United States Department of Agriculture

One Team, One Purpose

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness

Food Safety and Inspection Service (FSIS)

Proposed Rule: Modernization of Swine Slaughter Inspection

Webinar

March 22, 2018

Food Safety and Inspection Service:
Overview of Proposed Rule

- Proposed new voluntary inspection system for market hog slaughter establishments, the New Swine Slaughter Inspection System (NSIS), informed by the Agency's experiences under the Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP).
  - Market hog slaughter establishments that do not choose to operate under the new swine inspection system may continue to operate under traditional inspection.

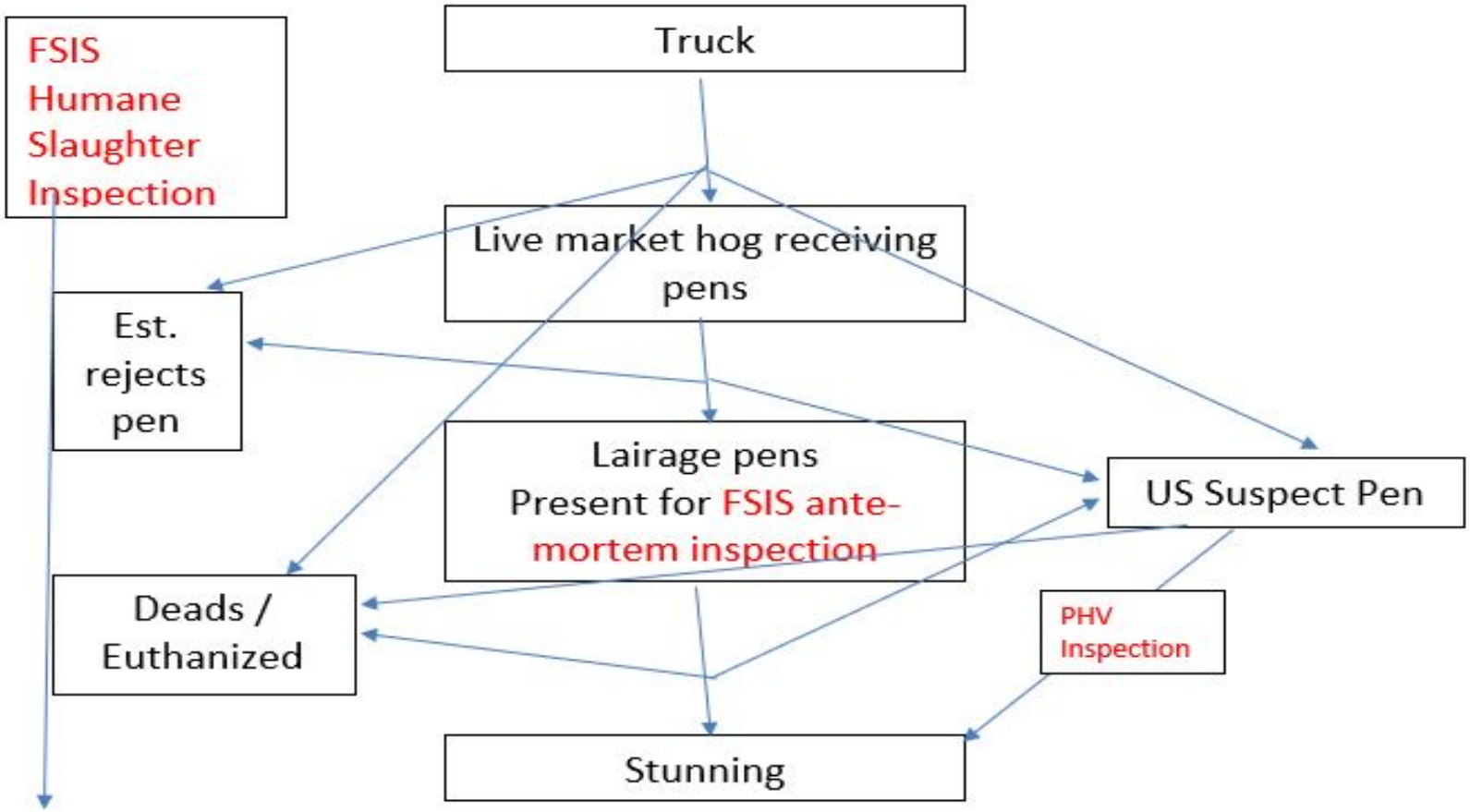
- The Agency is also proposing several changes to the regulations that would affect all establishments that slaughter any age, size, or class of swine.

