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens. The pre-operational environment comprises food contact surfaces, reuse water, and equipment, including knives, in edible food production departments before slaughter operations begin. These procedures would need to include sampling and analysis of food-contact surfaces in the pre-operational environment for microbial organisms to ensure that the surfaces are sanitary and free of enteric pathogens. The sampling frequency would need to be adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment. Please see the draft compliance guide for additional information about implementation of this provision. FSIS is proposing this requirement as a direct result of a recent outbreak of foodborne illness associated with a hog slaughter establishment where food contact surfaces were found to be contaminated with the outbreak strain. FSIS is requesting comments on this proposed sampling requirement and the extent to

which interventions in the pre-operational environment are needed to ensure food safety.

In Table 1 below, FSIS presents the estimated costs and benefits of the proposed rule. Later portions of the regulatory impact analysis section contain explanation of the assumptions, alternative adoption scenarios, and a discussion of the uncertainty surrounding the net benefits associated with how much of the industry would choose to adopt NSIS.

Table 1: Net Costs and (Benefits) (M\$)

	Number of Establishments	One-Time	Recurring
Costs To Industry		\$3.88	\$22.65
Voluntary*	40**	\$0.84	\$22.17
Mandatory	612	\$3.03	\$0.48
Potential Health Benefits***			(\$9.33)
Industrial Efficiency			(\$47.33)
Impacts to Agency's Budget		\$2.80	(\$8.73)
Totals			
One-Time Cost		\$6.68	
Recurring Cost			(\$42.75)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			(\$31.77)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			(\$30.40)

* Further explanation and details on the NSIS adoption rate are provided in section G. Expected Cost of the Proposed Rule, Table 6: NSIS Adoption Rate and section J. Net Benefits, Table 28: 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. Expected Benefits Associated With Public Health, Table 20: Health Benefits from Averted Cases of *Salmonella*. The value of health benefits ranges from \$0.19 million to \$18.97 million, with a mean of \$9.33 million.

Statutory Authority

FSIS inspects and regulates the production of meat and meat food products prepared for distribution in commerce under the authority of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.). The FMIA provides that the Secretary shall cause to be made by inspectors an examination and inspection of all amenable species before they enter into any establishment in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce (21 U.S.C. 603(a)). All amenable species found to show symptoms of disease are to be set apart and slaughtered separately; the carcasses of such animals are to be subject to a careful inspection (21 U.S.C. 603(a)). The FMIA requires that the livestock be slaughtered and handled in connection with slaughter in a manner that is consistent with the HMSA (21 U.S.C. 603(b)). Under the HMSA, the handling of livestock in connection with slaughter must be carried out only by humane methods (7 U.S.C. 1902).

The FMIA also requires inspectors to conduct a post-mortem examination and inspection, and any necessary reinspection, of carcasses and parts of amenable species prepared for human food (21 U.S.C. 604). The FMIA requires that all carcasses and parts found to be adulterated be condemned (21 U.S.C. 604). Under the FMIA, a meat or meat food product is adulterated, among other circumstances, if it bears or contains any poisonous or

deleterious substance that may render it injurious to health; it is unhealthful, unwholesome, or otherwise unfit for human consumption; it was prepared, packaged, or held under insanitary conditions whereby it may have been rendered injurious to health; or if damage or inferiority has been concealed in any manner (21 U.S.C. 601(m)(1), (3), (4), and (8)). Finally, 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. FSIS regulations and inspection programs are designed to verify that livestock are handled and slaughtered humanely, and that meat and meat food products are unadulterated, wholesome, and properly marked, labeled, and packaged.

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I. Background

A. Traditional Market Hog Slaughter Inspection under Existing Regulations

1. Description of the Inspection System under Existing Regulations

Under the existing regulations for traditional inspection, FSIS ante-mortem inspectors examine all market hogs for visible signs of condemnable diseases or conditions while they are at rest and in motion (see 9 CFR part 309). FSIS ante-mortem inspectors direct establishment personnel to set apart animals showing signs of condemnable diseases or conditions into separate "U.S. Suspect" pens for further examination by the FSIS Public Health Veterinarian (PHV). The FSIS PHV determines whether the animals shall be identified as "U.S. Condemned" and disposed of in accordance with 9 CFR 309.13 (9 CFR 309.2).

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 (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>). 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 are subject to additional FSIS inspection. FSIS requires these establishments to document their segregation procedures in their HACCP plans or prerequisite programs. FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion. 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" pens, and directs establishment employees to move animals to "U.S. Suspect" pens for final disposition. FSIS inspectors observe establishment employees performing segregation procedures at least once per month. 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.

Therefore, under the voluntary segregation procedures, FSIS inspectors are able to conduct a more efficient and effective ante-mortem inspection to determine whether each animal is fit for slaughter.

During post-mortem inspection at all market hog slaughter establishments, FSIS online inspectors inspect the head, viscera, and carcass of each animal for localized defects and direct establishment employees to remove the defects through trimming (9 CFR 310.1(b)(3)). FSIS online inspectors perform manual incisions, palpations, and other organoleptic inspections (i.e., using sight, smell, and touch) to detect signs of disease or contamination. In large establishments, up to seven online inspectors are assigned per line per shift to cover inspection stations for the head, viscera, and carcass at fixed points along the slaughter and evisceration line. In small or very small establishments, one inspector may perform all of the post-mortem inspection procedures on each animal. FSIS online inspectors identify and retain carcasses and parts with visible animal diseases and conditions. The FSIS PHV thoroughly examines retained carcasses and parts to determine whether they should be condemned; establishment personnel then dispose of condemned

carcasses under FSIS supervision in accordance with 9 CFR part 314.

Under the existing regulations for 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. These sorting functions are conducted by establishment personnel under HIMP. Rather, the existing regulations for traditional inspection require establishments to assign competent assistants to take such actions as directed by FSIS online inspectors after the inspectors have conducted the initial sorting activities (see 9 CFR 307.2(g)). Therefore, under the existing regulations for traditional inspection, establishments rely on FSIS online inspectors to effectively control and direct their processing. Moreover, because FSIS online inspectors are responsible for identifying unacceptable carcasses and parts, it takes online inspectors more time to conduct a carcass-by-carcass inspection than would be necessary if establishments sorted carcasses and parts, trimmed dressing defects and contamination that do not impact the FSIS inspectors' ability to assess the fitness of the

carcass or part, and identified pathology defects, before the carcasses and parts were inspected.

More FSIS resources also could be devoted to offline inspection activities if initial sorting and tagging functions were performed by establishment personnel. Under the existing regulations, only FSIS inspectors may direct the application and removal of "U.S. Condemned" tags from animals and carcasses condemned by FSIS inspectors on ante-mortem and post-mortem inspection (9 CFR 309.13 and 310.5). The tag must remain on the carcass until it goes into the tank, or the carcass is otherwise disposed of in accordance with 9 CFR part 314. Establishments are required to denature condemned carcasses and parts if they do not have tanking facilities and the carcasses and parts are to be rendered or otherwise disposed of off-site (see 9 CFR 314.3). FSIS inspectors enter the number on each "U.S. Condemned" tag into the Public Health Information System (PHIS). Under the existing regulations, most "U.S. Condemned" tags are applied during ante-mortem inspection to animals that arrive dead. Because FSIS inspectors are responsible for removing all of the "U.S. Condemned" tags and documenting each "U.S. Condemned" tag number into PHIS, it takes inspectors more time to complete ante-mortem and post-mortem inspections than it would if establishments sorted and removed these animals before FSIS inspection and maintained records that could be verified by

FSIS, as appropriate, and reported their daily totals to FSIS inspectors.

In addition to the post-mortem inspection activities conducted by online inspectors, offline inspectors conduct additional food safety related activities such as verifying that establishments' processing meets their HACCP critical limits and verifying whether sanitation SOPs are effective.

2. Need for Modernization

Modernization of market hog slaughter inspection is necessary because traditional inspection was developed before FSIS issued its HACCP regulations, and before the Agency began targeting its resources to address public health risks associated with foodborne pathogens. Traditional inspection obscures the proper roles of industry and inspection personnel by assigning to FSIS inspectors responsibility for sorting acceptable animals from unacceptable animals, finding carcass defects, identifying production control problems for the establishment, and verifying corrective actions in addition to determining whether the carcasses meet regulatory requirements. Additionally, traditional inspection requires FSIS to allocate significant inspection personnel resources towards online inspection activities in large and high volume market hog establishments to detect quality defects and conditions that present minimal food safety risks, thus limiting the resources

available for offline inspection activities such as verifying the effectiveness of HACCP plans and sanitation SOPs. FSIS has concluded, based on the Agency's analysis of the market hog HIMP pilot (discussed in more detail below), conducting more offline activities will be more effective in ensuring food safety and humane handling verification tasks.

Traditional inspection requires inspectors to conduct time-intensive ante-mortem and post-mortem sorting activities. This necessitates FSIS to allocate significant personnel resources to conduct activities that are more appropriately the responsibility of the establishment. As a result, traditional inspection limits line speeds, even if establishments can demonstrate that they are able to produce safe, unadulterated, wholesome products at more efficient rates. It also limits large and high volume market hog slaughter establishments' incentive to improve their processing methods and to develop more efficient slaughter and dressing technologies.

For example, under traditional inspection, the maximum line speed authorized for slaughter lines with one or two inspectors is partially based upon the distance walked (in feet) by the inspector between work stations to conduct the sorting activities mentioned above (see 9 CFR 310.1(b)(3)). For slaughter lines with three or more inspectors, line speeds may also depend on whether FSIS online inspectors observe the back

of the carcasses by looking in a mirror or whether they must turn the carcass to observe the back of the carcass (see 9 CFR 310.1(b)(3)). The maximum line speed under the existing regulations for market hogs is 1,106 head per hour (hph) with seven online inspectors. Establishments determine their line speeds based on their equipment, size and condition of the animals, and their ability to maintain process control when operating at a given line speed.

Additionally, traditional inspection restricts establishments' ability to reconfigure and consolidate lines if they determine that they need more space to conduct other activities in their facilities. For example, establishments slaughtering 1,025 market hogs per hour must configure their evisceration lines to accommodate three online head inspectors, three online viscera inspectors, and one online carcass inspector. The regulations require that establishments provide an inspection station consisting of five feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, eight feet for each viscera inspector on the inspector's side of the table (9 CFR 307.2 (m)(1)). As a result, the current regulations for traditional inspection prevent large and high volume market hog slaughter establishments from consolidating inspection stations or otherwise reconfiguring their evisceration lines in order to make room for more

innovative, automated equipment such as head dropping equipment, bung equipment (which separates digestive and urinary organs from pelvic attachments), eviscerating equipment, and back saws. Traditional inspection is generally sufficient for low volume establishments and for establishments that slaughter classes of swine other than market hogs because these establishments typically are less automated and run at slower line speeds than larger establishments.

Additionally, traditional inspection was developed when visually detectable animal diseases such as pneumonias, erysipelas, hog cholera, cystercercosis, parasites, and arthritis were more prevalent and considered to be more of a concern than they are today. The line speed limits prescribed under traditional inspection reflect the Agency's previous focus on the detection of visible defects and animal diseases and do not give establishments the flexibility to address these conditions before presenting the carcasses and parts to FSIS inspectors.

Traditional inspection focuses substantial FSIS resources on detecting visible trim and dressing defects that are not directly related to food safety, particularly in light of what is now known about the role microbial contamination plays in causing foodborne human illness. The traditional inspection model needs to be updated in light of the significant advances

that have been made in the control or eradication of many animal diseases that were more prevalent and were considered to present a greater concern when the existing inspection systems were designed, particularly in generally healthy classes of animals such as market hogs.

Moreover, the analysis in FSIS's "Assessment of the Potential Change in Human Health Risk Associated with Modernizing Inspection of Market Hog Slaughter Establishments" (hereafter referred to as the market hog risk assessment) conducted by FSIS suggests a statistically significant correlation between increased scheduled and unscheduled offline inspection procedures and a reduction in the prevalence of Salmonella in market hog establishments. Projecting out illness reductions based on reduction in Salmonella prevalence in 35 plants results in wide uncertainty, but the model confidently estimates that the level of protection from Salmonella illnesses would be at least as good as the current system. Based on these results, the redeployment of Agency resources dedicated to online inspection under the traditional inspection system to unscheduled offline activities, such as increased HACCP and sanitation SOP verification, has the potential to contribute to improved food safety resulting from a lower prevalence of carcasses contaminated with Salmonella, which may in turn lead to fewer human illnesses. While prevalence of Salmonella

measured in FSIS's market hog baseline study is low, Salmonella is a pathogen of public health concern for pork products, and the data available are adequate to estimate the potential changes in prevalence with changes in FSIS's swine inspection system.

B. Regulations for Microbiological Testing Under Traditional Inspection

1. Generic E. Coli Criteria for Measuring Process Control

The existing regulations require that official swine slaughter establishments conduct regular testing for generic E. coli at the end of the chilling process or after the final wash as a means to verify process control (9 CFR 310.25 (a)(1)). These regulations prescribe requirements for collecting the samples, obtaining analytical results, and maintaining records of such results (9 CFR 310.25(a)(2), (3), and (4)). They also include criteria for evaluating an establishment's generic E. coli testing results (9 CFR 310.25(a)(5)). The regulations provide that generic E. coli testing results that do not meet the criteria described in the regulations indicate that the establishment may not be maintaining process controls sufficient to prevent fecal contamination (9 CFR 310.25(a)(6)). If an establishment is not meeting the E. coli test results criteria, the regulations state that FSIS will take further action as

appropriate to ensure that all applicable provisions of the law are being met (9 CFR 310.25(a)(6)).

In 2014, FSIS rescinded the regulations that required that poultry establishments test carcasses for generic E. coli to monitor for process control (79 FR 49565, August 21, 2014). The final regulations replaced the generic E. coli regulations with new testing requirements that allow establishments to develop sampling plans that are more tailored to the specific establishment, and thus are more effective in monitoring their specific process control than the former generic E. coli criteria. The Agency concluded that the use of generic E. coli as an indicator for process control may not be as useful in certain poultry slaughter operations as originally thought. Therefore, FSIS made the change to allow poultry establishments to use other more relevant indicators of process control.

The Agency is aware that most swine slaughter establishments currently conduct additional sampling for microorganisms other than generic E. coli (e.g., Salmonella spp. and aerobic plate count bacteria (APC)) because they have found these organisms to be more relevant indicators of their process control. Therefore, FSIS is proposing to remove the generic E. coli sampling requirements for swine slaughter establishments to give establishments more flexibility in monitoring their process control and to make the Federal meat inspection regulations more

consistent with the Federal poultry products inspection regulations. FSIS is proposing that all swine slaughter establishments collect and analyze carcass samples for microbiological analysis at the pre-evisceration and post-chill points in the process. The discussion of the proposed testing requirements is set out later in this document.

2. Salmonella Pathogen Reduction/HACCP Performance Standards

In addition to generic E. coli criteria, the existing regulations contain Salmonella pathogen reduction performance standards for market hogs (9 CFR 310.25(b)). The codified performance standards are based on the prevalence of Salmonella found by two nationwide microbiological baseline surveys conducted from April 1995 to March 1996 and from June 1997 to May 1998. The regulations provide for FSIS to collect and analyze unannounced Salmonella samples sets in swine slaughter establishments to detect whether these establishments are meeting the pathogen reduction performance standards (9 CFR 310.25(b)(2)). The performance standards set a maximum number of Salmonella-positive samples allowable per sample set and are defined on a product class basis so that an establishment operating at the baseline level would have an 80 percent chance of meeting the standard. Establishments are required to take corrective actions when FSIS determines that they are not

meeting the performance standards (9 CFR 310.25(b)(3)(i) and (ii)).

Under the regulations, an establishment's failure to take the corrective actions necessary to comply with the Salmonella performance standards, or an establishment's failure to meet the standards on the third consecutive series of FSIS-conducted tests for that product, constitutes a failure to maintain sanitary conditions and to maintain an adequate HACCP plan (9 CFR 310.25(b)(3)(iii)). The regulations provide that such failure will cause FSIS to suspend inspection services (9 CFR 310.25(b)(3)(iii)). However, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in Supreme Beef Processors, Inc. v. USDA. In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the Salmonella performance standards. Since that time, FSIS has used Salmonella failures as a basis to conduct an in-depth evaluation of the establishment's HACCP systems, including its HACCP plan and sanitation SOPs.

From August 2010 to August 2011, FSIS conducted a third market hog baseline survey to estimate the national prevalence of Salmonella in market hogs (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-](http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES)

[2011.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES)). The third market hog baseline survey included 253 establishments that produce approximately 99.9 percent of market hogs slaughtered in the United States. For the third baseline survey, FSIS collected samples in 152 random establishments from market hog carcasses at two points in the slaughter process: pre-evisceration and post-chill. The Salmonella percent positive rate at pre-evisceration was 69.64 percent, but at post-chill it was reduced to 2.70 percent. The third baseline survey's percent positive rate at post-chill was significantly lower than the rates found in the two earlier surveys mentioned above, which reported Salmonella percent positive rates of 8.7 percent and 6.9 percent, respectively. Based on the data from the third baseline survey, FSIS estimated prevalence of Salmonella in market hogs was 1.66 percent with a 95 percent confidence interval between 0.82 percent and 2.51 percent. Because the estimated prevalence of Salmonella was low, and FSIS did not find enough pathogen positives to justify the resources needed (e.g., time and supplies) to conduct carcass swabbing, the Agency determined that this type of sampling was not an effective use of resources for verifying process control. As a result, FSIS did not develop new Salmonella performance

standards for market hogs. Rather, in September 2011, FSIS discontinued its Salmonella verification sampling program for market hogs to make better use of its resources.

Therefore, FSIS is proposing to eliminate the pathogen performance standards for market hogs in 9 CFR 310.25(b) because verifying the codified standards was not a good use of Agency resources and the standards have not been used since 2011. Instead, FSIS has decided to focus on its resources on sampling raw pork parts for pathogens of public health concern, as well as for indicator organisms.

FSIS is currently addressing Salmonella through the Salmonella Initiative Program (SIP) described below. In addition, FSIS has published a compliance guideline to help official establishments control and reduce the spread of Salmonella in hog slaughter facilities (79 FR 633, January 6, 2014). The guidance is available on the FSIS Web page at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. The guidance provides information on best practices that may be applied at a hog slaughter facility to prevent, eliminate, or reduce levels of Salmonella on hogs at all stages of slaughter and dressing. Importantly, FSIS has identified microbial performance measures, as guidance, at the pre-evisceration and post chill points.