Food Safety and Inspection Service:
Traditional Inspection

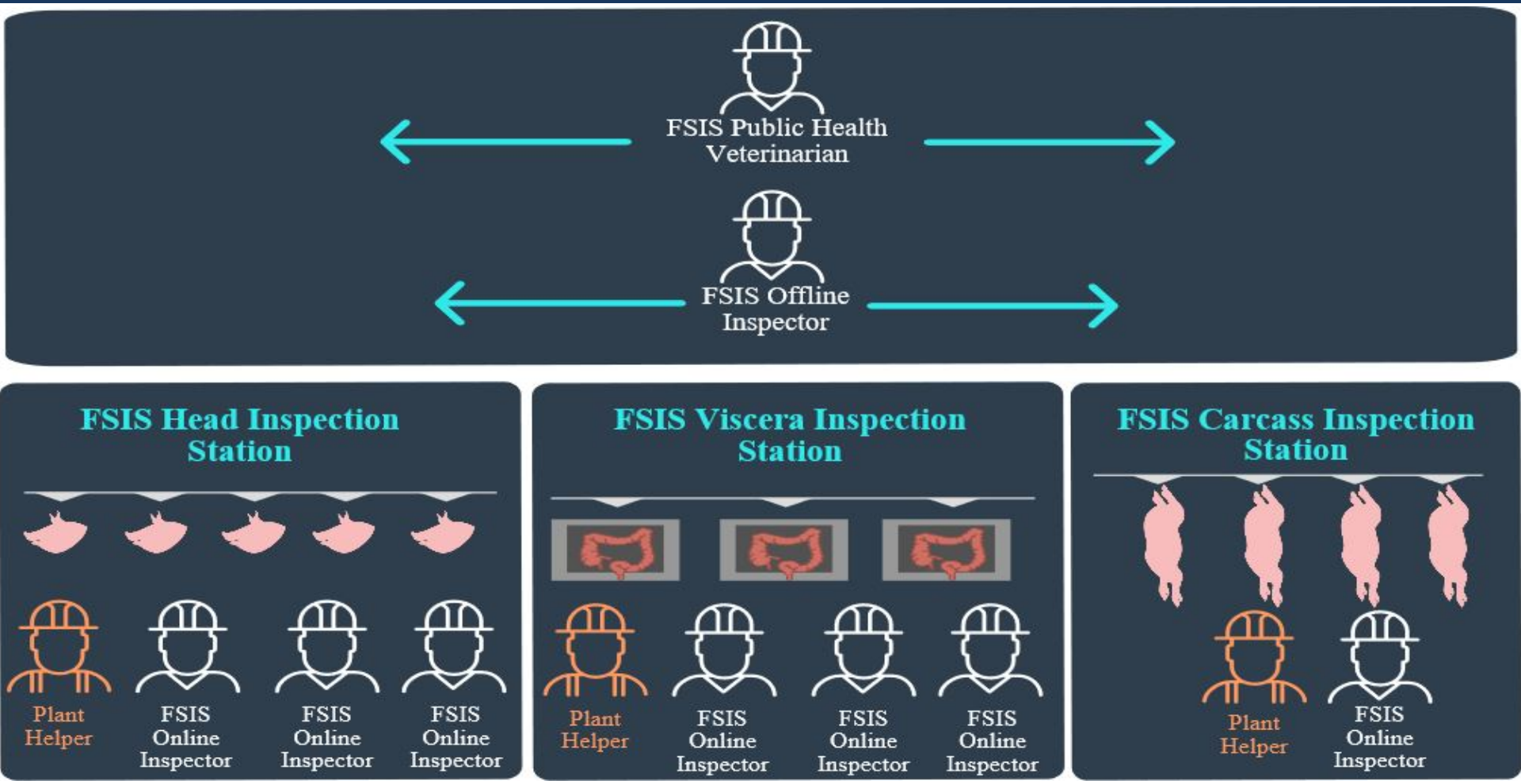
- Most market hog establishments voluntarily segregate animals that show signs of diseases or conditions from healthy animals before FSIS performs ante-mortem inspection.

- Establishment personnel conduct no post-mortem sorting activities under traditional inspection
  - FSIS inspectors check each carcass for food safety and non-food safety defects and direct plant employees to take corrective actions
  - FSIS Public Health Veterinarians (PHVs) condemn carcasses with animal diseases and plant employees dispose of condemned carcasses
  - FSIS inspectors spend too much time inspecting for non-food safety defects, e.g., scabs and bruises, that are related more to the marketability of the product.

Food Safety and Inspection Service:
Traditional Inspection: Voluntary Segregation and Ante-mortem Inspection



Food Safety and Inspection Service:
Traditional Inspection: Post-mortem Inspection



Food Safety and Inspection Service:
Traditional Inspection: Records

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- Establishment Profile
- Coverage Assignments
- Task Calendar
- Inspection Verification
- Sample Management
- Animal Disposition
  - Establishment Reporting
  - Weight Reporting
  - Frequency
  - No Kill Period
- Export
- View Report

Sub-Class Summary

Establishment: Kevin's Traditional Establishment - M38
Date: 3/12/2018
Shift: Shift 1
Class: Swine

Sub-Class*: Market Swine

Print Condemn. Cert

Head Count : 0
Live Weight: lbs
Dressed Weight: lbs
Weight Not Reported: ☐

Add Disposition Record Add Multiple Disposition Records

	TagType	TagNumber	Condition	Disposition	Edit	Delete
No records to display.						

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Food Safety and Inspection Service:
Need for Modernization

- Traditional inspection was developed before HACCP regulations, and before the Agency began targeting its resources to address public health risks associated with foodborne pathogens.

- Advances in animal science, market hog production systems, biosecurity and veterinary medicine have eliminated the vast majority of diseases inspected for under traditional inspection.

- Under traditional inspection, inspectors are required to spend a large amount of time conducting inspecting for quality-related defects rather than verifying food-safety-related process controls and effectiveness of HACCP systems.

- Traditional inspection limits line speeds.

- Traditional inspection restricts establishments' ability to reconfigure and consolidate lines.

Food Safety and Inspection Service:
Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP)

- FSIS initiated the HIMP study in 20 young chicken, five young turkey, and five market hog establishments on a waiver basis.

- Sorting activities shifted from FSIS inspectors to establishment personnel
  - Before FSIS ante-mortem inspection, establishment employees sort animals
  - Before FSIS post-mortem inspection, establishment employees 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 tag carcasses and parts intended for disposal under FSIS supervision (e.g., carcasses with malignant lymphoma).

- Establishments are required to implement process control plans and meet food safety and other consumer protection (OCP) performance standards.

- FSIS inspectors still conduct 100% ante-mortem and postmortem inspection.

Food Safety and Inspection Service:
HIMP: Food Safety Performance Standards

Model Performance Standards for Market Hogs Plants

Performance Standard Categories	Plant Performance Standards
FS-1—Condition – Infectious (for example: septicemia/toxemia, pyemia, cycticercus)	Zero
FS-2 – Condition – Digestive Content/Milk (for example: fecal material, ingesta, milk)	Zero
FS-3 – Ante-mortem Suspect (for example: neurologic conditions, moribund, pyrexic, severe lameness)	Zero

Food Safety and Inspection Service:
HIMP: Other Consumer Protection (OCP) Performance Standards

OCP-1 – Carcass- Pathology* **(for example: arthritis, emaciation,, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)**	**4.1%**
OCP-2 – Visceral Pathology* **(for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/ pyelonephritis, parasites—other than Cysticercus, peritonitis)**	**7.2%**
OCP-3 – Miscellaneous **(for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)**	**20.5%**

***Conditions exhibiting a septicemia or toxemia are considered food safety hazards**

Food Safety and Inspection Service:
HIMP: Verifying OCPs – Daily and 25-day Action Limits