Moreover, FSIS is currently conducting exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms (80 FR 12618). A summary of the Phase I positive sampling results collected from May 2015 to November 2015 are as follows: 16.7 percent Salmonella, 1 percent Campylobacter, 4.5 percent Methicillin-Resistant Staphylococcus aureus (MRSA), 1 percent Toxoplasma gondii, 1.5 percent Yersinia enterocolitica, 0 percent E. coli O157:H7, and 5 percent non-O157 shiga toxin-producing E. coli (non-O157 STEC). FSIS has posted more detailed sampling results on its Web site at <https://www.fsis.usda.gov/wps/wcm/connect/68f5f6f2-9863-41a5-a5c4-25cc6470c09f/Sampling-Project-Results-Data.pdf?MOD=AJPERES>. The Agency may develop pathogen reduction performance standards for pork parts at a later date. In 2019, the Agency will use this data to determine whether standards or additional policies (e.g., training, guidance to industry, or instructions to field personnel) are needed to address *Salmonella* in pork products.

C. Waivers of Regulatory Requirements

1. Waivers to Test New Technology

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

may only grant waivers from the provisions in the regulations that are not in conflict with the purposes or provisions of the FMIA or PPIA (9 CFR 303.1(h) and 381.3(b)).

FSIS decides whether to grant requests for waivers based on proposals and documentation submitted by establishments to demonstrate that the use of a new technology is scientifically sound; that it will facilitate definite improvements; and that issuing the waiver will not conflict with the provisions of the FMIA or PPIA.¹ If FSIS determines that the information submitted by an establishment supports the requested waiver, the Agency will waive the appropriate provisions in the regulation for a limited period of time to allow the establishment to conduct an in-plant trial. The purpose of the in-plant trial is to gather data on the effects of the use of the new technology. FSIS reviews the data that is developed in the trial to determine whether they establish that the purpose of the waiver is being met.

2. Salmonella Initiative Program Waivers

Under SIP, the Agency grants meat and poultry slaughter establishments waivers of regulatory requirements on condition that they will conduct regular microbial testing and share the

¹ For Agency New Technology waiver procedures, see <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/New-Technologies>.

resulting data with FSIS. The Agency described preliminary details of SIP in a January 28, 2008, Federal Register notice (73 FR 4767-4774) and announced its final terms and conditions in the July 13, 2011, Federal Register notice (76 FR 41186). SIP benefits public health in that it encourages slaughter establishments to conduct testing for microbial pathogens, which is a key feature of effective process control, and to respond to testing results by taking steps when necessary to regain process control. In addition, SIP enables FSIS to use establishment data to inform Agency policy aimed at enhancing public health protection.

SIP establishments test for Salmonella, Campylobacter (if applicable), and generic E. coli or other indicator organisms and share all sample results with FSIS. Establishments that had been operating under regulatory waivers before FSIS implemented the SIP were required to participate in SIP or forfeit their waivers. The list of establishments participating in SIP is available on FSIS's Web site at https://www.fsis.usda.gov/wps/wcm/connect/188bf583-45c9-4837-9205-37e0eb1ba243/Waiver_Table.pdf?MOD=AJPERES. To date the regulations waived for swine slaughter establishments under SIP include: 9 CFR 310.1(b)(3) - line speed; 9 CFR 310.25(a) - generic

E. coli testing²; 9 CFR 310.25(b) - Salmonella performance standards; 9 CFR 310.18(a) - contamination of organs; 9 CFR 310.11 - cleaning and hair removal; and 9 CFR 310.14 - handling of bruised parts. All swine slaughter establishments operating under SIP waivers will continue to operate under waivers and will continue to conduct testing under SIP if their waivers are not addressed in the final rule resulting from this proposal. If their waivers are addressed in the final rule resulting from this proposal, their waivers will end.

II. Consideration of Need for a New Swine Slaughter Inspection System

A. Early Development of the Inspection Models Program

In 1996, FSIS published its Pathogen Reduction/HACCP (PR/HACCP) final rule as the first step of a comprehensive initiative to target the Agency's resources to address the public health risks associated with foodborne pathogens, which cannot be detected by organoleptic inspection (61 FR 38868, July 25, 1996). Under FSIS's PR/HACCP regulations, establishments are required to develop and implement a system of preventive controls to ensure that their products are safe. This approach gives establishments more flexibility to determine how they can

² Some establishments continue to sample for generic e. coli to monitor their process control. The SIP waivers allow these establishments to use alternative sampling locations and frequencies.

best meet the Agency's regulatory requirements. FSIS verifies the adequacy and effectiveness of establishments' HACCP systems.

In 1997, in order to improve food safety and the effectiveness of inspection systems, reduce the risk of foodborne illness in the United States, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources, FSIS announced, in a Federal Register notice, that the Agency would be developing a new HIMP study (62 FR 31553, June 10, 1997). During the HIMP study, FSIS would design and test various new inspection models in a series of trials in volunteer meat and poultry slaughter establishments.

Under the initial HIMP inspection models approach, establishment personnel were responsible for sorting and removing animals unfit for slaughter and identifying and removing abnormal carcasses and parts, and FSIS inspection personnel performed inspection activities that focused on the areas of greatest risk in the hog slaughter inspection system in each establishment.

In 1998, the American Federation of Government Employees, several FSIS inspectors, and a public interest organization filed suit to enjoin FSIS from implementing the HIMP model. The plaintiffs alleged that HIMP violated the requirement in the FMIA that government inspectors conduct a post-mortem inspection of each carcass. Specifically, the FMIA provides that the

Secretary shall cause to be made by inspectors a post-mortem inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment (21 U.S.C. 604). The district court upheld HIMP, finding that the word "inspection", as used in the statute, does not necessarily mandate a direct, physical examination of each carcass by an FSIS inspector, and that the model program was a rational policy judgment within the discretion afforded to the Secretary.

The plaintiffs appealed, and the Court of Appeals for the District of Columbia Circuit reversed the district court's decision. The Court of Appeals found that the FMIA requires Federal inspectors - rather than plant employees - to make the decision whether each carcass is adulterated within the meaning of the statute (AFGE v. Glickman, 215 F.3d 7, 11 (D.C. Circ. 2000)). The case was remanded to the district court for further proceedings.

In response to the Court of Appeals' opinion, FSIS modified HIMP to position up to three³ online inspectors at fixed locations along the slaughter lines: in the area where the carcass and head were separated; where the carcass and viscera

³ FSIS is able to assign fewer than three online inspectors if the physical configuration of the slaughter line allows one inspector to inspect both the head and viscera or the viscera and carcass. For example, in one establishment, the chain that carries the carcass is adjacent to the viscera pans, which enables one inspector to examine both the carcass and viscera.

were separated; and at the pre-wash carcass verification location. These inspectors were responsible for examining the head, viscera, and carcass of each hog. The modified models project also included FSIS offline inspectors who were responsible for conducting HACCP and sanitation system verification activities and for closely examining a sample of carcasses for food safety defects to ensure that the establishment's process was under control and that adulterated carcasses and parts were not getting past the establishment sorters. On remand, the district court found that HIMP, as modified, complied with both the applicable statutory provisions and the opinion issued by the Court of Appeals.

The plaintiffs again appealed to the Court of Appeals for the DC Circuit. The plaintiffs argued that the modified inspection procedures were not in compliance with the Court of Appeals' prior opinion because FSIS had delegated some inspection duties to plant employees who were responsible for sorting defective carcasses and making preliminary decisions regarding adulteration. The Court of Appeals rejected this argument, finding that the FMIA does not prohibit plant employees from paring down the overall number of carcasses by sorting and removing carcasses before they reach the Federal inspector (AFGE v. Veneman, 284 F.3d 125, 131 (D.C. Cir. 2002)). The Court held that the modified inspection model program

satisfied the FMIA because it required Federal inspectors to personally examine all hog carcasses, heads, and viscera, as required by 21 U.S.C. 604.

The plaintiffs also argued that the line speeds allowed in the HIMP plants were too fast to allow Federal inspectors to make a critical appraisal of each carcass. The Court found that FSIS's decision to allow higher line speeds was reasonable in light of the fact that establishment employees are required to sort carcasses and parts and identify defects prior to Federal inspection, resulting in fewer adulterated carcasses and parts being presented for Federal inspection. The Court also noted that although the FMIA delineates what must be inspected and by whom, it does not define exactly what constitutes an inspection. The court concluded that HIMP, as modified, reflected a reasonable design of an inspection system by the agency charged with responsibility for administering the FMIA and that it would rely on the Agency's experience and informed judgment in evaluating the validity of the system under the law. Under these circumstances, the Court of Appeals upheld HIMP, as modified.

B. Existing HACCP-Based Inspection Models Program

The revised HIMP study was initiated in five market hog slaughter establishments on a waiver basis.

Similar to the voluntary segregation procedures described above in establishments that slaughter only market hogs under

traditional inspection, establishment personnel sort animals before they are presented to FSIS ante-mortem inspectors under HIMP. Establishment personnel sort animals that appear to be healthy into "Normal" pens and animals that appear to have condemnable diseases or conditions into "Subject" pens. Establishment personnel remove and dispose of dead and moribund animals and animals suspected of having central nervous system disorders (CNS) or pyrexia. Under HIMP, FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion. 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. FSIS PHVs examine all animals in the establishment's "Subject" pens, and direct establishment employees to move animals to "U.S. Suspect" pens for final disposition by the FSIS PHV. The FSIS PHV determines if any animals must be identified as "U.S. Condemned" and disposed of in accordance with 9 CFR 309.13 (9 CFR 309.2). While establishment personnel sort and remove animals unfit for slaughter, only FSIS inspectors have the authority to condemn an animal. FSIS inspectors observe establishment employees performing sorting procedures at least twice per shift under HIMP compared to at least once per month under the voluntary

segregation procedures permitted under traditional inspection of market hogs.

Under HIMP, post-mortem inspection is conducted by up to three online inspectors who visually inspect the head, viscera, and carcass of each hog at fixed locations on the evisceration line. Before FSIS online inspection, establishment personnel sort carcasses and parts and trim dressing defects and contamination (e.g., hair, bruises, feces, ingesta, and milk). Establishment employees also mark with ink localized pathology defects intended for removal under FSIS supervision (e.g. localized nephritis and localized arthritis) and carcasses and parts intended for disposal under FSIS supervision (e.g., carcasses and parts with malignant lymphoma). Online inspection is conducted much more efficiently and effectively under HIMP than under traditional inspection because establishment personnel have already sorted carcasses and parts, trimmed dressing defects and contamination, and identified pathology defects on the carcasses, thereby correcting most removable defects, before the FSIS online inspectors perform their carcass-by-carcass inspection.

Under HIMP, offline inspection consists of system verification activities through which FSIS continuously monitors and evaluates establishment process control. FSIS conducts more offline, food safety related verification inspection activities

under HIMP than under traditional inspection. Some examples of food safety related verification inspection activities include: HACCP, sanitation SOP, and other prerequisite program verification procedures, including 24 carcass verification checks per shift specifically for generalized diseases and conditions and for contamination (compared to 11 carcass verification checks per shift under traditional inspection). FSIS also conducts more offline humane handling verification tasks under HIMP than under traditional inspection.

FSIS has concluded that the HIMP model has a number of benefits, such as focusing FSIS inspection personnel on the areas of greatest risk in the hog slaughter system and providing an incentive to establishments to improve and innovate, while ensuring effective online inspection.

C. U.S. General Accountability Office (GAO) and the USDA's Office of the Inspector General (OIG) Reports on HIMP

In 2013, the U.S. General Accountability Office (GAO) and the USDA's Office of the Inspector General (OIG) evaluated FSIS's HIMP pilot study and issued findings and recommendations.^{4,5} GAO identified strengths in the pilot study,

⁴ 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>.

⁵ 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>

including that of giving plants responsibility and flexibility for ensuring food safety and quality and allowing FSIS inspectors to focus more on food safety activities. However, GAO also identified what it believed to be data gaps in the HIMP pilot study. GAO recommended that FSIS collect and analyze information to determine if the HIMP pilot study is meeting its purpose, and FSIS agreed with the recommendation.

The OIG report also included recommendations related to HIMP procedures. According to the OIG, FSIS did not adequately oversee the HIMP program because the Agency did not evaluate whether the program resulted in a measurable improvement of the inspection process; allowed one HIMP plant to forgo the standard FSIS policy to manually inspect viscera; and did not have formal agreements with the HIMP plants. In response to OIG, FSIS agreed to complete an evaluation of HIMP market hog establishments.

D. Analysis of HIMP

1. FSIS Evaluation of HIMP

In 2014, in response to the GAO and OIG reports, FSIS conducted a comprehensive analysis of data collected from the operation of HIMP in market hog establishments and prepared a written report (the "Hog HIMP Report") that presents a thorough evaluation of the models tested. Based on this evaluation, FSIS concluded that market hog slaughter establishments participating in HIMP were performing as well as comparable large non-HIMP

market hog establishments and meeting FSIS requirements for operating under waivers through the HIMP project.

A summary of the Hog HIMP Report is provided below. The full Hog HIMP Report is available on the FSIS Web site at: <http://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AJPERES>.

Before implementation of the HIMP project, an 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 program. These data reflect the performance of the establishments under traditional inspection and provided the basis to establish HIMP performance standards for food safety defects and non-food safety "Other Consumer Protection" (OCP) defects.

FSIS established three categories of food safety related performance standards under HIMP for these conditions: "FS-1" addresses infectious conditions (e.g., septicemia, toxemia, pyemia, and cysticercosis); "FS-2" addresses contamination from fecal material, ingesta, and milk; and "FS-3" addresses certain conditions identified at ante-mortem (e.g. moribund, pyretic, and neurologic conditions). FSIS has a zero tolerance policy for food safety conditions identified as FS-1, FS-2, and FS-3 to protect consumers from conditions that may be harmful.

Therefore, the HIMP performance standard for food safety defects was set at zero.

FSIS established the performance standard for non-food safety OCP defects based on the performance level of the establishment representing the 75th percentile for each category of OCP defects (i.e., slightly below the fourth of the five baseline results for each category). FSIS established three categories of OCP performance standards for various types of trim and dressing defects that primarily affect the quality of products: "OCP-1" addresses carcass pathology defects (e.g., arthritis, emaciation, and erysipelas) and was set at 4.1 percent of carcasses, "OCP-2" addresses visceral pathology defects (e.g., cystic kidneys, enteritis, and nephritis) and was set at 7.2 percent of carcasses, and "OCP-3" addresses miscellaneous defects such as bile, bruises, and skin lesions and was set at 20.5 percent of carcasses. The HIMP performance standards were finalized in November 2000 (see 65 FR 65828, November 2, 2000). To participate in the program, establishments operating under HIMP are required to maintain process control plans to meet the performance standards for food safety and non-food safety OCP defects. The HIMP performance standards are a measure for comparing the performance of establishments operating under the HIMP inspection system with performance when

operating under the current non-HIMP, traditional inspection system.

a. Overview of the HIMP Report

The Hog HIMP Report describes FSIS's microbiological and inspection findings in the five market hog slaughter establishments participating in HIMP and compares them with 21 non-HIMP establishments of comparable production volume, line speed, and days of operation. The evaluation is based on establishment performance results for calendar years CY2006 through CY2010, and CY2012 through CY2013. Establishment performance results from CY2006 to CY2010 are based on data from the previously used Performance Based Inspection System (PBIS) database and results from CY2012 to CY2013 are based on data from the new Public Health Information System (PHIS) database. FSIS began transitioning establishments from PBIS to the PHIS in April 2011. The period April 2011 to December 2011 was a transitional period during which the inspection results for some establishments were recorded under PBIS, while others were recorded under PHIS. The data under the two systems are not completely compatible because inspection task codes and noncompliance records (NRs) were recorded differently in PHIS than in PBIS. For this reason, the transitional period CY2011 is not included in the Hog HIMP Report, and the analysis of CY2006

through CY2010 data is separate from the CY2012 through CY2013 data.

Across HIMP and non-HIMP establishments, analyses compared the number of offline inspection procedures, the rates of health-related regulatory non-compliances, Salmonella positive rates, and violative chemical residue rates. FSIS evaluated offline inspection procedures to determine whether comparable levels of inspection are being performed in HIMP establishments compared to non-HIMP establishments. The Hog HIMP Report found that establishments participating in HIMP performed as well as comparable large non-HIMP establishments and met the Agency's requirements for participating in the HIMP project.

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

The Hog HIMP Report found that the rate of ante- and post-mortem sorting by HIMP establishment personnel was comparable to the rate of ante- and post-mortem condemnation by FSIS inspectors at non-HIMP market hog establishments (3.0 per 1,000 hogs compared to 2.7 per 1,000 hogs, respectively). The Hog HIMP Report also found that FSIS inspectors in HIMP establishments performed more offline inspection activities than in non-HIMP establishments to verify that the establishments are executing

their HIMP slaughter process control plans. In CY2010, FSIS inspectors performed an average of 2,061 offline verification inspections per HIMP market hog establishment compared to an average of 1,482 offline verification inspection procedures per non-HIMP establishment. Accordingly, FSIS inspectors performed 1.4 times more offline verification inspection procedures in HIMP market hog establishments than in non-HIMP market hog establishments. In CY2013, FSIS inspectors performed an average of 19,180 Public Health Regulation (PHR)⁶ verification tasks per HIMP market hog establishment compared to an average of 14,099 PHR verification tasks per non-HIMP establishment. Thus, FSIS inspectors performed 1.4 times more of the offline inspection verifications of mandatory regulations in HIMP market hog establishments than in non-HIMP market hog establishments. The HIMP Report concluded that this increased level of offline inspection activities provides increased assurance that HIMP establishments are maintaining OCP and food safety defects at levels that are to or less than the levels in non-HIMP establishments.