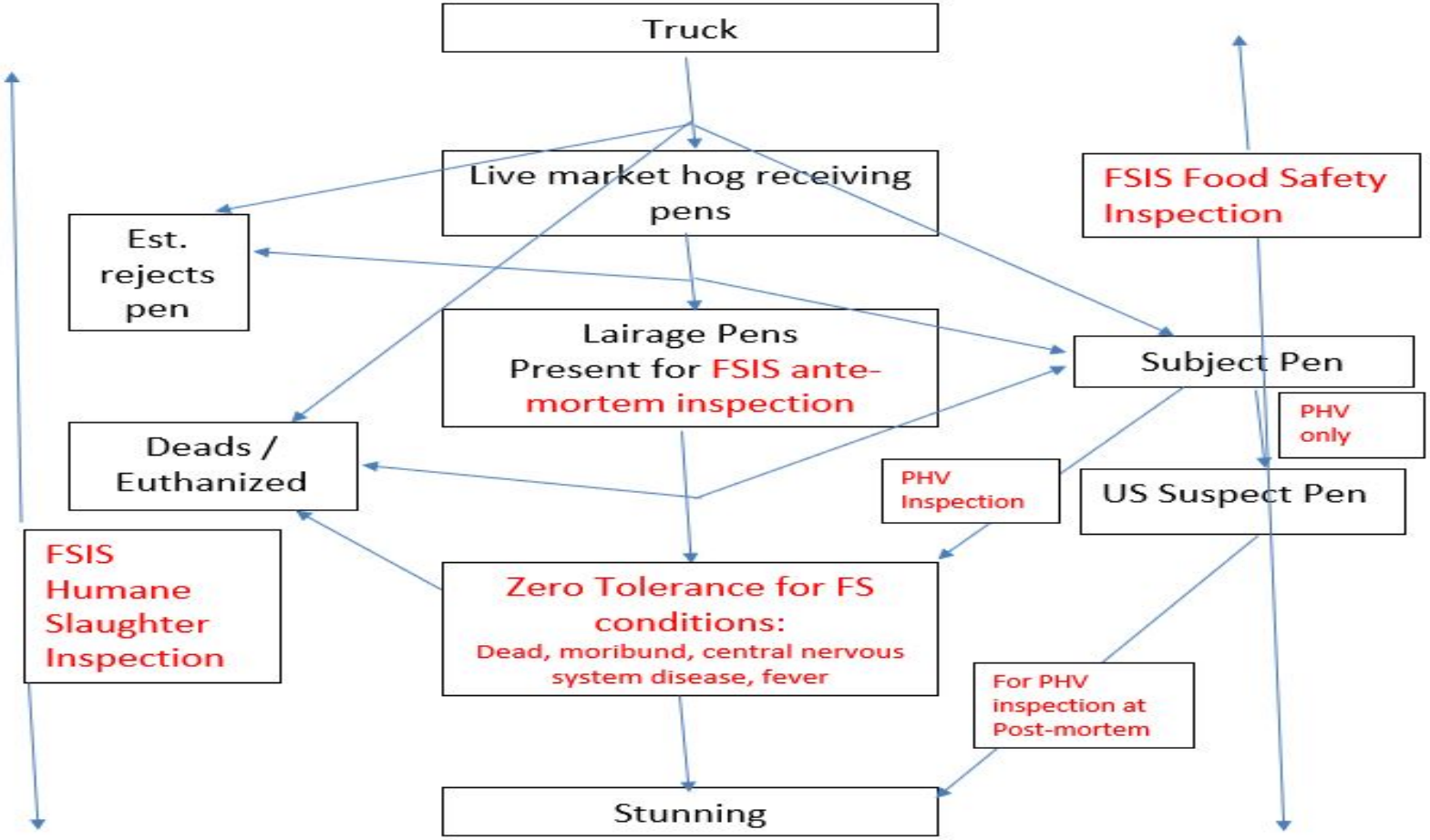
Table 1: Maximum Daily OCP Performance Standards Per Shift

Condition							
CARCASSES SAMPLED>	n=24		n=27		n=30		n=33
OCP1	2		2		2		2
OCP2	3		3		3		3
OCP3	7		7		8		9

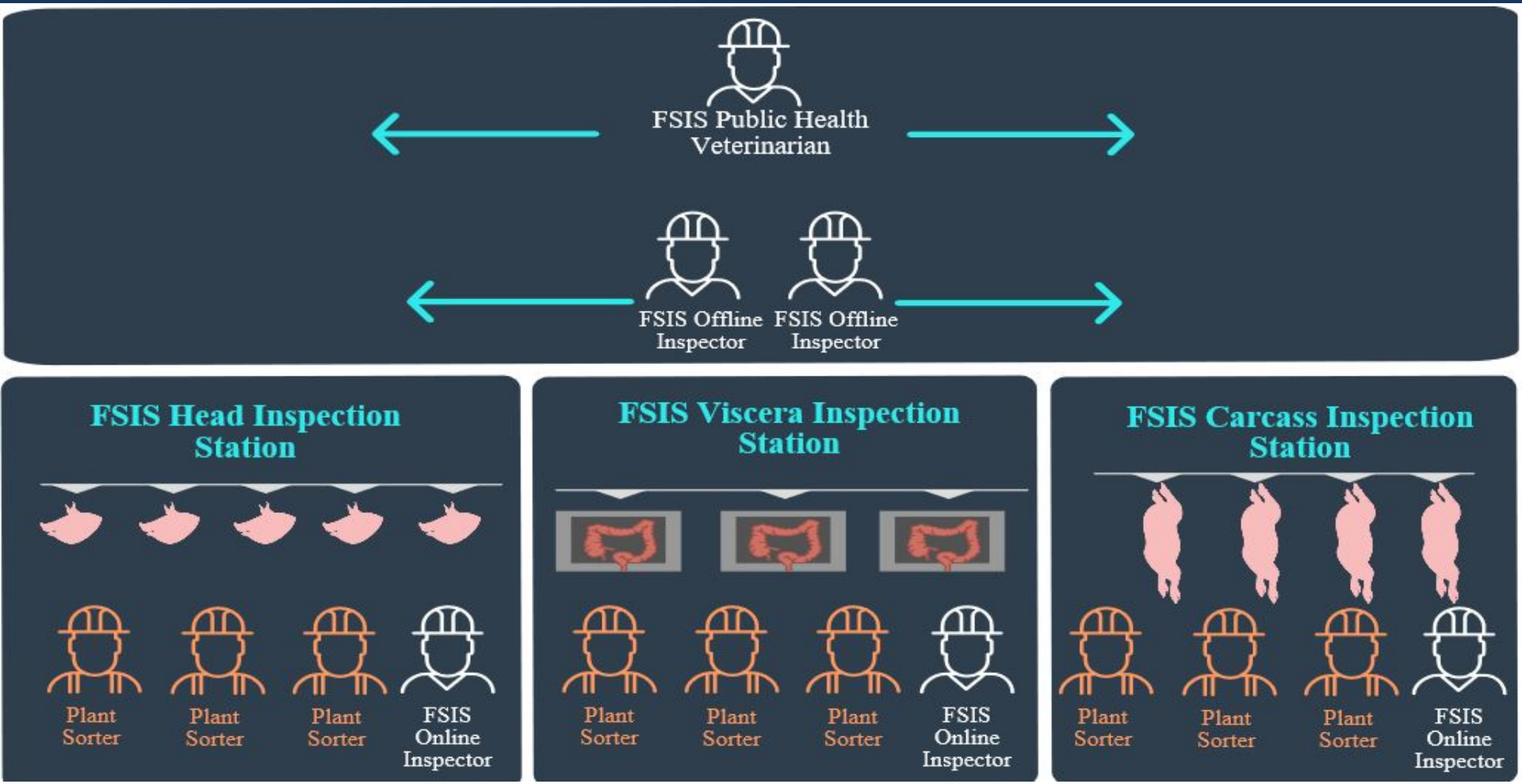
Table 2: Maximum # of Days out of 25 Days OCPs are allowed to exceed the Performance Standard.

Condition				NR is written		
OCP1	2 days			3+ days		
OCP2	4 days			5+ days		
OCP3	3 days			4+ days		

Food Safety and Inspection Service:
HIMP: Sorting and Ante-mortem Inspection



Food Safety and Inspection Service:
HIMP: Post-mortem Inspection



Food Safety and Inspection Service:
HIMP: Identifying Defects

Food Safety and Inspection Service:
HIMP: Recordkeeping

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- View Report

Sub-Class Summary

Establishment: Tom's HIMP Plant - M38
Date: 3/12/2018
Shift: Shift 1
Class: Swine

Sub-Class*: (select one)

Print Condemn. Cert

Head Count : 0
Live Weight: lbs
Dressed Weight: lbs
Establishment Ante-mortem Condemned: 0
Establishment Post-mortem Condemned: 0
Establishment U.S.Suspects: 0
Weight Not Reported: ☐

Add Disposition Record Add Multiple Disposition Records

	TagType	TagNumber	Condition	Disposition	Edit	Delete
No records to display.						

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Food Safety and Inspection Service:
HIMP: Enforcement and Line Speeds

- Who can stop the line?
  - Online and offline inspectors and the PHV

- When should they stop the line?
  - When they find insanitary conditions, contaminated organs / parts that will create insanitary conditions or interfere with inspection
  - When online IPP find a zero tolerance defect at the final rail
  - When there is an immediate personnel safety concern

Food Safety and Inspection Service:
HIMP: Enforcement and Line Speeds

- Who can slow the line?

  Only the PHV can slow the line

- When should the PHV slow the line?
  - Excessive disease and/or OCP defects
  - Deficiencies in carcass presentation or preparation that can affect FSIS's ability to adequately inspect
    - Missing organs or parts
    - Excessive contamination, evisceration errors

Food Safety and Inspection Service:
HIMP: 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 the following:

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.

Food Safety and Inspection Service:
HIMP: Humane Handling

- Under HIMP, FSIS inspectors completed more humane handling verification activities.
  - 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 inspectors also 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.

- 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.

Food Safety and Inspection Service:
Evaluation of Market Hog HIMP

- Key Questions
  - Are HIMP market hog establishments preventing contamination as well as non-HIMP market hog establishments?
  - Are HIMP market hog establishments meeting Food Safety (FS) and Other Consumer Protection (OCP) performance standards?