⁶ PHRs consists of regulations and specific provisions of regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. The inclusion of provisions of regulations in the PHR list allows FSIS to focus on specific health related provisions of regulations that may be most informative for prioritizing Food Safety Assessments (FSAs). FSAs are in-depth evaluations of an establishment's food safety system. FSAs can be routine or for cause.

c. Verification of the Establishment Executing its HACCP System under 9 CFR Parts 416 and 417

The sanitation SOP regulations in 9 CFR 416 and the HACCP regulations in 9 CFR 417 are among the regulations most strongly related to public health. The Hog HIMP Report found that in CY2010, FSIS inspectors performed 1.5 times more offline sanitation SOP and HACCP inspection verifications of public health-related regulations in HIMP than non-HIMP market hog comparison establishments. In CY2012 and CY2013, FSIS inspectors performed 1.1 times more offline sanitation SOP and HACCP inspection verifications of public health-related regulations in HIMP than non-HIMP market hog comparison establishments.

The regression analysis of historical data that was included in FSIS's "Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection," which was used to inform the final rule "Modernization of Poultry Slaughter Inspection" (79 FR 49565), showed a statistically significant correlation between unscheduled offline inspection procedures and reduction in the prevalence of Salmonella and Campylobacter positive samples. Based on these modeling results, FSIS thought it was reasonable to conclude that the redeployment of Agency resources to unscheduled offline activities was likely to contribute to improved food safety resulting from a lower prevalence of carcasses contaminated with Salmonella and Campylobacter, which

in turn could lead to fewer human illnesses. Depending on how reallocation of inspection activities was implemented, it was likely that changes in off-line inspection could have resulted in a decrease in the numbers of positive microbial samples in FSIS-regulated young chicken and young turkey establishments. Specifically, the scenario that only increased unscheduled inspection procedures performed much better than the scenario that did not target specific types of procedures, and the results suggest a reasonable degree of confidence that the discriminate scenario would do no harm. That poultry slaughter risk assessment is available on FSIS's Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/haccp-based-inspection-models-project/himp-study-plans-resources/poultry-slaughter-inspection>. The risk model and model results are also posted on-line as a technical support document for the risk assessment on the FSIS Web site. The market hog risk assessment uses a similar approach and model as the poultry slaughter risk assessment and estimates the reduction in illnesses likely to result from the reallocation of inspectors contemplated by this proposed rule. The market hog risk assessment is discussed in more detail below.

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

To assess the microbiological outcomes of HIMP establishments' process control plans, the Hog HIMP Report analyzed data from FSIS's Salmonella verification program. For the years CY2006 - CY2009, the differences in Salmonella positive rates between HIMP market hog establishments and non-HIMP comparison establishments were not statistically significant for any of the years. The Hog HIMP Report also analyzed data from FSIS's Salmonella baseline study on market hog slaughter establishments, conducted from August 2010 to August 2011. The Salmonella positive rates in HIMP market hog establishments were not statistically significantly different from those in the subset of 21 non-HIMP comparison establishments. This is probably the result of the small sample size relative to the low Salmonella positive rate. However, in the August 2010 to August 2011 baseline study the Salmonella positive rates in HIMP market hog establishments were statistically significantly lower than those in all 147 non-HIMP market hog establishments (which included the subset of 21 non-HIMP comparison establishments, as well as all other non-HIMP market hog establishments) (0.65 percent versus 3.05 percent).

The Hog HIMP Report also analyzed data from FSIS's residue sampling program for chemical contaminants including approved and unapproved veterinary drugs, pesticides, and environmental compounds. FSIS conducts directed sampling scheduled by FSIS

Headquarters and inspector-generated sampling when the FSIS PHV suspects that an animal may have a violative level of chemical residue. The Hog HIMP Report found no differences in the number of scheduled directed samples collected in the HIMP market hog establishments and those in the non-HIMP market hog comparison establishments. However, the Hog HIMP Report found that FSIS offline inspectors at the HIMP market hog establishments were able to collect 2.7 times more inspector-generated residue samples than inspectors at the non-HIMP market hog comparison establishments for CY2009-2010, and 1.7 times more for CY2012-2013 because the inspectors had more time to conduct offline activities. Data from FSIS's residue sampling program showed that from CY2006 to CY2010, the number of samples that tested positive for violative levels of chemical residues in HIMP market hog establishments were not statistically significantly different from those in the non-HIMP market hog comparison establishments (zero versus six (0.057 percent of samples)). However, from CY2012 to CY2013, the amount of samples that tested positive for violative levels of chemical residues in HIMP market hog establishments was statistically significantly lower than non-HIMP market hog comparison establishments (nine violative levels (0.15 percent of samples) versus 115 (0.76 percent of samples)). The Hog HIMP Report explained that this difference could suggest that the HIMP market hog establishments

are exercising active control of potential chemical hazards in their products, and that this approach may result from better control over contract grower relationships by the five HIMP market hog establishments.

e. Conclusion of HIMP Report

The Hog HIMP Report concluded that HIMP market hog establishments are receiving more offline food safety related inspection verification checks than the non-HIMP market hog comparison establishments, and that the HIMP inspection system, which provides for increased offline inspection activities that are directly related to food safety, results in greater compliance with sanitation and HACCP regulations (9 CFR parts 416 and 417); carcasses with equivalent or lower levels of Salmonella contamination; and carcasses with lower levels of violative chemical residues.

f. Verification of Humane Handling

FSIS inspectors verify that establishments comply with the HMSA by performing Humane Activities Tracking System (HATS) tasks that are divided into nine categories. The HATS tasks provide FSIS with data on the time that FSIS inspectors spend verifying whether 1) establishments adapt their facilities to inclement weather; 2) humanely handle livestock during truck unloading; 3) provide water and feed to livestock in holding pens; 4) humanely handle livestock during ante-mortem inspection;

5)humanely handle "U.S. Suspect" and disabled livestock; 6)move livestock without excessive prodding or the use of sharp objects after ante-mortem inspection; 7)prevent livestock from slipping and falling; 8)effectively administer stunning methods that produce unconsciousness in the animals; and 9)ensure that animals do not regain consciousness throughout the shackling, sticking, and bleeding process. FSIS inspectors enter the hours devoted to verifying humane handling activities for the HATS categories. The data is entered into PHIS in one-quarter hour increments (e.g., .25, .5, .75, 1.0).

The Hog HIMP Report did not address compliance with the HMSA, but FSIS reviewed HATS task data in PHIS from January 2013 through September 2015 and compared the number of offline humane handling activities performed in five HIMP market hog establishments and the same 21 comparable large non-HIMP market hog establishments that FSIS used in the Hog HIMP Report. The Agency found that FSIS inspectors spent more time verifying that specific humane handling and slaughter requirements were met in HIMP market hog establishments than in non-HIMP market hog establishments. FSIS inspectors devoted approximately 5.33 hours per shift to verifying humane handling activities for the HATS categories in HIMP market hog establishments compared to approximately 4.29 hours per shift in the 21 non-HIMP market hog comparison establishments. FSIS also compared the rate of humane

handling NRs issued in HIMP market hog establishments and non-HIMP market hog establishments. FSIS inspectors documented fewer humane handling NRs in HIMP market hog establishments than in non-HIMP market hog establishments. From January 2013 through September 2015, FSIS recorded 11 humane handling NRs in five HIMP market hog establishments and 117 NRs in the 21 non-HIMP market hog comparison establishments. It should be noted that none of the 11 NRs recorded in the HIMP establishments documented market hogs being forced to move faster than normal walking speeds to keep up with faster evisceration line speeds. The data demonstrate that HIMP establishments have higher compliance with humane handling regulations than non-HIMP establishments, and that increased offline inspection may improve compliance with the HMSA.

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

1. Market Hog Risk Assessment

FSIS completed a quantitative risk assessment to determine how performing a greater number of offline inspection procedures in market hog slaughter establishments might affect the number of human illnesses from Salmonella. These offline inspection procedures primarily involve activities that FSIS inspection personnel perform to verify the effectiveness of establishment

sanitary operations and other food safety-related activities. The Hog HIMP Report, discussed above, found that FSIS inspectors performed more offline inspections to verify compliance with sanitation SOP and HACCP regulations in HIMP establishments than they do in non-HIMP establishments. The risk assessment is available for viewing by the public in the FSIS docket room and on the FSIS Web site at:

http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.

FSIS developed the market hog risk assessment to help the Agency inform its judgement about the potential impact of changes to FSIS's swine inspection system on risks to public health associated with pork products. To give the Agency the information it needed, the market hog risk assessment focused on three risk management questions:

(1) What predicted effects will various models for increasing the number of offline inspection tasks in non-HIMP establishments have on human salmonellosis rates?

(2) Where can inspectors be relocated to have the most impact toward reducing Salmonella prevalence and corresponding human illness?

(3) What is the magnitude of uncertainty about the predicted prevalence of pathogens and corresponding illness effects?

2. Model

FSIS developed a risk assessment model for exploring the potential relationships between current variations in inspection personnel assignments and prevalence of Salmonella on hog carcasses, and estimating the subsequent possible reductions in human illnesses attributable to that pathogen. FSIS paired inspection data with Salmonella prevalence data for the same establishments and timeframes. As explained above, FSIS based this risk assessment model on the model for the risk assessment that FSIS used to inform the final rule "Modernization of Poultry Slaughter Inspection" (79 FR 49565).

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, and (2) contamination of hog carcasses with Salmonella.⁷ 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.

⁷ Scheduled procedures are assigned to inspectors at an establishment by PBIS or PHIS. Unscheduled procedures are performed according to inspector needs at an establishment and may include verification checks for fecal, 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.

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. 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.

3. Conclusions of the Market Hog Risk Assessment

The regression analysis of 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. 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 we expect to lead to fewer human illnesses.

In answer to the first risk-management question, the market hog risk assessment results suggest that, depending on how reallocation of inspection activities is implemented, it is likely that changes in offline inspection would not result in an increase in the prevalence of Salmonella in hog carcasses, and could even result in a decrease in the prevalence of Salmonella in hog carcasses. Specifically, the scenario that simultaneously increases unscheduled and scheduled inspection procedures and decreases scheduled but not performed procedures performs better than scenarios that target the three specific types of procedures one at a time. Under the scenario where all types of procedures are targeted for increase, with resulting decrease in scheduled but not performed procedures and decrease in instances of observed and reported establishment non-compliance, the model estimates an average decrease of 2,533 Salmonella-related illnesses per year attributable to pork products. FSIS assumes that 65,869 expected annual Salmonella illnesses are attributed to consumption of pork products. Thus, a reduction of 2,533 expected Salmonella illnesses annually, would reflect a 3.8 percent reduction in Salmonella illnesses attributable to pork products.

Responding to the second question, modeling and scenario analysis results suggest that increasing scheduled and unscheduled procedures and decreasing scheduled but not

performed procedures would be most effective in reducing pathogen occurrence on carcasses because of consistency in the decision variable parameter's effect across all models. However, each category of offline procedures relates to an individual decrease in Salmonella contaminated carcasses which if any one of the three categories or a combination of categories of offline procedures were implemented still would result in decreased contamination, but less than if the scenario combining all three decision variables was adopted.

In answer to the third risk-management question, on the uncertainty of the results for pathogen prevalence and illness reductions, FSIS's modeling approach includes the inherent uncertainty about the relationship between the frequency of inspection activities and pathogen prevalence, about the actual change in future inspection activities that would likely be observed, and about the representativeness of the rates of human Salmonella illnesses attributable to pork products.

III. Proposed NSIS

FSIS is proposing to create a new swine slaughter inspection system, the NSIS, informed by the Agency's experiences under HIMP and NPIS. All establishments that slaughter market hogs would be permitted to operate under the proposed NSIS. Establishments that slaughter classes of swine other than market hogs would be permitted to operate under NSIS

under a waiver through the SIP. FSIS would consider the data collected in swine slaughter establishments operating under a SIP waiver to determine whether to expand NSIS to other classes of swine. Establishments that slaughter market hogs and other classes of swine, and that do not want to slaughter other classes of swine under NSIS under a waiver through the SIP, would be permitted to slaughter market hogs under NSIS and to slaughter the other classes of swine under traditional inspection. FSIS would staff such establishments to NSIS and would not add additional staff for traditional inspection; therefore, establishments would need to operate traditional inspection under slower line speeds than they are currently operating to accommodate for the reduced number of inspectors. FSIS seeks comment on the impact of staffing at establishments that slaughter market hogs and other classes of swine and how it will impact their decision to participate in NSIS.

A. Live Market Hog Sorting by Establishment Personnel

Under the proposed NSIS, establishment personnel would be required to sort market hogs and remove for disposal animals unfit for slaughter before they are presented to FSIS PHVs for inspection and final disposition. Establishment personnel would sort animals that appear to be healthy into "Normal" pens and animals that appear to have diseases or abnormal conditions into "Subject" pens. Establishment personnel may also sort and remove

animals with localized conditions (e.g., animals with arthritis or abscesses) or animals that do not meet establishment specifications (e.g., hogs that are the wrong size or underweight) to be diverted to another official establishment for slaughter. Establishment personnel would remove and properly dispose of dead and moribund animals and animals suspected of having CNS conditions or pyrexia. Under the proposed NSIS, FSIS inspectors would inspect all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion. If any animals exhibit signs of condemnable conditions, FSIS inspectors would direct establishment employees to move the animals to the "U.S. Suspect" pens for final disposition by the FSIS PHV. The FSIS PHV would inspect all animals in the "Subject" and "U.S. Suspect" pens and render a final disposition decision. FSIS inspectors would observe establishment employees performing sorting procedures at least twice per shift. During this time, FSIS inspectors would 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. FSIS inspectors also would conduct HACCP verification tasks in PHIS at least twice per shift to verify that establishments meet the regulatory requirements found in 9 CFR 417 for implementation, monitoring, recordkeeping, prerequisite programs (when

applicable), and corrective actions. Under the proposed rule, if any market hogs become non-ambulatory disabled after ante-mortem inspection, establishments would be required to move them to the "Subject" pens for re-inspection by FSIS PHVs. All sorting would be a function of the establishment's HACCP plan or pre-requisite program. Because establishments operating under the proposed NSIS would be required to sort and remove market hogs that are unfit for slaughter before FSIS ante-mortem inspection, FSIS is proposing that establishments under the proposed NSIS 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 CNS conditions or pyrexia.

FSIS also is proposing to require that establishments immediately notify FSIS inspectors in the rare circumstance that they suspect animals of having notifiable or foreign animal diseases during sorting activities. For example, establishments may suspect that market hogs have notifiable or foreign animal diseases if they observe animals with abnormal lesions or behavior, or an abnormal change in the amount of animals that arrive to the establishment dead. Notifiable diseases are those that are designated by the World Animal Health Organization (Office International des Epizooties or OIE). The list of

notifiable diseases includes anthrax, cysticercosis, scabies, bovine tuberculosis, myiasis (screwworm), and vesicular diseases. Of these diseases, anthrax, cysticercosis, and bovine tuberculosis are transmissible to humans. The complete list is available on OIE's Web site at <http://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2016/>. FSIS would report any animal disease issues to the USDA Animal and Plant Health Inspection Service (APHIS).

Under the proposed NSIS, FSIS would maintain its zero tolerance for market hogs exhibiting signs of moribundity, CNS conditions, and pyrexia. Market hogs exhibiting signs of these generalized diseases or conditions, if not sorted and removed by the establishment before ante-mortem inspection, would be condemned by FSIS PHVs, as under the existing regulations (9 CFR 309.3). FSIS PHVs would issue an NR for every animal exhibiting signs of moribundity, CNS conditions, or pyrexia found by the FSIS inspector after the establishment sorting step is completed.

Additionally, under the proposed NSIS, FSIS would maintain its zero tolerance for violative levels of chemical residues. Establishments would be required to address chemical hazards through their HACCP program including preventing animals with violative levels of chemical residues from being presented for slaughter. FSIS inspectors would continue to select animals at

post-mortem and perform chemical residue sample collection and testing procedures in accordance with FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products (available on FSIS's Web site at <http://www.fsis.usda.gov/wps/wcm/connect/147066f0-564c-4590-b36f-97ffc5ab9797/10800.1.pdf?MOD=AJPERES>).

Under the proposed NSIS, establishment personnel would be required to identify carcasses of market hogs sorted and removed by establishment employees before FSIS inspection and intended for disposal and destruction with a unique tag, tattoo, or similar device. Establishment personnel also would be required to immediately denature all carcasses and parts removed as unacceptable by plant sorters on-site, even if establishments have tanking facilities, to ensure that the carcasses and parts are properly disposed of and never enter commerce. Under the proposed NSIS, establishment personnel would be required to maintain records to document the number of animals and carcasses and parts sorted and removed by establishment personnel per day. These records and procedures would be subject to daily review by FSIS inspectors. Under NSIS, FSIS inspectors would document in PHIS the total number of animals that the establishment employees have sorted and removed per day. Under the proposed rule, FSIS would still direct the application and removal of

"U.S. Condemned" tags to animals condemned during ante-mortem inspection. FSIS would also continue to enter each and every "U.S. Condemned" tag into PHIS. However, FSIS inspectors should be able to complete these tasks faster because they would be presented animals that have been sorted by establishment employees and are thus more likely to pass ante-mortem inspection and not have condemnable conditions.

In addition to the total number of animals sorted and removed by establishment personnel per day before FSIS ante-mortem and post-mortem inspection, FSIS is requesting comments on whether or not the Agency should require establishments under NSIS to specify in their records the reason that the animals were removed from slaughter, including animals sorted and removed because they were dead on arrival or suspected of having CNS conditions, pneumonia, pyrexia, septicemia, erysipelas, or tuberculosis (e.g., 20 sorted and removed; 10 pneumonia, 10 dead on arrival) and how this information should be collected. Under traditional inspection, FSIS inspectors record similar condemnation information into PHIS for APHIS' swine slaughter condemnation monitoring system; however, this information is not being collected under HIMP. APHIS Veterinary Services (VS) uses this type of data to monitor changes in the rate or count of swine condemnations by swine type (market, roaster, sow, and boar) and by selected condemnation categories (e.g., central

nervous system disorders, dead on arrival, pneumonia, pyrexia, septicemia, erysipelas, and tuberculosis). APHIS conducts weekly monitoring to compare baseline (expected) condemnation counts by condemnation category to current weekly counts to identify noteworthy increases (signals) in condemnations in near-real time. APHIS produces a weekly report, and shares it with the National Pork Board to identify any noteworthy increases in condemnations which could indicate the emergence of disease and may warrant further investigation. FSIS and APHIS recognize that "presumptive diagnoses" by establishment personnel under the NSIS may not be as accurate as condemnation information entered by an FSIS PHV under traditional inspection. However, FSIS and APHIS believe that the self-reported information may still be useful and significant in monitoring disease conditions in the United States.

B. Post-Mortem Carcass Sorting by Establishment Employees and Online Carcass Inspection

Under the proposed NSIS, establishment personnel would be required to sort carcasses and parts and trim dressing defects and contamination (e.g., hair, bruises, feces, ingesta, and milk) before the carcasses and parts are presented to an FSIS online inspector for post-mortem inspection. Establishment personnel also would be required to mark with ink, or otherwise identify, localized pathological defects intended for removal

under FSIS supervision (e.g. localized nephritis and localized arthritis) and carcasses and parts intended for disposal under FSIS supervision (e.g., carcasses and parts with malignant lymphoma). Under the proposed NSIS, the head, and viscera of each hog must be handled in a way as to identify them with the rest of the carcass and as being derived from the particular animal involved, until FSIS's post-mortem inspection of the carcass and parts thereof have been complete. FSIS would not complete an inspection of the carcass if the head or viscera were missing before the final rail, unless the head or viscera were properly disposed of under FSIS supervision. Consistent with traditional inspection, only FSIS inspectors would be authorized to condemn carcasses and parts.

Carcasses and parts contaminated with fecal material, ingesta, or milk or that exhibit signs of septicemia, toxemia, pyemia, or cysticercosis during post-mortem examination are likely to contain infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth organisms, which can be transmitted to humans. For this reason, they present a food safety risk if they are permitted to enter the cooler.

Therefore, FSIS is proposing that establishments under the new system address, as part of their HACCP systems, procedures for ensuring that carcasses and parts contaminated with fecal material, ingesta, or milk or affected by septicemia, toxemia,

pyemia, or cysticercosis are trimmed or identified by the establishment before they are presented to the FSIS carcass inspector and disposed of under FSIS supervision. These procedures must cover establishment sorting activities for these conditions.

Under this proposal, FSIS would maintain its zero tolerance for carcasses and parts contaminated by fecal material, ingesta, or milk, or affected by septicemia, toxemia, pyemia, or cysticercosis. If FSIS online inspectors discover a carcass contaminated by fecal material, ingesta, or milk, they would stop the line for carcass reexamination and trimming by the establishment unless the establishment elected to provide a rail-out loop to rail contaminated carcasses offline for reexamination, trimming, and positioning back on the line for reinspection, consistent with the existing regulations (9 CFR 310.17 and 310.18) and FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations (available on FSIS's Web site at http://www.fsis.usda.gov/wps/wcm/connect/478aca76-37c5-4dc3-9925-1556402d8daf/PHIS_6420.2.pdf?MOD=AJPERES). An NR would be issued by the FSIS offline inspector at or after the final rail for every carcass contaminated by fecal material, ingesta, or milk. FSIS online inspectors would also stop the line if they discover carcasses exhibiting septicemia, toxemia, pyemia, or

cysticercosis, as under the existing regulations (9 CFR 311.16 and 311.17). The carcasses would be retained for FSIS PHV disposition. An NR would be issued by the PHV for every carcass affected by septicemia, toxemia, pyemia, or cysticercosis that reaches the online carcass inspection station. Moreover, because establishments would be required to address these food safety hazards in their HACCP systems, the Agency continuously would assess the effectiveness of an establishment's procedures for ensuring that carcasses are prevented from becoming contaminated with fecal material, ingesta, or milk, and that carcasses affected by septicemia, toxemia, pyemia, or cysticercosis do not reach the final FSIS inspection station.

FSIS is not proposing to prescribe specific sorter training or certification to give establishments operating under the NSIS the flexibility to select the training program that would best assist them to meet the requirements of this proposed rule. However, the Agency has developed a draft guidance document to assist establishments in training their sorters should this rule become final. The draft guidance is based on the training that FSIS provides to online inspection personnel that are responsible for identifying these non-food safety defects on carcasses and parts under traditional inspection. FSIS has posted this draft compliance guide on its Web page (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory->

compliance/compliance-guides-index) and is requesting comments on the guidance.

FSIS believes that training of sorters is important to ensure that they are able to properly perform their duties. Proper training is necessary if sorters are to make accurate decisions on how to address animal disease conditions and trim and dressing defects. Under the proposed NSIS, if sorters do not make these decisions correctly, FSIS inspection personnel would take appropriate action such as stopping the line, issuing NRs, and directing the establishment to reduce the line speed. FSIS would thereby ensure that the establishment is able to maintain process control as evidenced by preventing fecal contamination and meeting microbial performance measures, that the establishment sorters are able to successfully perform their duties, and that the FSIS online inspectors are able to conduct a proper food safety inspection.

Establishments that operate under the proposed NSIS would have greater flexibility over their production process. For example, establishments operating under the proposed NSIS would have the flexibility to reconfigure lines if they decided to change the way that the head, viscera, and carcasses are presented to FSIS inspectors to improve ergonomics and process control and to maintain optimum line speed. FSIS would still inspect the head, viscera, and carcass of each animal. However,

under the proposed NSIS, establishments may reconfigure their lines so that they present a ready-to-inspect head, viscera, and carcass for FSIS post-mortem inspection in one location or separately in two or three locations. FSIS would assign one to three inspectors to conduct online inspection activities, depending on need and line configuration. These inspectors would also rotate to conduct offline inspection activities. FSIS would assign one online inspector only if the Agency had the data and experience (including processes and procedures) to ensure that one inspector is able to conduct all online post-mortem inspection activities. Under the proposed NSIS, all establishments with fewer than three inspection stations would be required to provide a mirror at the carcass inspection station in accordance with 9 CFR 307.2 (m) (6) so that the inspector standing at the inspection station can readily view the back of the carcass for evidence that could impact food safety.

Under NSIS, as under HIMP, establishment sorters would be required to incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (e.g., Mycobacterium Avium) as part of their sorting activities before FSIS post-mortem inspection. FSIS is requesting comments on whether or not the Agency should allow establishments that operate under the proposed NSIS to use discretion when deciding,

on a lot-by-lot basis, whether or not to incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (e.g., M. Avium) if they submit documentation to FSIS supporting that the presence of M. Avium is not likely to occur, such as records documenting their on-farm controls. In the last 10-15 years, industry led initiatives like the Pork Quality Assurance Plus certification program (<http://www.pork.org/pqa-plus-certification>) and the Common Industry Audit (<http://www.pork.org/common-industry-audit>) have improved biosecurity practices which not only reduce disease spread but also address risk factors for M. Avium such as exposure to birds.^{8,9} Because on-farm practices have improved, the prevalence of M. Avium in U.S. swine is very low. After reviewing PHIS condemnation data from 21 large market hog establishments from 2012 through 2015, FSIS found that only 0.9 percent of all condemnations are due to M. Avium. The animal disease M. Avium does not present a food safety concern, and can be detected visually by inspectors.

⁸ United States Department of Agriculture, Animal and Plant Health Inspection Service. (2008). National Animal Health Monitoring System Swine 2006, Part IV: Changes in the U.S. Pork Industry, 1990-2006. Retrieved from https://www.aphis.usda.gov/animal_health/nahms/swine/downloads/swine2006/Swine2006_dr_PartIV.pdf.

⁹ United States Department of Agriculture, Animal and Plant Health Inspection Service. (2015). National Animal Health Monitoring System Swine 2012, Part 1: Baseline Reference of Swine Health and Management in the United States, 2012. Retrieved from https://www.aphis.usda.gov/animal_health/nahms/swine/downloads/swine2012/Swine2012_dr_PartI.pdf.

Moreover, Denmark and the Netherlands already conduct alternative post-mortem visual inspections and allow establishments to use discretion when determining, on a lot-by-lot basis, whether or not to incise lymph nodes and palpate the viscera. Under the FMIA and the regulations that implement it, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 620). FSIS has reviewed Denmark's and the Netherlands' market hog slaughter inspection systems and found them to be equivalent to the United States' market hog slaughter inspection system. FSIS determined that visual post-mortem inspection will still allow veterinary inspectors to palpate and incise lymph nodes and organs (as occurs in traditional inspection) at their discretion. Each herd of hogs that arrives at establishments to be slaughtered is accompanied by historical "Supply-Chain Information," which consists of paperwork that documents the health status and history of each herd, complete traceback information, as well as details about the originating farm (e.g., history of disease, use of medications, and on-farm practices that contribute to maintenance of the herd's health.) FSIS concluded that this documentation, as well as any ante-mortem inspection observances, will be sufficient to inform the veterinary inspector's decision whether or not to perform visual

inspection or traditional inspection. Importantly, because lymphatic tissue may be contaminated with pathogens, not incising the lymphatic tissue may reduce contamination of food contact surfaces and other carcasses.

FSIS also is proposing to require establishment personnel to maintain records to document the number of carcasses and parts disposed of by establishment personnel per day as part of their sorting activities. The records would not need to include the number of carcasses condemned by FSIS. These records would be subject to review by FSIS inspectors. Under NSIS, FSIS inspectors would document in PHIS the total number of carcasses and parts sorted and disposed of by plant employees per day. FSIS inspectors would continue to enter dispositions for each and every carcass condemned by FSIS into PHIS.

C. Offline Verification Inspection

In addition to the online inspectors performing carcass inspection, FSIS is proposing that up to two inspectors be assigned for each evisceration line per shift to conduct offline verification activities in establishments operating under the proposed NSIS. Inspectors conducting offline inspection activities would rotate with the inspectors conducting online inspection activities. FSIS is also proposing to assign one PHV to make carcass and parts dispositions.

As in HIMP, offline inspectors under the new inspection system would conduct food safety related inspection activities and would continuously monitor and evaluate establishment process control. Offline inspectors would conduct inspection activities including HACCP, sanitation SOP, and other prerequisite program verification procedures; verification checks for septicemia, toxemia, pyemia, cysticercosis, fecal material, ingesta, or milk contamination; checks to verify and ensure that sanitary dressing requirements are being met; and ante-mortem inspection. Under this proposed rule, offline inspectors would also conduct more humane handling verification tasks than are conducted under traditional inspection. The offline verification inspectors would work with the Inspector-In-Charge (IIC) to ensure that food safety related or non-food-safety related conditions do not impair the online carcass inspectors' ability to conduct the inspection of each head, viscera, and carcass or would notify the IIC whenever circumstances indicate a loss of process control. When circumstances indicate a loss of process control, the IIC will be authorized to require that the establishment slow the evisceration line speed.

D. RTC Pork Product

As discussed above, under HIMP, OCP standards are non-food safety standards concerned primarily with diseases of no public

health significance and carcass processing defects. Data collected from market hog establishments operating under HIMP show that from CY 2012 through 2013, HIMP establishments maintained OCP defect levels that average about half the corresponding OCP performance standards derived from the performance of non-HIMP establishments. Thus, the data show that establishments operating under the HIMP system do exceptionally well in controlling OCP defects.

Accordingly, FSIS is not proposing OCP requirements as a condition for establishments to participate in the proposed NSIS. Under this proposal, establishments operating under NSIS would be allowed to implement the process controls that they have determined will best allow them to produce an RTC pork product that is wholesome and not adulterated. The new proposed definition of RTC pork product is any slaughtered pork product 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.

Under the proposed NSIS, establishments would have the flexibility to design and implement measures to address OCP defects that are best suited to their operations. They would also be responsible for determining the type of records that will best document that they are meeting the RTC pork product

definition. The records would be subject to review and evaluation by FSIS inspectors.

For their record reviews, FSIS inspectors would verify that establishments operating under the proposed NSIS have written criteria for determining whether carcasses meet the RTC definition and that they are documenting that the pork products resulting from their slaughter operations meet these criteria before packaging or further processing that would conceal a defect. Records that would meet the proposed requirements include:

- The records system that the establishment uses to document that it is producing RTC pork. For example, an establishment may use statistical process control charts, HACCP records, or other documentation.
- The points in the operation where the establishment monitors carcasses to determine whether they meet the RTC definition and records the results of its monitoring activities. For example, an establishment may conduct monitoring and record the results at a pre-evisceration and a post-chill station.
- The frequency with which the establishment conducts monitoring activities. The records should specify how often the establishment monitors carcasses per line per shift. For example, an establishment may conduct and document its monitoring activities at least every two hours per line per shift at the pre-evisceration location and at least twice per shift per line for post-chill location.

- The definitions of the OCP non-conformances or processing and trim defects for which the establishment is monitoring. For example, the establishment may be monitoring carcasses for processing and trim non-conformances as specified for trim and processing OCP defects specified under the HIMP OCP performance standards, or defects as defined in a published study or a study that the establishment conducted itself. If the establishment references a study, it should give a brief description of the study and have the supporting information on file.
- The criteria that the establishment would use to determine that the products resulting from its slaughter operation meet the RTC definition. For example, an establishment may follow the subgroup limits for non-conformances and defects in the trim and processing defect levels for the HIMP OCP performance standards, or it may determine the upper limits for non-conformances using a statistical process control program.
- The corrective actions that the establishment would take if the levels of defects and non-conformances exceed its evaluation criteria for RTC pork.

Under this proposed rule, pork carcasses that meet the OCP performance standards under HIMP would be considered "suitable for cooking without the need for further processing," and as such, meet the RTC pork product definition. Therefore, establishments operating under the NSIS that adopt the OCP HIMP performance standards as their criteria for determining whether they are producing RTC pork product would meet the regulatory requirements if: (1) They can document that the products

resulting from their slaughter operations consistently meet these standards, and (2) FSIS inspectors do not observe persistent, unattended defects on the products resulting from the establishment's slaughter operations. Establishments that adopt criteria other than the HIMP OCP standards would be required to have documentation to demonstrate how they will use these criteria to demonstrate that the products resulting from their slaughter operations meet the RTC pork product definition.

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

appropriate action to ensure that the establishment remedies the defects, including requiring that the establishment slow the evisceration line speed.

E. Line Speeds under NSIS

Based on FSIS's experience under HIMP, the Agency is proposing to allow establishments operating under NSIS to determine their own evisceration line speeds if Agency personnel verify that process control is maintained. 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 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 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 hogs. Establishments determine their line speeds based on their equipment, animal size and herd condition, and their ability to maintain process control when operating at a given line speed. In addition, line speeds under HIMP depend on the number of employees the establishments hire and train to perform sorting activities. If FSIS finalizes the proposed NSIS, establishments choosing to operate under the NSIS will likely determine their line speeds based on the same factors that

establishments considered when setting line speeds under HIMP for the past 16 years.

Establishments operating under HIMP have demonstrated that they are capable of consistently producing safe, wholesome, and unadulterated pork products while operating at these line speeds. Moreover, they have consistently met pathogen reduction and other performance standards when operating at the line speeds they established under HIMP. The proposed new inspection system was informed by the Agency's experience under HIMP and, as discussed later in this document, also incorporates additional measures that will apply to all swine slaughter establishments. These measures, which include testing for microbial organisms at pre-evisceration and post-chill, are designed to ensure that establishments maintain process control.

FSIS recognizes that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety. FSIS compared in-establishment injury rates between HIMP and traditional establishments from 2002 to 2010. The preliminary analysis shows that HIMP establishments had lower mean injury rates than non-HIMP establishments. The analysis uses injury rate data by occupational injury estimates that are derived from the BLS annual Survey of Occupational Injuries and Illnesses (SOII) (<http://www.bls.gov/iif/data.htm>). The survey captures data from

Occupational Safety and Health Administration (OSHA) logs of workplace injuries and illnesses maintained by employers. Fifty-six FSIS inspected market hog slaughter establishments voluntarily submitted injury rate data to OSHA (approximately nine percent of all market hog slaughter establishments). From these 56 establishments, 27 low volume establishments were excluded, leaving 29 plants (5 HIMP and 24 Traditional). The low volume plants were excluded to provide a better comparison group of traditional plants because all HIMP plants are high volume plants. The results showed HIMP plants had a lower mean number of injuries using three OSHA injury rate measures: Total Case Rate (TCR), Days Away Transferred Restricted (DART), and Days Away From Work (DAFW). However, FSIS realizes that factors other than line speed may affect injury rates (e.g., automation and number of sorters per line).

FSIS is requesting comments on the effects of faster line speeds on worker safety. Specifically, FSIS is requesting comments on whether line speeds for the NSIS should be set at the current regulatory limit of 1,106 hph or some other number. The Agency is also interested in comments on the availability of records or studies that contain data that OSHA or the National Institute for Occupational Safety and Health (NIOSH) may be able to use in analyzing the effects of increased line speed on the safety and health of employees throughout the establishment,

including effects prior to and following the evisceration line. FSIS is also requesting comments on whether the Agency should maintain the 1,106 hph maximum line speed for establishments operating under NSIS but grant waivers from the maximum line speed to establishments that agree to work with the National Institute for Occupational Safety and Health NIOSH to evaluate the effects of waivers of line speed restrictions on employee health. FSIS is requesting comments on best practices and other measures that establishments can take to protect workers throughout the plant, including possible protective factors such as increasing the size of the workforce, rotating assignments, increased automation, or improved tools and techniques.

FSIS is proposing to require each establishment that operates under the NSIS to provide an annual attestation to the management member of the local FSIS circuit safety committee stating that the establishment maintains a program to monitor and document any work-related conditions that arise among establishment workers. The elements of this program would include:

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

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

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

FSIS is also proposing to create a new severability clause (proposed 9 CFR 310.28), which would state that should a court of competent jurisdiction hold any provision of the proposed worker safety attestation requirement (proposed 9 CFR 310.27) to be invalid, such action would not affect any other provision of 9 CFR parts 309 and 310.

As OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health, FSIS would forward the annual attestations to OSHA for further review. OSHA, in turn, may use the information in the attestations in its own enforcement program. FSIS employees would not be responsible for determining the merit of the content of each establishment's monitoring program or enforcement of noncompliance with this section. FSIS would work with OSHA to

develop the poster that establishments must display providing information on the signs and symptoms of occupational injuries and illnesses experienced by market hog slaughter workers, and about workers' rights to report these conditions without fear of retaliation.