- Key components of the assessment
  - Selection of comparable non-HIMP market hog establishments
  - Evaluation incorporating multiple FSIS data sources
    - Inspection data
    - Regulation verifications and non-compliances associated with public health-related regulations (encoded W3NR and PHR)
    - Microbiological and residue testing data
    - Food safety and OCP records

Food Safety and Inspection Service:
Evaluation of Market Hog HIMP

- Data indicate generally comparable performance between HIMP and similar non-HIMP establishments
  - More off-line tasks are being performed in HIMP plants
  - Lower PHR non-compliance rates were observed in HIMP plants
  - Less frequent observations of food safety-related concerns such as fecal contamination, septicemia, toxemia in HIMP plants
  - Similar rates of *Salmonella* detection
  - Sorting rates in HIMP similar to condemnations in non-HIMP
  - Meeting OCP performance standards

Food Safety and Inspection Service:
Market Hog Risk Assessment

- Quantitative food safety risk assessment to evaluate the public health impact of reallocating inspection procedures to increase offline tasks.

- Scenarios considered included:
  - Three category-specific scenarios, adjusting frequency of procedure categories one at a time
  - One combined scenario, adjusting all procedure categories simultaneously as done in Market Hog HIMP

Food Safety and Inspection Service:

Market Hog Risk Assessment Model Structure

FSIS microbiological sampling data (*Salmonella*)

Inspection procedure data: same plants and day as sampling data

Regression Model Inputs

Stage 1: Estimate relationships between FSIS inspection procedures and percentage of *Salmonella* positive market hog carcass samples.

Regression Model Output

Coefficients which estimate the relationship between inspection activities and *Salmonella* prevalence (approximated as percent positive samples).

Human illness data: estimated mean number of human *Salmonella* illnesses attributable to consumption of market hog products.

Simulation Model Inputs

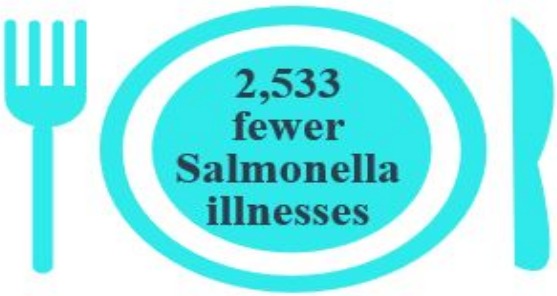
Stage 2: Scenarios to predict the effect of modifying offline inspection procedure rates using the relationships estimated in Stage 1.

Prediction Output

Estimated change to annual number of human *Salmonella* illnesses attributable to consumption of market hog products

Food Safety and Inspection Service:
Market Hog Risk Assessment Results

What changes will be expected to result from increasing offline inspection task rates in non-HIMP establishments, in terms of human *Salmonella* illnesses?



Baseline number of human salmonellosis cases: 69,857

The following modeled scenarios predict *Salmonella* prevalence reductions on market hog carcasses and thus reductions in human *Salmonella* illnesses:

Adjust scheduled but not performed tasks: -1.79% (-1,257 cases)
Adjust unscheduled tasks: -0.72% (-506 cases)
Adjust scheduled and performed tasks: -1.10% (-770 cases)
Combined adjustment scenario (HIMP-like): -3.63% (-2,533 cases)

Food Safety and Inspection Service:

Market Hog Risk Assessment Conclusions

- Improved the agency's understanding of the public health impact of different FSIS inspection activities in hog slaughter facilities

- The risk assessment estimates the potential public health risks or benefits—that is, possible predicted increases or decreases in foodborne *Salmonella* illnesses—from increasing different categories of inspection activities

- All modeled scenarios predict a reduction in *Salmonella* prevalence on market hog carcasses and thus predict reductions in human salmonella illness case counts with implementation of an NSIS
  - Combined adjustment scenario, increasing offline procedures in all categories, predicted greatest reductions in contamination prevalence and illnesses
  - Estimated most likely reduction of 3.63% relative to baseline values

Food Safety and Inspection Service:
Key Elements of the Proposed NSIS

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 that they have sorted and removed for disposal before FSIS ante-mortem 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 before FSIS ante-mortem and post-mortem inspections 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;