IV. Other Proposed Changes That Affect All Swine Slaughter Establishments

A. Procedures to Address Enteric Pathogens, Fecal Material, Ingesta, and Milk Contamination as Hazards Reasonably Likely to Occur

In 1997, FSIS published a Federal Register document entitled "Notice on complying with food safety standards under the HACCP system regulations" (62 FR 63254, November 28, 1997). The purpose of the document was to ensure that establishments understood the Agency's zero tolerance policy for visible fecal material as food safety hazards, as establishments prepared to comply with the then newly enacted HACCP system regulations. The document explained that under 9 CFR 310.18, establishments must handle livestock carcasses and carcass parts to prevent contamination with fecal material and promptly remove contamination if it occurs. Based on this regulation, FSIS enforces a zero tolerance policy for visible fecal contamination. Then, the document explained that "to meet the zero tolerance standard, an establishment's [HACCP] controls

must (among other things) include limits that ensure that no visible fecal material is present by the point of post-mortem inspection of livestock carcasses" (citing 9 CFR 417.2(c)). Finally, the document explained that "Under the HACCP system regulations, critical control points to eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' HACCP plans." As a result, all swine slaughter establishments' HACCP plans currently include critical control points (CCPs) for preventing carcasses contaminated with visible fecal material at or after the final rail.

FSIS also enforces a zero tolerance policy for contamination by ingesta and milk because the microbial pathogens associated with ingesta and milk contamination are likely sources of potential food safety hazards in slaughter establishments. As mentioned above, the regulations require establishments to handle livestock carcasses and carcass parts to prevent contamination and promptly remove contamination if it occurs (9 CFR 310.18) The regulations also require that lactating mammary glands and diseased mammary glands of swine be removed without opening the milk ducts or sinuses because if pus or other objectionable material is permitted to come in contact with the carcass, the parts of the carcass are contaminated and must be removed and condemned (9 CFR 310.17). Because such

contamination is largely preventable, most slaughter establishments already have in place procedures designed to prevent and remove ingesta and milk.

FSIS is now proposing to amend 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 post-mortem inspection of swine carcasses. Such a requirement would ensure that establishments maintain the records to verify that they have implemented the necessary measures and, when necessary, have taken appropriate corrective actions to prevent carcasses contaminated with visible fecal material, ingesta, or milk at or after the final rail.

Although the existing requirements for establishments to prevent visible fecal material, ingesta, or milk at or after the final rail, and the proposed requirement described above that establishments must have procedures addressing how they do so, are important safeguards, those safeguards would not be fully effective if an appropriate effort is not made to prevent contamination from occurring throughout the slaughter and dressing operation. Fecal material is a major vehicle for spreading pathogenic microorganisms, such as Salmonella, to raw pork products, and therefore, it is vital for establishments to

maintain sanitary conditions and to prevent, to the maximum extent possible, contamination from occurring before slaughter and throughout the slaughter and dressing process.

Under HACCP, establishments are responsible for identifying food safety hazards that are reasonably likely to occur in the production process and for implementing preventive measures to control those hazards. Failure to implement preventive measures throughout the slaughter and dressing process can lead to the creation of insanitary conditions in the establishment and increases the potential for carcasses and parts to become contaminated with enteric pathogens, fecal material, ingesta, and milk. Interventions with chemical antimicrobials applied at the end of the process are less likely to be fully effective on carcasses that contain high levels of pathogens, and these chemical treatments are not effective in preventing insanitary conditions throughout the slaughter establishment.

To ensure that establishments implement appropriate measures to prevent carcasses from becoming contaminated with pathogens, and to ensure that both FSIS and establishments have the documentation they need to verify the effectiveness of these measures on an on-going basis, FSIS is proposing to require that all swine slaughter establishments develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, fecal material,

ingesta, and milk throughout the entire slaughter and dressing operation. FSIS is proposing that establishments incorporate these procedures into their HACCP systems and that they maintain records sufficient to document the implementation and monitoring of these procedures. These proposed requirements are necessary to fully implement the existing HACCP regulations.

Information that FSIS has collected from investigations it has conducted in establishments that have received a Notice of Intended Enforcement due to Salmonella serotypes linked to human illness demonstrate the need for establishments to adopt preventive measures to control contamination throughout the entire production process, as well as the need to maintain documentation to verify the effectiveness of those measures on an ongoing basis.

For example, FSIS conducted an investigation at a swine slaughter establishment that resulted in a Notice of Intended Enforcement after a State department of health conducted sampling and found the presence of Salmonella serotypes linked to human illness, and after FSIS requested a voluntary recall in 2015. FSIS reviewed the establishment's controls, and records associated with the establishment's sanitary dressing procedures and microbial interventions, and observed the establishment's implementation of these controls and procedures. The Agency's review found that the establishment had contamination of

Salmonella throughout the slaughter process, including carcasses, environmental samples and pre-operational swabs. The cross contamination and failure to maintain sanitary procedures appeared to have overwhelmed any subsequent in-process interventions. FSIS determined that the establishment's HACCP system was inadequate due to multiple or recurring noncompliance (see 9 CFR 500.4(a)). If this rule becomes final, establishments may choose to incorporate measures to address the prevention of contamination by enteric pathogens and contaminants (e.g., fecal, ingesta, and milk) into their procedures addressing how they prevent contamination from occurring during slaughter and dressing operations. Examples of such measures include: sanitary dressing protocols, statistical process control programs, and sampling.

Under this proposed rule, establishments will be required to incorporate these procedures into HACCP systems, and to maintain on-going documentation to demonstrate that the procedures are effective. FSIS is not proposing to prescribe the specific procedures that establishments must follow to prevent carcasses from becoming contaminated by enteric pathogens, fecal material, ingesta, or milk because the Agency believes that establishments should have the flexibility to implement the most appropriate measures that will best achieve the requirements of this proposed rule. However, on-going verification and

documentation to demonstrate that an establishment's process controls are effective in preventing food safety hazards are critical components of the food safety system. FSIS believes that microbiological test results that represent levels of microbial contamination at key steps in the slaughter process are necessary for establishments to provide comprehensive, objective evidence to demonstrate that they are effectively preventing carcasses from becoming contaminated with pathogens before and after they enter the cooler.

In light of these changes, FSIS is proposing to rescind the generic E. coli testing requirements in 9 CFR 310.25 and to replace them with a new testing requirement that would provide establishments the flexibility to sample for other, potentially more useful indicator organisms. Under this proposal, establishments would continue to conduct sampling and analysis of carcasses for microbial organisms at the post-chill location, but in addition the Agency is proposing a second testing location at the pre-evisceration position in order to ensure establishments would be able to monitor the effectiveness of process control for enteric pathogens throughout the slaughter and dressing operation.

Under this proposed rule, instead of following a prescribed microbiological testing program, each establishment would be responsible for developing and implementing its own

microbiological sampling plan, which would be required to include carcass sampling at pre-evisceration and post-chill. FSIS considers the microbial load of hog carcasses at pre-evisceration to be a valuable source of data about how well an establishment is taking into account the sanitary condition of live hogs coming to slaughter and the processing steps (i.e., washing, dehairing) they implement to reduce the external contamination of the carcass prior to evisceration. Following a similar logic, FSIS considers the microbial characteristics of hog carcasses post-chill (after all processing steps have taken place) to be a valuable source of data about how well an establishment is minimizing contamination during chilling as well as the overall effectiveness of all process control interventions the establishment has chosen to apply throughout its production process. Because most establishments apply one or more interventions between the pre-evisceration and post-chill sampling points to help control microbiological hazards, FSIS would expect that a reduction in microbiological contamination between these two sampling points to be an indication of the effectiveness of those controls. The establishment would be responsible for determining which microbiological organisms would best help it to monitor the effectiveness of its process control procedures.

Because FSIS is proposing that establishments' microbiological sampling plans be part of their HACCP systems, all swine slaughter establishments would be required to provide scientific or technical documentation to support the judgments made in designing their sampling plans (see 9 CFR 417.4(a)). Under this proposal, establishments could develop sampling plans to test carcasses for enteric pathogens, such as Salmonella, at pre-evisceration and post chill, or they could test for an appropriate indicator organism. FSIS has developed draft sampling guidance to assist small and very small establishments in developing sampling plans that meet the Agency's expectations for testing designs and sampling frequency should this rule become final. FSIS has posted this draft compliance guide on its Web page (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>) and is requesting comments on the guidance.

FSIS is proposing to prescribe a minimum frequency with which establishments would be required to collect two samples, one at pre-evisceration and one at post-chill, or, for very small and very low volume establishments, a single post-chill sample. Under the proposed rule, establishments, except for very

small and very low volume establishments¹⁰, would be required to collect samples at a frequency of once per 1,000 carcasses. Very small and very low volume establishments would be required to collect at least one sample during each week of operation each year. FSIS is proposing to allow very small and very low volume establishments to collect and analyze samples for microbial organisms at the post-chill point in the process only because these establishments typically are less automated and run at slower line speeds than larger establishments. The lower level of automation and the slower line speeds require less complicated measures for maintaining and monitoring process control on an ongoing basis. If, after consecutively collecting 13 weekly samples, very small and very low volume establishments can demonstrate that they are effectively maintaining process control, they can modify their sampling plans to collect samples less frequently. These proposed frequencies reflect the frequencies prescribed under the existing regulations for generic E. coli testing. In light of these changes, FSIS is proposing to remove the current requirement that swine establishments test carcasses for generic E. coli to monitor process control. FSIS is also proposing to eliminate the

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

pathogen performance standards for market hogs in 9 CFR 310.25(b) because, as explained above, the codified standards are no longer in use.

FSIS is proposing to allow establishments to substitute alternative sampling locations if they are able to demonstrate that the alternative sampling locations provide a definite improvement in monitoring process control than at pre-evisceration and post-chill. FSIS is also proposing to allow establishments to substitute alternative sampling frequencies if they are able to demonstrate that the alternative is an integral part of the establishments' verification procedures for their HACCP plans.

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

need to routinely evaluate the effectiveness of their procedures in preventing carcass contamination.

Under this proposed rule, FSIS would verify the effectiveness of establishments' process control procedures in preventing carcasses from becoming contaminated with enteric pathogens, fecal material, ingesta, and milk by reviewing the establishments' monitoring records, including the establishments' microbial testing results, observing establishments implementing their procedures, and inspecting carcasses and parts for visible fecal, ingesta, and milk contamination when conducting both online carcass inspection and offline verification inspection procedures.

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

Finally, FSIS is proposing to require that all official swine slaughter establishments develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens. These procedures must include sampling and analysis of food-contact surfaces, reuse water, and equipment, including knives, in edible food production departments in the pre-operational environment for microbial organisms to ensure that the surfaces are sanitary and free of enteric pathogens. The sampling frequency must be adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment. FSIS is proposing this environmental sampling requirement because in 2015, 152 people became ill after consumption of product produced at an establishment where FSIS found evidence during an investigation of insanitary conditions, including, but not limited to, tables and knives in the pre-operational environment that were contaminated with Salmonella. The proposed environmental sampling requirement would reduce the risk of cross-contamination from insanitary conditions in the pre-operational environment. FSIS is requesting comments on this proposed environmental sampling requirement. The proposed environmental sampling does not specifically include lairage (e.g., holding pens for live swine) although scientific literature conclusively

shows that contamination occurs in this area of the establishment. FSIS is also asking for comments on how to ensure that lairage does not contribute to insanitary conditions.

V. Implementation

If this proposed rule becomes final, establishments interested in NSIS would need to notify FSIS in writing of their intent to operate under the new inspection system. The Agency is also considering establishing separate applicability dates for large, small, and very small establishments to comply with the proposed regulations that prescribe procedures for controlling visible fecal, ingesta, and milk contamination; the regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process; and the regulations that prescribe recordkeeping requirements. The applicability dates would provide additional time for small and very small establishments to comply with these provisions. The Agency is requesting comments on its proposed implementation plan, especially the phased in applicability dates for the proposed provisions in the rule that prescribe requirements for all swine slaughter establishments.

VI. Executive Orders 12866 and 13563

Executive Orders 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, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "significant" regulatory action under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under Executive Order (E.O.) 12866.

A. Request for Comments Summary

FSIS is requesting comments on:

1. Whether or not the Agency should require establishments under NSIS to specify in their records the reason that the animals were removed from slaughter and how this information should be collected.
2. The draft compliance guides.
3. Whether or not the Agency should allow establishments that operate under the proposed NSIS to use discretion when deciding, on a lot-by-lot basis, whether or not to incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (e.g., M. Avium) if they submit documentation to FSIS supporting that the presence of M. Avium is not likely to occur, such as records documenting their on-farm controls.
4. The effects of faster line speeds on worker safety.
 - a. Whether line speeds for the NSIS should be set at the current regulatory limit of 1,106 hph or some other number.

b. The availability of records or studies that contain data that FSIS may be able to use in analyzing the effects of increased line speed on the safety and health of employees throughout the establishment, including effects prior to and following the evisceration line.

c. Whether the Agency should maintain the 1,106 hph maximum line speed for establishments operating under NSIS but grant waivers from the maximum line speed to establishments that agree to work with the National Institute for Occupational Safety and Health to evaluate the effects of waivers of line speed restrictions on employee health.

5. The proposed sampling requirements, especially the environmental sampling requirement.

6. The proposed implementation plan, especially the phased in applicability dates for the proposed provisions in the rule that prescribe requirements for all swine slaughter establishments.

In addition, FSIS is requesting the following data to further inform its consideration of the proposed rule. Further discussions of these requests are provided in their corresponding sections.

1. Are very small establishments that exclusively slaughter market hogs likely to convert to the NSIS?

2. How soon do establishments plan on adopting the NSIS?

3. Depending on establishment size, how many additional establishment employees would the NSIS system require?

4. What are the capital costs for establishments associated with the NSIS?
5. How long will it take establishment personnel such as a quality technician to collect, record, and analyze data required to verify that an establishment's products meet the definition of RTC?
6. How many swine establishments have written sanitary dressing plans?
7. How many establishment employees perform sanitary dressing tasks in a swine slaughter establishment?
8. How many establishments conduct generic E. coli sampling at an alternative frequency?
9. What are the alternative frequencies at which establishments are conducting process control sampling?
10. How will changes in line speeds affect market hog prices, establishment hours of production, consumer prices, and export volumes?

B. Need for the Rule

The swine slaughter industry in the U.S. has evolved since the advent of the current swine inspection regulations used by the FSIS. 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.¹¹ For these producers,

¹¹ Key, Nigel and William McBride. 2007. The Changing Economics of U.S. Hog Production. USDA ERS. Report No. 52

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, adherence to current regulations at large and high volume establishments that exclusively slaughter market hogs prevents 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, one that is less prescriptive, creates incentives for establishments to develop and invest in food quality controls and safety procedures, and allows FSIS to improve inspection methods, is needed.

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 88 percent between 2005 and 2015.¹² According to the Food and Agricultural Organization, pork is consistently

¹² USDA ERS Livestock and Meat Domestic Data. <<http://www.ers.usda.gov/data-products/livestock-meat-domestic-data.aspx#26105>> Accessed on 12/2/15. Last up dated on 11/30/15

ranked as the top meat in per-capita consumption worldwide¹³ and is ranked third in the United States.¹⁴

Table 2: US Pork Supply and Demand

Year	US Production*	Imports*	Exports*	Domestic Consumption*	Per Capita Consumption**
2005	20,705	1,024	2,666	19,093	65
2006	21,074	990	2,995	19,055	64
2007	21,962	968	3,141	19,763	66
2008	23,367	832	4,651	19,431	64
2009	23,020	834	4,094	19,869	65
2010	22,456	859	4,223	19,077	62
2011	22,775	803	5,196	18,382	59
2012	23,268	802	5,379	18,607	59
2013	23,204	880	4,986	19,105	60
2014	22,858	1,011	5,092	18,836	59
2015	24,517	1,116	5,009	20,593	64

* Measured in carcass weight, million pounds

** Measured in carcass weight, pounds

Source: USDA ERS Livestock and Meat Domestic Data.

<<http://www.ers.usda.gov/data-products/livestock-meat-domestic-data.aspx#26105>> accessed on 11/29/16. Last up dated on 10/27/16

In 2016, there were approximately 612 swine slaughter establishments under Federal Inspection, Table 3.¹⁵ Combined, these establishments process roughly 118 million hogs annually. FSIS divides these swine into the following production categories for data collection: roaster swine, market hog, sow,

¹³ FAO Livestock commodities. <

<http://www.fao.org/docrep/005/y4252e/y4252e05b.htm>> Accessed on 11/29/16.

¹⁴ USDA ERS Livestock and Meat Domestic Data. <<http://www.ers.usda.gov/data-products/livestock-meat-domestic-data.aspx#26105>> Accessed on 11/29/16. Last up dated on 10/27/16

¹⁵ USDA, FSIS, Public Health Information System (PHIS).

and boar/stag. Today, the majority (96%) of the pork products available in the market are derived from market hogs.¹⁶

Table 3: Number of Swine Slaughter Establishments by Size, 2016

HACCP Processing Size	No. 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 hog, a species sub class which due to technological and managerial improvements, such as improved genetics, nutrition, and medical services, generally presents fewer food safety and quality issues.¹⁷

D. Overview of the Proposed Rule's NSIS

Eight of the proposed rule's provisions apply to only those establishments that voluntarily participate in the NSIS. Meeting these provisions will likely increase an establishment's labor and training costs. Additionally, only market hogs are eligible to participate in the NSIS. Due to these economic constraints discussed above, we expect that only large and small high volume

¹⁶ Source: PHIS

¹⁷ Key, Nigel and William McBride. 2007. The Changing Economics of U.S. Hog Production. USDA ERS. Report No. 52

establishments that exclusively slaughter market hogs would voluntarily participate in the NSIS. In 2016 there were 40 high volume establishments that exclusively slaughter market hogs, 27 large¹⁸ (5 HIMP + 22 non-HIMP)¹⁹ and 13 small establishments, Table 4. These establishments account for 92 percent of total swine slaughter, Table 4. Given their large share of the market and the ability to slaughter a sufficient amount of market hogs to justify the likely costs associated with NSIS, these establishments are expected to voluntarily implement the proposed NSIS. Therefore, this analysis calculates the costs and benefits associated with the voluntary provisions for these 40 market hog establishments. However, because the 5 HIMP establishments are already practicing the proposed NSIS methods, 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	No. of Establishments	Total Swine Slaughter (Head Count)	Percent of Total Head Count

¹⁸ 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.