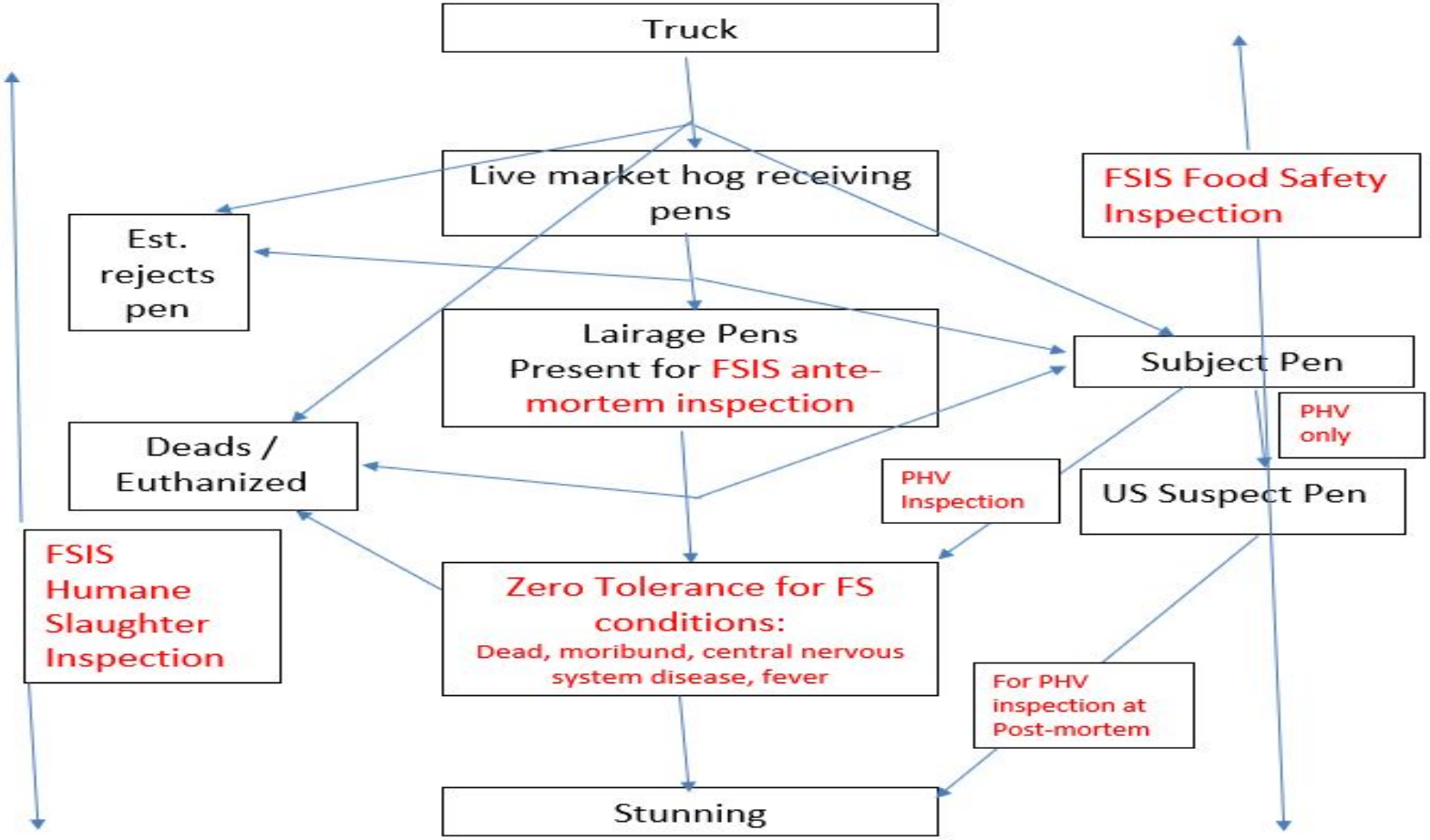
Food Safety and Inspection Service:
Key Elements of the Proposed NSIS

4. Shifting Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which would allow for 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;