¹⁹ In 2016 there was 1 large establishment that did not exclusively slaughter market hogs.

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 Proposed Rule's Mandatory Components

All swine slaughter establishments would need to comply with the three mandatory provisions of the proposed rule, which are described in more detail in section IV. A.

1. Written Sanitary Dressing Plans

FSIS is proposing to amend 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 post-mortem inspection of swine carcasses. This requirement would address a weakness of the current 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 contamination from entering the cooler. While preventing swine carcasses contaminated with visible fecal material from entering the chiller 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 controls for them. Requiring establishments to keep daily written records to document the implementation and monitoring of their process control procedures is a positive step forward for public health. This ongoing documentation will allow both the establishment and FSIS to identify specific points in the production process where a lack of process control may have resulted in product contamination or insanitary conditions. This will allow the establishment to take the necessary corrective action to prevent further product contamination. FSIS seeks comment on the extent

to which written sanitary dressing plans are necessary for ensuring that existing process controls are effective.

While many establishments may already have written sanitary dressing plans, due to data limitations, this analysis assumes that every establishment will need to develop a written sanitary dressing plan. This assumption will help ensure a conservative estimate. Ongoing sanitary dressing documentation will allow both the establishment and FSIS to identify specific points in the production process where a lack of process control may have resulted in product contamination or insanitary conditions.

2. Process Control Sampling and Analysis for Microbial Organisms

Under this proposed rule, instead of following a prescribed microbiological testing program, each establishment would be responsible for developing and implementing its own microbiological sampling plan, which would be required to include carcass sampling at pre-evisceration and post-chill. Current microbiological standards prescribe that all establishments monitor process control by sampling for generic E. coli. High volume establishments are required to take one sample per 1,000 carcasses, or request an alternative rate. The Agency is seeking comment on both the number of establishments conducting alternative sampling rates and approved alternative sampling rates. Very low volume establishments are required to take 1 sample per week of operation up to 13 times a year. An

industry survey found that many establishments elect to perform other microbiological tests in addition to testing for generic E. coli.²⁰

3. Environmental Sampling

FSIS is proposing to require that all official swine slaughter establishments develop, implement, and maintain in their HACCP systems written procedures to prevent contamination of the pre-operational environment by enteric pathogens.

Such procedures must be incorporated into an establishment's HACCP, sanitation SOP, or other prerequisite program. This analysis assumes an establishment will incorporate its procedures for controlling contamination in the pre-operational environment into its sanitation SOP. These procedures must include sampling and analysis of food contact surfaces in the pre-operational environment at a frequency adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment.

F. Overview of the Proposed Rule's Agency Impact

This analysis also takes into consideration potential impacts to the Agency's budget, which is expected to be impacted by changes in staffing and training requirements. Under traditional inspection, each slaughter line requires up to 11

²⁰ Viator C. et. al. 2015. (a) Meat Industry Survey in Support of Public Health Risk-Based Inspection. P5-42. Question 3.1.

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 establishments expected to convert to NSIS, Table 5. When these establishments convert to NSIS, Agency personnel will require NSIS training. Additionally, the number of Agency personnel required to inspect the slaughter process will likely change, see Agency Staffing section for details.

Table 5: Current FSIS Slaughter Line Positions at Non-HIMP Facilities that Slaughter Exclusively Market Hogs

OPM Job Code	No. of Positions
1862	120
1863	245
701	53
Total	418

Source: PHIS

G. Expected Cost of the Proposed Rule

1. Associated with the NSIS Components of the Rule

This analysis estimates the cost associated with the proposed rule's NSIS components. The Agency assumes that 22 large high volume and 13 small high volume establishments, that

have a history of exclusively slaughtering market hogs, will adopt the NSIS portions of the rule. These 35 establishments have similar characteristics as 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, the benefits from adopting NSIS are expected to outweigh the 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. The Agency is seeking comment on this assumption. While the 5 HIMP establishments are expected to adopt the NSIS, they have already implemented the proposed changes associated with the NSIS by their participation in the HIMP program 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. This analysis excludes further consideration in the Preliminary Regulatory Impact Analysis of the costs of submitting an attestation of work related conditions due to its small expected cost.²¹ Costs

²¹ 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

examined generally fall under three categories: labor, capital expenses, and developing written procedures.

In the following sections, this analysis presents the costs and benefits that would be 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 which are likely to adopt the NSIS will incur additional costs associated with adoption. The Agency is seeking comment on this assumption. Note, the 5 HIMP establishments are not expected to incur any additional costs associated with adopting the NSIS and are therefore excluded from this portion. Also, based on actual NPIS adoption rates thus far, the assumptions presented in this analysis may be an overestimate of adoption of NSIS.

Table 6: NSIS Adoption Rate

Year	Total No. Of Establishments Adopted		Percent Adopted
	Large	Small	
1	4	2	17%
2	8	4	34%
3	12	7	54%
4	17	10	77%

28 large and 13 small establishments approximately \$93.64 annually (2 minutes * \$68.52 per hour * 41).

5	22	13	100%
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a. Costs of Additional Establishment Workers

This analysis expects establishments operating under NSIS to experience an increase in labor costs. Under NSIS, establishments will be required to dedicate labor to sort and remove unfit animals before ante-mortem inspection and trim; identify defects, such as dressing defects, contamination, and pathology defects, on carcasses and parts before post-mortem inspection; ensure product is presented to Agency inspectors in an appropriate manner; identify carcasses condemned on ante-mortem inspection; denature all major portions of condemned carcasses on-site; maintain records to document the number of animals condemned on ante-mortem inspection; and notify Agency inspectors if they suspect that an animal or carcass has a reportable or foreign animal disease, while conducting sorting activities. Based on observations²² of HIMP establishments, this increase in work is expected to require an increase in labor demand ranging from 6-10 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,

²² 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.

this analysis assumes small establishments that convert to the NSIS will require 1 additional worker per line per shift. The Agency seeks comment on the number of additional employees each establishment will require due to the NSIS. 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 will adopt NSIS operate multiple lines and shifts. Taking these multiple lines and shifts into consideration, the number of industry positions is expected to increase by 383. The majority of these, 369, are attributable to the large establishments (41 (number of lines) x 9)²³, Table 7. The remaining 14 positions are attributable to the small establishments (14 (number of lines) x 1)²⁴, Table 7. According to the Bureau of Labor Statistics (BLS) the expected hourly wage for a Slaughter and Meat Packer occupation ("production employee") is \$13.00.²⁵ 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

²³ Source: PHIS

²⁴ Source: PHIS

²⁵ BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2016. 51-3023 Slaughters and Meat Packers <http://www.bls.gov/oes/current/oes513023.htm> accessed on 7/24/17. Last modified 3/31/17.

benefits and overhead, is \$26.00 per hour ($\13.00×2^{26}). 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, ($369 \times \$26.00 \times 269 \times 8$), Table 7. The average small establishment slaughters on 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, ($14 \times \$26.00 \times 244 \times 8$), Table 7. These cost estimates take into consideration the fact that some establishments operate multiple lines and multiple shifts.

Training Online Sorters and Carcass-Inspection Helpers

Establishments are expected to incur costs associated with initially training employees to fill these 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.²⁷ To ensure a conservative estimate and account for employee rotation patterns

²⁶To 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.

²⁷ Viator. C. Et. Al. 2015. (b) Costs of Food Safety Investments. Table 4-4. Training Costs for Management and Production Employees.

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 \times \549), Table 7.

To account for expected turnover of establishment employees, FSIS projects that establishments will have to train approximately 452 ($1,532 \times 0.295$) replacement employees annually, 435 at the large and 17 at the small establishments.²⁸ The additional annual training cost for new employees is expected 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 \times \549), with large establishments accounting for approximately \$0.24 million ($435 \times \549) and small establishments accounting for approximately \$9,333 ($17 \times \549), Table 7.

FSIS assumes that 1,080 ($1,532 \times 0.705$) retained employees, 1,041 at the large and 39 at the small establishments, will

²⁸ 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. <<http://www.bls.gov/news.release/jolts.t16.htm>> Accessed on 7/21/17. Last updated on 3/16/17.

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, with a mid-point of \$24.²⁹ Using the mid-point value, this analysis estimates the combined average recurring cost for continuing education is \$25,920 (1,080 x \$24), with large establishments accounting for approximately \$24,984 (1,041 x \$24) and small establishments accounting for approximately \$936 (39 x 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 \$16.45 million, applying a 3 percent discount rate 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

²⁹ Viator. C. *Et. Al.* 2015. (b) Table 4-4. Training Costs for Management and Production Employees.

	Initial Training	56	\$0.03	
	Training Due to Labor Turnover	17		\$0.009
	Continuing Education	39		\$0.03
Totals				
One-Time				\$0.84
Recurring Cost				\$21.66
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				\$16.62
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				\$15.99

b. Costs of Capital Improvements: Line Configuration and Inspection Stations

As proposed, participating in NSIS does not necessitate capital improvements. As such, this analysis does not include capital expenditures. However, if establishments believe that capital expenditures would result in a benefit they may voluntarily reconfigure or update their facilities so as 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 to \$250,000³⁰, and the creation of an inspection station, which can

³⁰ In a May 2004 study, ERS estimated the cost of compliance per establishment with PR/HACCP rule. Capital expenditures in Hog Slaughter establishments were estimated to be \$251,800. Ollinger, Michael, Danna Moore, Ram Chandran (2004). Meat and Poultry Establishments' Food Safety Investments. USDA, Economic Research.

cost between \$5,000 and \$6,000.³¹ Establishments may reduce these costs by coordinating these facility updates with previously planned establishment renovations. The Agency is seeking comment on both the required and voluntary capital costs associated with the NSIS.

c. Costs of Developing Ante-Mortem Written Procedures

Under the proposed rule, establishments operating under NSIS are required to develop and maintain in their HACCP systems (HACCP plans, Sanitation Standard Operating Procedures, 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, fecal material, ingesta, and milk throughout the entire slaughter and dressing operation, a mandatory component of the proposed rule. Details of these costs can be found in the sanitary dressing costs section VI.2.a.

d. Ready-to-Cook Pork Standards

³¹ Modernization of Poultry Slaughter Inspection; Final Rule, 79 FR. 49566 (2014).

As proposed, establishments operating under NSIS are required to collect, record, and analyze documentation to demonstrate that the products resulting from their slaughter operation meet the proposed definition of RTC pork products. While the Agency is seeking comment on this requirement, this analysis estimates the labor costs to conduct such documentation under two assumptions. First, FSIS assumes that establishments would assign the task to a quality control technician, QC, with an hourly compensation rate, which included wages, benefits, and overhead, of \$68.52.³² Second, FSIS assumes that this work would take 1 hour at a large establishment and ½ hour at a small establishment. The Agency is seeking comment on this assumption. Based on information obtained through PHIS, the average large establishment operates 269 days per year. This equates to an annual cost of approximately \$18,432 ($268 * 1 * \68.52), or approximately \$0.41 million for all 22 establishments ($\$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

³² 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.

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\$)

		Recurring
Type of Market Hog Only Establishment	No. of Establishments	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

2. Costs Associated with the Mandatory Components of the Rule

The mandatory costs of the proposed rule are expected to apply to all 612 swine slaughter establishments and begin within the first year after the rule is finalized. These costs are associated with a) establishing and implementing written sanitary dressing plans to prevent contamination of carcasses and parts by enteric pathogens, fecal material, ingesta, and milk, throughout the entire slaughter and dressing operation; b) modernizing process control sampling programs for microbial organisms; and c) sampling the slaughter environment for microbiological contamination.

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

Under the mandatory portion of the proposed rule affecting all federally inspected establishments that slaughter swine, FSIS is proposing to require 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, fecal material, ingesta, and milk throughout the entire slaughter and dressing operation. This cost component includes: (1) developing these procedures into their food safety system, (2) training, and (3) monitoring, recordkeeping, and verification.

Developing and Composing

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 the Research Triangle Institute's (RTI) Costs of Food Safety Investments report,³³ 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 \$365.³⁴ To ensure a conservative cost estimate, this analysis assumes all 612 swine establishments

³³ Viator. C. Et. Al. 2015. (b) 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.

³⁴ Viator. C. Et. Al. 2015. (b) Table 4-2. Costs of Sanitation SOP Plan Development, Validation and Reassessment

will incur this cost. The Agency is seeking comment on this assumption. The cost to all large establishments is approximately \$20,440 (28 * \$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 612 swine slaughter establishments is approximately \$0.03 million, Table 9.

Table 9: Written Sanitary Dressing Plan Development (M\$)

HACCP Size	Number of Plants	One-Time Cost
Large	28	\$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

Training

Training programs should 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.³⁵ As is noted in the

³⁵ Viator, C. et. al. 2015. (b)

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 actually 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.³⁶ 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. The Agency is seeking comment on this assumption.

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 Bureau of Labor Statistics', BLS, 2016 turnover rate for non-durable manufacturing goods.³⁷ 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 612 establishments

³⁶ 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]

³⁷ This analysis uses the industry turnover rate for non-durable manufactured goods to estimate. Source: BLS Economic News Release Table 16. Annual total separations rates by industry and region, not seasonally adjusted. <<http://www.bls.gov/news.release/jolts.t16.htm>> Accessed on 7/21/17. Last updated on 3/16/17.

is roughly \$1.13 million, while the total recurring costs is roughly \$0.49 million, Table 10. The annualized costs with a 3 percent discount rate over 10 years for Sanitary Dressing task related training is \$0.62 million, Table 10.

Table 10: Sanitary Dressing Training Costs (M\$)

			Training Costs		
			One-Time	Recurring	
HACCP Size	No. of Establishments	Average No. of Employees	Initial	New Hires	Refresher
Large	28	179	\$0.61	\$0.18	\$0.09
Small	105	25	\$0.32	\$0.09	\$0.04
Very Small	479	3	\$0.20	\$0.06	\$0.03
Totals					
One-Time Cost					\$1.13
Recurring Cost					\$0.49
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years					\$0.62
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years					\$0.64

Monitoring, Recordkeeping, and Verification

This analysis also measures the annual monitoring, recordkeeping and verification costs associated with maintaining sanitary dressing procedures. Similar to the Modernization of Poultry Slaughter Inspection Final Rule,³⁸ 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 expected to verify the plan each day of production. In addition,

³⁸ 79 FR 49566 - 49637, August 21, 2014.

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 \$0.85 million annually, applying a 3 percent discount rate over 10 years, Table 11.

Table 11: Monitoring, Record Keeping and Verification Costs (M\$)

Recurring Costs				
HACCP Size	Monitoring	Record Keeping	Verification	Combined
Large	\$0.016	\$0.02	\$0.04	\$0.07
Small	\$0.038	\$0.04	\$0.12	\$0.20
Very Small	\$0.070	\$0.07	\$0.44	\$0.58
Totals				
Recurring Cost				\$0.85
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				\$0.85
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				\$0.85

Summary Cost 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 \$1.50 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\$)

	One-Time Costs	Recurring Costs

HACCP Size	No. Of Establishments	Development	Initial Training	Training	Monitoring, Recording, Validating
Large	28	\$0.02	\$0.61	\$0.27	\$0.07
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					\$1.36
Recurring Cost					\$1.34
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years					\$1.50
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years					\$1.53

b. Process Control Sampling and Analysis for Microbial Organisms

This section reviews the expected changes in costs associated with the proposed alterations to microorganism process control verification. These costs are limited to the changes associated with removing the requirement that swine establishments test carcasses for generic E. coli and replacing them with new testing requirements described above. While the proposed 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 expected 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 report³⁹ and Costs of Food Safety Investments report.⁴⁰ Each of these categories is explained in detail below.

Process Control Sampling Plan Reassessment

This analysis assumes establishments will incur one-time costs of conducting a process control sample plan reassessment under the proposed 9 CFR 310.25(a)(2)(i). The RTI Costs of Food Safety Investment 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.⁴¹ The annualized reassessment cost to industry is roughly \$0.19 million, assuming a 3 percent discount rate over 10 years, Table 13.

Table 13: Costs of Process Control Sampling Plan

³⁹ 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 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.

⁴⁰ Viator C. et. al. 2015. (b)

⁴¹ 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.

Reassessment (M\$)

HACCP Size	No. of Establishments	Per Establishment (Mid-Point Estimate)*	Total One-Time Costs
Large	28	\$0.05	\$1.53
Small	105	\$243	\$0.03
Very Small	479	\$243	\$0.12
Totals			
One-Time Cost			\$1.67
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			\$0.19
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			\$0.22

*The values for Small and Very Small Establishments are in dollars.

Transferring from prescriptive to process testing requirements

Current regulation prescribes that each slaughter facility will test for generic E. coli.⁴² In addition to mandated generic E. coli testing, many establishments voluntarily conduct additional microbiological testing to verify process control. Common microbiologic tests include aerobic plate count (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.⁴³ Establishments voluntarily conducting additional testing are an indication that the generic

⁴² 9 CFR 310.25

⁴³ Viator C. et. al. 2015. (a) P5-42. Question 3.1.

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 would 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 28 large (28 * 1.00), 41 small high volume (51 * .80), 43 small low volume (54 * .80) and 342 very small (479 * .714) establishments that currently test for generic E. coli and at least one other microbial or pathogen indicator⁴⁴ would 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 and small high volume establishments conduct 1 test, every

⁴⁴ 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.

1,000 carcasses, and all small low volume and very small establishments conduct 13 tests annually.⁴⁵ The Agency is seeking comment on this assumption. 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 \$24.92.⁴⁶ To have the sample tested at a contracted lab, the cost is \$48.76.⁴⁷ 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.⁴⁸ For these 454 establishments, the combined reduction in testing costs of no longer being required to test for generic E. coli is expected to reduce annual testing costs by approximately \$3.92 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	No. of Establishments	(Savings)
Large	28	(\$3.28)
Small High Volume	41	(\$0.40)
Small Low Volume	43	(\$0.02)

⁴⁵ 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

⁴⁶ Viator C. et. al. 2015. (b) Table 5-1

⁴⁷ Viator C. et. al. 2015. (b) Table 5-1

⁴⁸ Viator, C. et. al. 2015. (b)

Very Small	342	(\$0.22)
Totals		
Recurring Cost		(\$3.92)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(\$3.92)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(\$3.92)

Process Control Sampling Rates

The proposed rule would require large and small high volume establishments to take samples at pre-evisceration and post-chill, which would increase the number of samples taken from 1 sample per 1,000 carcasses to 2 samples per 1,000 carcasses for large and small high volume establishments. The proposed rule does not require small low volume and very small establishments to increase their sampling rates. Under the proposed regulations, large establishments annual process control sampling costs are expected to increase by roughly \$2.34 million, which is roughly \$83,639 per establishment (\$2.34 million / 28), Table 15. Small high volume establishments annual process control sampling costs are expected to increase by roughly \$0.29 million, which is roughly \$5,740 (\$0.29 million / 51) per establishment, Table 15.

Process Control Sample Record Keeping

This analysis takes into consideration the increase in record keeping 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 establishment slaughters approximately 3.77 million swine per year. As such, this analysis estimates that a large establishment currently takes approximately 3,774 samples annually ($3,774,223 / 1,000$). The average small high volume swine establishment slaughters 0.23 million swine per year and requires approximately 229 samples ($228,784 / 1,000$) annually. Assuming it takes 2.5 minutes to record the results of each sample, the average large establishment currently requires 9,435 minutes ($2.5 * 3,774$) per year and the average small high volume establishment currently requires 573 minutes ($2.5 * 229$) per year. Requiring establishments to increase their sampling rates from 1 to 2 samples per 1,000 head would increase the average large establishment's annual number of samples to 7,548 samples annually ($3,774,223 / 1,000 * 2$), which would require approximately 18,870 minutes ($2.5 * 7,548$) annually. The same requirement would increase a small high volume establishment's annual sampling to 458 ($228,784 / 1,000 * 2$), which would require approximately 1,145 minutes ($2.5 * 458$) annually. As such, the expected additional time required for recordkeeping is approximately 9,435 minutes ($18,870 - 9,435$) for large establishments and 572 minutes ($1,145 - 573$) for small high volume establishments. Assuming a quality control technician with a compensation rate of \$68.52 per hour⁴⁹ conducts this work,

⁴⁹ To be consistent with analyses done by the Department of Health and Human

the additional costs to the average large establishment is approximately \$10,775 ($9,435/60 * \68.52). Similarly, the additional cost to the average small high volume establishment is approximately \$653 ($572 / 60 * 68.52$). Scaling this up to all establishments, the total increase in costs to all large establishments is approximately \$0.30 million ($\$10,775 * 28$) and \$0.03 million ($\$653 * 51$) for small high volume establishments, Table 15.

The combined annualized sampling and recordkeeping cost to all large and small high volume establishments is roughly \$2.97 million, applying a 3 percent discount rate over 10 years. Large establishments are expected to incur the majority of this cost.

Table 15: Costs Changes Associated With Increase Sampling Rates (M\$)

	No. Of Establishments	Costs		
		Sampling	Recordkeeping	Combined
Large	28	\$2.34	\$0.30	\$2.64
Small - High Volume	51	\$0.29	\$0.03	\$0.33
Totals				
Recurring Cost				\$2.97
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years				\$2.97
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years				\$2.97

Summary of Process Control Sampling Costs Changes

Services, this analysis accounts for benefits and overhead by multiplying wages by a factor of 2.

Overall, the changes in sampling requirements under the proposed rule are expected to reduce industry wide sampling costs by about \$0.76 million annualized over 10 years, applying a 3 percent discount rate, Table 16. However, only the 454 establishments that currently conduct multiple types of microbiological tests are expected to experience a reduction in cost. The remaining establishments, roughly 158 small and very small establishments, are expected to 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 and small high volume establishments.

Table 16: Summary of Changes to Process Control Sampling (M\$)

Type of Change	Cost (Savings)	
	One-Time	Recurring
Plan Reassessment	\$1.67	-
Converting to Process Control Sampling	-	(\$3.92)
Testing Costs	-	\$2.63
Recordkeeping	-	\$0.33
Totals		
One-Time Cost		\$1.67
Recurring Cost		(\$0.95)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(\$0.76)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(\$0.72)

c. Environmental Sampling

As proposed, all swine slaughter establishments will be required to control for enteric pathogen contamination in the pre-operational environment. Such controls will have to be included in an establishment's HACCP system, requiring a plan reassessment. This analysis assumes establishments will coordinate this work with the HACCP plan reassessment required by the development of written sanitary dressing procedures. As such the cost of incorporating pre-operational environment sampling plans into an establishment's HACCP system is included in the reassessment costs associated with written sanitary dressing procedures.

While establishments will set sampling frequency so as to ensure effective control, this analysis assumes each large establishment will take 4 samples per 30 days of operation per line, while each small high volume establishment will take 2 samples per 30 days of operation per line, and small low volume and very small establishments will take 1 sample per 30 days of operation per line.⁵⁰ Under this assumption, the annual number of

⁵⁰ In absence of other data we assumed establishments would conduct environmental sampling similar to the recommended frequencies described on Page 91 in: FSIS Compliance Guidelines: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. January 2014. Accessed on 12/3/15. Available at <http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>. Industry is familiar with this methodology for sampling food-contact-surfaces in the post lethality environment to ensure that the surfaces are sanitary and free of *Listeria monocytogenes* or an indicator organism. We assumed industry would

tests required by the entire industry is approximately 3,266. The Agency is seeking comment on this assumption. Establishments are permitted to conduct a variety of tests, including testing for Aerobic Plate Count, APC, Coliforms, Generic E. coli, Total Plate Count, TPC, and Salmonella. The laboratory testing costs for these test range from \$15 to \$32, with an average mean testing cost of \$19, Table 17.⁵¹

Table 17: Laboratory Testing Costs

Test	Minimum	Mean	Maximum
APC	\$16	\$18	\$20
Coliforms	\$15	\$18	\$22
E. coli	\$15	\$18	\$22
Salmonella	\$17	\$25	\$32
TPC	\$16	\$16	\$17
Average	\$16	\$19	\$23

Source: Viator. C. Et. Al. 2015. Costs of Food Safety Investments. Table 5-1. Laboratory Testing Costs.

To ensure a conservative estimate this analysis assumes establishments will test for Salmonella, which is the most expensive option, Table 17. Under these assumptions, the combined total annual environmental sampling cost is approximately \$0.08 million (3,266 x \$25). The annualized cost of these combined expenditures is roughly \$0.08 million, assuming a 3 percent discount rate over 10 years, Table 18.

take a similar approach in sampling food-contact-surfaces in market hog establishments to meet the proposed environmental sampling requirements.

⁵¹ Viator. C. Et. Al. 2015. (b) Table 5-1. Laboratory Testing Costs.

Table 18: Costs of Environmental Sampling (M\$)

HACCP Size	No. of Establishments	Sampling Costs
Large	28	\$0.03
Small High Volume	51	\$0.02
Small Low Volume	54	\$0.004
Very Small	479	\$0.03
Totals		
Recurring Cost		\$0.08
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		\$0.08
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		\$0.08

Summary of Voluntary and Mandatory Costs

The total annualized value of all costs to industry, under the assumed five year adoption rate as shown in Table 6, is roughly \$17.84 million, assuming a 10 year annualization and a 3 percent discount rate, Table 19. 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 establishments have already incurred these costs, suggesting for those five establishments, the benefits of NSIS outweigh the costs. It also suggests that the benefits of adopting 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 are expected to decrease for those establishments that

currently conduct microbiological tests in addition to generic E. coli.

Table 19: Combined Costs to Industry (M\$)

Type of Cost	No. of Establishments	Total Costs	
		One-Time	Recurring
<i>Voluntary</i>			
Establishment Labor	35	\$0.84	\$21.66
Ready to Cook	35		\$0.51
<i>Mandatory</i>			
Written Sanitary Dressing Plan	612	\$1.36	\$1.34
Process Control Sampling	612	\$1.67	(\$0.95)
Environmental Sampling	612	\$0.0	\$0.08
Totals*			
Number of Establishments			612
One-Time Cost			\$3.88
Recurring Cost			\$22.65
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			\$17.84
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			\$17.24

Totals Mandatory*	
Number of Establishments	612
One-Time Cost	\$3.03
Recurring Cost	\$0.48
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	\$0.82
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	\$22.17
Annualized Costs, Assuming a 3% Discount	\$17.02

Rate Over 10 Years	
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	\$16.36

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

H. Expected Benefits of the Proposed Rule

1. Expected 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 expected to reduce pathogen levels in swine slaughter establishments. 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 HACCP-based Inspection Models Project (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. 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 change in carcass

contamination prevalence under the inspection procedures of NSIS.

Changes in expected 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.^{52,53} 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, if the proportion of carcasses with no detectable Salmonella contamination increases with implementation of the NSIS, illnesses caused by consumers' exposure to these carcasses are expected to decrease proportionally.

The market hog Salmonella illness risk model estimates that the prevalence of Salmonella detected in carcasses will decline on average from an initial prevalence of 0.9407% to a final

⁵² 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.

⁵³ 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.

prevalence of 0.9066% if the 35 establishments identified adopt the new inspection system. The uncertainty of the final prevalence ranges from 0.8982% to 0.915%, at the 10th and 90th percentiles, respectively. 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.⁵⁴

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

⁵⁴ 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

inactivation and growth between production and consumption.⁵⁵ 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 768 and 4,287 decreased cases, respectively. The total case uncertainty distribution is dependent on the uncertainty in the change in Salmonella prevalence in market hogs which has an average percent uncertainty of a 3.626% decrease and is bounded at the 10th and 90th percentiles by a decrease of 1.0989% and 6.1362%, respectively.

The prevalence estimates are modeled with data variability and robust uncertainty components taken from sampling data and model parameter estimates. 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

⁵⁵ 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.

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, without intervention. With adoption of the new inspection system, the average number of cases is likely to decrease to 67,324 with 10th and 90th percentiles of 38,653 and 101,417 cases, respectively.

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 illness attributed to products derived from market hogs could reduce by an average of 2,533 Salmonella illnesses. The combined robust model estimate of total 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 768 and 4,287 decreased cases, respectively. 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 \$3,682.⁵⁶ These estimates factor in the costs of physician office, emergency room, and outpatient clinic visits, as well as hospitalizations, productivity loss,

⁵⁶ 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.

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 20. The cost savings assuming the lowest cost per illness and only 768 cases avoided, which corresponds to the 10th percentile, is \$0.25 million, Table 20. Alternatively, the cost savings assuming the highest cost per illness and 4,287 averted illnesses, which corresponds to the 90th percentile, is \$24.95 million, Table 20. 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 20. 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 detectable with Salmonella.

Table 20: Health Benefits from Averted Cases of Salmonella

Percentile	Illnesses Averted by Scenario	Cost Per Illness*		
		Low	Mid	High
		\$321	\$3,682	\$5,820
Scenario Costs, \$M				
10 th	768	(\$0.25)	(\$2.83)	(\$4.47)
Mean	2,533	(\$0.81)	(\$9.33)	(\$14.74)
90 th	4,287	(\$1.38)	(\$15.79)	(\$24.95)

Totals (Low) (M\$)	
Recurring Cost	(\$0.25)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	(\$0.19)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	(\$0.18)
Totals (Mid) (M\$)	
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)
Totals (High) (M\$)	
Recurring Cost	(\$24.95)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years	(\$18.97)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years	(\$18.22)

*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

2. Other Benefits Associated With Modernizing Existing Regulations

The proposed regulation is expected to reduce the regulatory burden on establishments by shifting from prescriptive to performance based regulation. Specifically, the proposed rule amends requirements related to slaughter line speeds,⁵⁷ microbiological testing, and sorting activities. Based

⁵⁷ According to the Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs Final Report, November 2014, "In CY 2013, the estimated line speeds at the 5 HIMP market hog establishments varied from 885 to 1,285 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".

on the Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs report, the five HIMP establishments' average line speed were approximately 12.49 percent faster than comparable establishments.⁵⁸ 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' average pork packer margins for 2010-2014, which was reported to be \$4.10 per head in NAMI's 2015 Meat and Poultry Facts.⁵⁹ The pork packer margin is the price the packer receives less the cost of the hog and production costs, making the packer margin an approximation for producer surplus. FSIS requests comment on refining this estimate so as to distinguish between accounting profit and economic profit – the latter being more precisely associated with producer surplus.

Assuming establishments increase their line speeds by 12.49 percent and have a packer margin of \$4.10 per head, an average large establishment's surplus could increase by approximately \$2.04 million, while an average small high volume establishment's surplus could increase by \$0.18 million, all else being equal. Combined, such an increase in efficiency at

⁵⁸ 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--himp> Accessed on 1/6/2017. Last updated on 11/14/2014.

⁵⁹ Nalivka, J. S., The 2015 Meat and Poultry Facts, NAMI December 2015

all 35 establishments would increase producer surplus by roughly \$47.33 million⁶⁰ (22 x \$2.04 million + 13 x \$0.18 million), which has an annualized benefit of roughly \$47.33 million, assuming a 3 percent discount rate over 10 years, Table 21. 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, consumer benefits would be conditional on how an increase in line speed affects retail prices. As such, the Agency is seeking comment on the extent to which such an increase in line speeds would affect market hog prices, establishment hours of production, consumer prices, and export volumes.⁶¹

Table 21: Industrial Efficiency, (Benefits) M\$

Type of Establishment	No. of Establishments	Change in Efficiency	
		Per Establishment	Combined

⁶⁰ Note, some of the totals may not equal the sum due to rounding.

⁶¹ The Agency further notes that marginal costs typically increase as a function of production quantity, in which case profit margins reach zero for the last unit of production; indeed, the phenomenon of rising marginal costs is consistent with the observation of HIMP line speed increases that are less than the maximum increase that is theoretically permissible. Assuming linearity of the relevant marginal cost curve would yield a margin of \$2.05 per head, thus making producer surplus half the amount estimated here as the change in industrial efficiency. Meanwhile, if demand and supply elasticities for pork products are similar--which may or may not be plausible--then consumer surplus would increase by half the industrial efficiency amount estimated here, thus making the overall efficiency change estimate a reasonable approximation for the total (consumer plus producer) surplus gain.

Large	22	(\$2.04)	(\$44.97)
Small	13	(\$0.18)	(\$2.37)
Combined*	35		(\$47.33)
Totals			
Recurring Cost			(\$47.33)
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years			(\$36.14)
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years			(\$34.74)
* 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.⁶² The five establishments that participated in the pilot project account for 15 percent of total swine production.

Additionally, NSIS inspection increases the Agency's ability to conduct more process and product verification and 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 HATS categories in HIMP market hog

⁶² 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-+himp> Accessed on 1/6/2017. Last updated on 11/14/2014.

establishments compared to approximately 4.29 hours per shift in the 21 non-HIMP market hog comparison establishments.⁶³ Under 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. Expected Budgetary Impacts

Under the proposed rule, the Agency would shift Agency resources from online to offline activities. This analysis estimates such a shift will reduce labor expenses by approximately \$6.67 million annually, Table 22. However, Agency personnel at NSIS establishments will require additional training, the annualized cost of which is estimated to be approximately \$0.30 million. Both of these annualized estimates apply a 3 percent discount rate over 10 years. Details of these costs are provided below.

1. Agency Staffing

⁶³ 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--himp> Accessed on 1/6/2017. Last updated on 11/14/2014.

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 and up to 2 FTEs at a small market hog establishment. Under NSIS, a single slaughter line at a large establishment is expected to require 6 FTEs, while a small market hog establishment is expected to require 3 FTEs. Large establishments with two slaughter lines are expected to require 10 FTEs, while a small market hog establishment with 2 slaughter lines is expected to require 4 FTEs.

This analysis considers likely staffing changes at the 22 large and 13 small establishments which are expected to convert to NSIS over a course of five years. Combined, these establishments operate 46 shifts and 55 lines.⁶⁴ 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

⁶⁴ The 22 large establishments operate 41 slaughter lines during 32 shifts, while the 13 small establishments operate 14 lines during 14 shifts, source PHIS.

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 22. If all 22 large non-HIMP and 13 small high volume market hog only establishments convert to the NSIS, the Agency would 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 would have up to 3 FTEs assigned to them and each of the 32 shifts at the large establishments would have up to 2 FTEs assigned to them ((41 lines x 3 FTEs) + (32 shifts x 2 FTEs) = 187 FTEs). Likewise, under NSIS, the 13 small establishments would 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 22. This cost estimate includes expected grade increases associated with converting to the NSIS. As is shown in Table 22, 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 would require 147 fewer FTEs for swine slaughter inspection, with an expected 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, Table 22.

Table 22: Expected Changes in Agency Staffing (M\$)

Type	Traditional		Proposed NSIS		Increases (Reductions)	
	No. Positions	Labor Costs	No. Positions	Labor Costs	No. 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 23 for details. The Agency plans to utilize all personnel made available as a result of conversion to NSIS to fill these vacant positions.

Table 23: Annual Turnover of Food Inspectors

Fiscal Year	No. Of Positions
2008	307
2009	264
2010	231
2011	268
2012	266
2013	246
2014	273
2015	305
Average	270

Source: OFO

2. Agency Training

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 expects to train 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 24. 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 program, 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 (\$550,942 for all large establishments and \$81,697 for all small establishments), Table 24. This one-time cost equals approximately \$0.07 million if it were annualized over 10 years under a 3 percent discount rate, Table 24.

Table 24: Three day NSIS Training Course (M\$)

Type of Establishment	Cost of Trainee		Replacement Labor		Combined Costs
	No. Of Inspectors Requiring Training	Costs of Wages and Benefits For Trainees	No. 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

Fill an Increase Need for Consumer Safety Inspectors

As proposed, 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 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 25. Nearly half of this cost stems from the need for replacement labor. Again, under the proposed five year adoption rate, as set forth in Table 6, and under a 3 percent discount rate the annualized costs is approximately \$0.23 million, Table 25.

Table 25: 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 MI 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

Combined Expected Budgetary Impacts

The Agency's budget is expected to be impacted both by changes to personnel and training requirements. First, there will be a reduced need for Agency personnel to inspect a slaughter line operating under NSIS. If all 22 large and 13 small establishments convert to NSIS over the course of five

years, the Agency would require approximately 147 fewer FTEs to inspect the 55⁶⁵ slaughter lines operating at these establishments. The annual remuneration value of these 147 positions is roughly \$8.73 million, Table 26. Second, the Agency will need to train approximately 266 personnel on NSIS methods at a one-time cost of approximately \$0.64 million, Table 26. 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 26. 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 26.

Table 26: 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

⁶⁵ Source: PHIS

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

With the expected impact on the Agency's budget and industry's revenue included, and assuming all 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 \$31.77 million a year, annualized over 10 years assuming a 3 percent discount rate, Table 27. The majority of the costs are experienced by the 35 non-HIMP establishments expected to voluntarily switch to the NSIS in the form of increased labor needs.

Table 27: Net Costs and (Benefits) (M\$)

	Number of Establishments	One-Time	Recurring
Costs To Industry		\$3.88	\$22.65
Voluntary*	40**	\$0.84	\$22.17
Mandatory	612	\$3.03	\$0.48
Health Benefits***			(\$9.33)
Industrial Efficiency			(\$47.33)

Impacts to Agency's Budget		\$2.80	(\$8.73)
Totals			
One-Time Cost		\$6.68	
Recurring Cost		(\$42.75)	
Annualized Costs, Assuming a 3% Discount Rate Over 10 Years		(\$31.77)	
Annualized Costs, Assuming a 7% Discount Rate Over 10 Years		(\$30.40)	

* Further explanation and details on the NSIS adoption rate are provided in section G. Expected Cost of the Proposed Rule, Table 6: NSIS Adoption Rate and section J. Net Benefits, Table 28: Quantified Cost and (Benefits) of Various Adoption Rates

** Note, this includes 5 HIMP establishments, which are not expected 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. Expected Benefits Associated With Public Health, Table 20: Health Benefits from Averted Cases of Salmonella. The value of health benefits ranges from \$0.19 million to \$18.97 million, with a mean of \$9.33 million.

Given the lack of data with which to make cost-benefit comparisons across the industry, Table 28 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 would not be any additional voluntary costs or benefits associated with these 5 establishments adopting the NSIS. However, all 612 establishments would incur costs associated with the proposed 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 40 establishments converting to the NSIS, respectively. Each of these scenarios are net beneficial.

Table 28: Quantified Cost and (Benefits) of Various Adoption Rates (M\$) ^

	No. to Adopt *	Costs		(Benefits)			Net
		Mandatory ^e	NSIS	Health	Line Speeds	Agency Budget	
A	5	\$0.82	\$0.0	\$0.0	\$0.0	\$0.0	\$0.82
B	6	\$0.82	\$0.86	(\$0.27)	(\$2.04)	(\$0.38)	(\$1.00)
C	23	\$0.82	\$8.35	(\$3.59)	(\$18.01)	(\$3.14)	(\$15.57)
D	32	\$0.82	\$13.09	(\$5.52)	(\$27.82)	(\$4.88)	(\$24.30)
E	40	\$0.82	\$17.02	(\$7.09)	(\$36.14)	(\$6.38)	(\$31.77)

* 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.

^e These costs are incurred by all 612 swine establishments.

[^] Annualized Assuming a 3% Discount Rate Over 10 Years

K. Alternatives

Table 29: 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 Proposed Rule Only	1. In comparison to the baseline, potential \$0.76M in Process Control Sampling cost savings.	1. In comparison to the baseline, potential \$1.58M in Other Industry Costs.	Costs of \$0.82M
C. Proposed Rule (40 Establishments Adopt NSIS)	1. Potential \$7.09M in averted illnesses.	1. Potential \$16.62M Increase in Industry Labor Costs	Benefits of \$31.77M
	2. Potential \$36.14M in Industrial Efficiency.		
	3. Potential \$0.76M in Process Control Sampling cost savings.	2. Potential \$1.97M in Other Industry Costs	
	4. Roughly \$6.67M in Agency Labor Savings.	3. Roughly \$0.30M in Agency Training Costs	
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 \$16.83M
	2. Potential \$36.14M in Industrial Efficiency.		
	3. Potential \$0.76M in Process Control Sampling cost savings.	2. Potential \$3.3M in Other Industry Costs	

	4. Roughly \$2.72M in Agency Labor Savings.	3. Roughly \$0.68M in Agency Training Costs	
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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 NSIS. These benefits include the establishment’s ability to innovate and develop process controls which increase foodborne hazard detection and more efficiently use all of 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 proposed rule.

B - The Mandatory Portion of the Proposed Rule

FSIS considered limiting the proposed rule to only include the mandatory sections. Under such a scenario quantified benefits are limited to an estimated \$0.76 million reduction in process control sampling costs. This cost reduction is expected to be off-set by a \$1.58 million increase in other industry costs associated with requiring written sanitary dressing plans

and environmental sampling. In comparison to the baseline, this scenario has a net cost of roughly \$0.82 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 expected \$6.67 million. However, because FIs will 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 proposed 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 expected net cost as compared to the baseline as well as the decrease in net benefits as compared to the proposed rule.

C - The Proposed Rule

Applying a 3 percent discount rate over 10 years the costs associated with the proposed rule include \$16.62 million in additional industry labor costs, \$1.97 million in other industry costs including costs associated with meeting ready to cook standards, written sanitary dressing plans, and environmental sampling, and \$0.3 million in Agency training costs. The quantified health benefits of the proposed 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 is expected to increase their efficiency by \$36.14 million, assuming a 3 percent discount rate. The proposed rule is also expected to reduce industry costs associated with process control sampling by roughly \$0.76 million, assuming a 3 percent discount rate. Additionally, the proposed rule is expected to reduce the Agency's labor costs by roughly \$6.67 million, assuming a 3 percent discount rate. In comparison to the baseline, the proposed rule has an estimated net benefit of \$31.77 million, assuming a 3 percent discount rate over 10 years and as such the Agency recommends the proposed 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 HIMP, 27 large, and 13 small high volume establishments expected to convert under the proposed rule to include 572 additional establishments. This expansion would include low volume establishments that slaughter all types of swine as well as 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 \$36.14 million increase in industrial efficiency, \$0.76 million in industrial savings associated with process control sampling requirements, and \$2.72 million in Agency labor cost savings, assuming a 3 percent discount rate over 10 years. 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 proposed 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 proposed 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. While compared to the baseline, this alternative reduces Agency labor costs; it would result in additional promotions reducing the benefit in comparison to the proposed rule.

In comparison to the baseline, the potential costs associated with this alternative include a \$25.90 million increase in industrial labor, a \$3.30 million increase in other industry costs which include costs associated with ready to cook standards, written sanitary dressing plans, and environmental sampling, and roughly \$0.68 million in Agency training costs. In comparison to the proposed rule, the additional increases in costs to industry predominately fall on small and very small business. While this alternative has a net benefit of \$16.83 million, assuming a 3 percent discount rate over 10 years, the Agency rejects it because its net benefit is less than the proposed rule.

VII. Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would 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. At the beginning of section VI is a list of specific economic issues that the Agency is seeking comment on. Section VI also provides additional details on costs incurred by small businesses.

The proposed rule's mandatory requirements would 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 plant, applying a 3 percent discount rate over 10 years. Second, the mandatory proposed changes to process control sampling requirements are expected to decrease small establishments' sampling costs by roughly \$1,296 per establishment annually, applying a 3 percent discount rate over 10 years. In addition to this sampling cost reduction, the Agency would allow small and very small establishments to modify their sampling plans to collect samples less frequently once they have collected 13 consecutive weekly samples and have demonstrated that they are effectively maintaining process

control. FSIS is also proposing to allow establishments to develop sampling plans that are more tailored to their specific establishment, and thus more effective in monitoring their specific process control than the current generic E. coli criteria. Third, the mandatory environmental sampling program is expected to increase the average small and very small establishments' costs by \$87 per establishment annually, assuming a 3 percent discount rate over ten years. Therefore, the proposed rule's mandatory requirements are expected to increase small establishments' costs by roughly \$660 ($\$1,869 - \$1,296 + \$87 = \660) per establishment annually, an amount that is expected to have little effect on small entities. To put this in perspective, the average small and very small establishment slaughters over 21 thousand swine annually. Using the American Meat Institute's average pork packer dollars per head margins for 2010-2014, the average small and very small establishment's marginal revenue is \$0.09 million ($21,858$ (heads slaughtered) \times $\$4.10$ (average margin per head)). Additionally, the voluntary NSIS portion of the rule is expected to provide an overall cost savings for the 13 small high volume establishments or roughly \$87,449 per establishment that adopt the NSIS. This estimate takes into consideration the increase in labor cost (\$43,439 per establishment), cost associated with meeting ready-to-cook standards (\$6,300 per establishments) and cost savings from

increased industrial efficiency (\$137,189 per establishment).
See section VI for additional details.

Executive Order 13771

Consistent with EO 13771 (82 *FR* 9339, February 3, 2017), we have estimated that this proposed rule would yield cost savings. Assuming a 7 percent discount rate and a perpetual time horizon and a starting year of 2018, the proposed rule would yield approximately \$24.97 million (2016\$) in cost savings, not including health benefits. Therefore, if finalized as proposed, this rule is expected to be an EO 13771 deregulatory action.

VIII. 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.

IX. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 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.

X. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with 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.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

XI. 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.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

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

Fax: (202) 690-7442

E-mail: 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).

XII. 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 Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4 (b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4 (b)(6)).

Establishments that operate under the proposed NSIS are expected to 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 sales is very small, 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.

XIII. Paperwork Reduction Act

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

Title: Swine Slaughter Inspection.

Type of Collection: New.

Abstract: Under this proposed rule, establishments operating under NSIS would have to develop, implement, and maintain in their HACCP systems written procedures for the segregation, identification, and disposition of animals exhibiting signs of moribundity, central nervous system

disorders, or pyrexia. In addition, each official swine slaughter establishment would need to maintain, as part of its HACCP system, written procedures for (1) preventing throughout the entire slaughter and dressing operation, contamination of carcasses and parts by enteric pathogens, fecal material, ingesta, and milk and (2) preventing contamination of the pre-operational environment by enteric pathogens. The procedures addressing prevention of contamination by enteric pathogens would need to include microbial testing. Furthermore, all swine slaughter establishments operating would have to maintain records that document that the products resulting from its slaughter operations meet the definition of RTC pork products. Each establishment operating under the NSIS would also need to submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers.

The requirement that 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 proposed rule would create no new burden on establishments.

The proposed requirement that swine slaughter establishments monitor their systems through microbial testing and recordkeeping would create a new information collection burden. For each sample on which a microbiological test is conducted, there are two "responses" for the establishment: one response for the actual collecting of the sample and sending it to the laboratory for analysis, and the other for recording the sample result. Under the proposed rule, large establishments would test and record microbiological results for enteric pathogens, at both pre-evisceration and post-chill, 13 times a day; small high-volume establishments, one-time a day; and small low-volume and very small establishments, 13 times a year. FSIS estimates that large establishments would test and record microbial results for the pre-operational environment weekly; small establishments, biweekly; small low-volume and very small establishments, monthly.

Estimated Annual Recordkeeping Burden: Swine Slaughter Inspection.

Respondents: Official swine establishments.

Estimated Number of Respondents: 612 (28 large, 51 small high volume, 54 small low volume, and 479 very small).

Estimated Average Annual Number of Responses (samples) per Respondent: Large establishments 6,846; small high volume

establishments 430; and small low volume and very small establishments 25.

Estimated Total Annual Responses: 226,558.

Estimated Total Annual Recordkeeping Burden: 9,440 hours.

Respondents		Estimated No. of Respondents	Average Annual No. of Responses per Respondent	Total Annual Responses	Time per Response in Minutes	Total Annual Burden Hours
Large establishments	Microbial testing data recordkeeping	28	6,846	191,688	2.5	7,987
Small high volume establishments	Microbial testing data recordkeeping	49	430	21,070	2.5	878
Small low volume establishments	Microbial testing data recordkeeping	54	25	1,350	2.5	56
Very small establishments	Microbial testing data recordkeeping	479	25	11,975	2.5	499

Respondents		Estimated No. of Respondents	Average Annual No. of Responses per Respondent	Total Annual Responses	Time per Response in Minutes	Total Annual Burden Hours
	Total Recordkeeping Burden for process control	612	7,326	226,083		9,420

Estimated Annual Reporting Burden: Swine Slaughter Inspection.

Respondents: Official swine establishments.

Estimated Number of Respondents: 612 (28 large, 51 small high volume, 54 small low volume, and 479 very small).

Estimated Average Annual Number of Responses per Respondent: Large establishments 6,846; small high volume establishments 430; and small low volume and very small establishments 25.

Estimated Total Annual Responses: 226,083.

Estimated Total Annual Recordkeeping Burden: 47,655 hours.

Respondents		Estimated No. of Respondents	Average Annual No. of Responses per Respondent	Total Annual Responses	Time per Response in Minutes	Total Annual Burden Hours
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Respondents		Estimated No. of Respondents	Average Annual No. of Responses per Respondent	Total Annual Responses	Time per Response in Minutes	Total Annual Burden Hours
Large establishments	Microbial testing data recordkeeping	28	6,846	191,688	12.5	39,702
Small high volume establishments	Microbial testing	49	430	21,070	12.5	4,389
Small low volume establishments	Microbial testing	54	25	1,350	15	338
Very small establishments	Microbial testing	479	25	11,975	15	2,993
	Total Reporting Burden	612	7,326	226,083		47,655

FSIS is also proposing a new regulation that would create a new information collection burden, in that it would require 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. This is a new recordkeeping requirement that FSIS has submitted to OMB for approval.

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: 41.

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

Estimated Maximum Total Potential Annual Responses 41.

Estimated Total Annual Recordkeeping Burden: 1.37 hours.

Respondents		Estimated No. of Respondents	Average Annual No. of Responses per Respondent	Total Annual Responses	Time per Response in Minutes	Total Annual Burden Hours
Large establishments	Attestation on Work-Related Conditions	28	1	28	2	.93
Small high volume establishments	Attestation on Work-Related Conditions	13	1	49	2	.43
	Total Reporting Burden	41	1	41		1.37

SUMMARY OF BURDEN Swine Slaughter Inspection	
TOTAL NO. RESPONDENTS	612
AVERAGE ANNUAL NO. RESPONSES PER RESPONDENT	14,693
TOTAL ANNUAL RESPONSES	453,157
AVERAGE HOURS PER RESPONSE	.125
TOTAL ANNUAL BURDEN HOURS	57,216.37

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 methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both Gina Kouba, Office of Policy and Program Development, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20253. To be most effective, comments should be sent within 60 days of the publication date of this proposed rule. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. XIV. 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 also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is 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 e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

<http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices.

Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

XV. Proposed 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 proposing to amend 9 CFR Chapter III as follows:

PART 301 -- TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

1. The authority citation for part 301 continues 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 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 SOP, or other prerequisite program.

(c) The establishment must identify carcasses of livestock that establishment employees have sorted and removed from slaughter or that FSIS inspectors have condemned on ante-mortem inspection with a unique tag, tattoo, or similar device. The establishment must immediately denature all major portions of the carcass on-site and dispose of the carcass according to 9 CFR part 314.3.

(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. 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 9 CFR 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 of the regulations as provided by 9 CFR 303.1(h). The Administrator also may permit establishments that slaughter market hogs and other classes of swine to slaughter market hogs under NSIS and slaughter 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).

* * * * *

7. Amend § 310.18 by adding paragraphs (c) through (e) to read as follows:

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

* * * * *

(c) *Procedures for controlling contamination throughout the slaughter and dressing operation.* Official swine slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, fecal, 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 small establishments or very low volume establishments, must collect and analyze samples for microbial organisms at the pre-evisceration and post-chill points in the process. Very small establishments and 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, or jowl areas.

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

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

(iii) An establishment may substitute alternative sampling locations if:

(A) The establishment has support to demonstrate the alternative sampling locations are able to provide a definite improvement in monitoring process control than at pre-evisceration and post-chill; and

(B) FSIS does not determine, and notify the establishment in writing, that the alternative sampling locations are inadequate to verify the effectiveness of the establishment's process controls for enteric pathogens.

(2) *Sampling frequency.* Establishments, except for very small and very low volume establishments as defined in paragraphs (c)(1)(i) and (ii) 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 small and very low volume establishments as defined in paragraphs (c)(1)(i) and (ii) 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 small and very low volume establishments as defined in paragraph (c)(1)(i) and (ii) of this section must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, very small and very low volume establishments can demonstrate that they are effectively maintaining process control, they may modify their sampling plans.

(iii) An establishment may substitute an alternative frequency if:

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan; and

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's process controls for enteric pathogens.

(iv) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (e) of this section.

(d) *Procedures for controlling contamination in the pre-operational environment.* Official swine slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of the pre-operational environment by enteric pathogens. Establishments must incorporate these procedures into their HACCP plans, sanitation SOPs, or other prerequisite programs. These procedures must include sampling and analysis of food contact surfaces in the pre-operational environment for microbial organisms to ensure that the surfaces are sanitary and free of enteric pathogens and that water used to clean food contact surfaces is free of enteric pathogens. The sampling frequency must be adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (e) of this section.

(e) *Recordkeeping requirements.* Official swine slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraphs (c), (d) and (e) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this

section must be maintained for at least one year and must be accessible to FSIS.

8. Amend § 310.25 as follows:

a. Remove paragraph (a) (2) (ii) (C);

b. Remove the second sentence in paragraph (a) (2) (iii) (A);

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

d. Remove the "swine" row in Table 1—Evaluation of E. Coli Test Results;

e. Remove the "Hogs" and "fresh pork sausages" rows and footnote (b) from Table 2—Salmonella Performance Standards.

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. If the establishment has less than three inspection stations, 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. The establishment must develop, implement, and maintain written procedures to ensure that market hog carcasses contaminated 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 SOP, or other prerequisite program. These procedures must cover establishment sorting activities required under this section.

(c) *Line speed limits.* The line speed limits in 9 CFR 310.1 do not apply to the establishment, provided that they are able to maintain effective process control and prevent contamination of carcasses and parts by fecal material and enteric pathogens. Establishments operating under 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 9 CFR 301.2. These records are subject to review and evaluation by FSIS personnel.

(2) The establishment must maintain records to document the number of animals disposed of per day by plant sorters or

condemned per day by FSIS inspectors upon post-mortem inspection. 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 New Swine Slaughter Inspection System (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 9 CFR 310.27 to be invalid, such action will not affect any other provision of 9 CFR parts 309 or 310.

Done in Washington, DC, on: January 19, 2018

Paul Kiecker,

Acting Administrator.

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