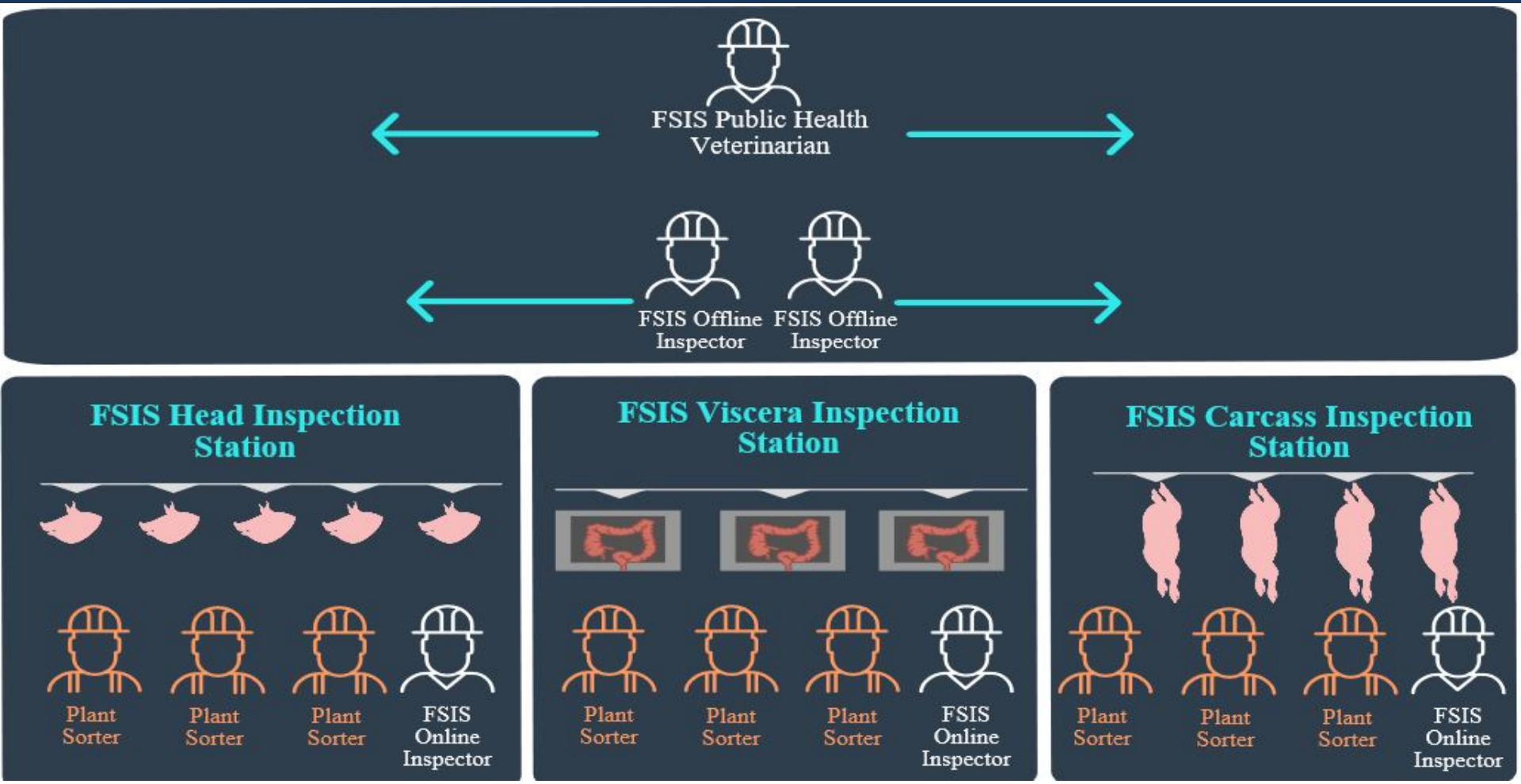
5. Requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the new proposed definition of Ready-to-cook (RTC) pork product, which would be defined as any slaughtered pork product free from bile, hair, scurf, dirt, hooves, toe nails, claws, 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.

Food Safety and Inspection Service:
NSIS: Sorting and Ante-mortem Inspection



Food Safety and Inspection Service:
NSIS: Post-mortem Inspection



Food Safety and Inspection Service:
Summary: Traditional Inspection vs. NSIS

Traditional Inspection

- Developed before HACCP
- Allows establishments to sort live hogs before FSIS ante-mortem inspection
- Requires 100% FSIS ante-mortem inspection
- Requires 100% FSIS post-mortem inspection
- Only FSIS PHV can condemn animals, carcasses, and parts

Proposed NSIS

- Based on HACCP principles
- Requires establishments to sort live hogs and remove animals unfit for slaughter before FSIS ante-mortem inspection
- Requires 100% FSIS ante-mortem inspection
- Requires 100% FSIS post-mortem inspection
- Only FSIS PHV can condemn animals, carcasses, and parts

Food Safety and Inspection Service:
Summary: Traditional Inspection vs. NSIS

Traditional Inspection

- Requires FSIS to use inspection resources to detect quality defects and conditions that present minimal food safety risks
- Restricts establishments' ability to reconfigure and consolidate lines
- Restricts line speeds

Proposed NSIS

- Requires establishments to identify and trim defects on carcasses and parts before FSIS post-mortem inspection, which allows FSIS to conduct a more efficient inspection
- Allows establishments to consolidate inspection stations or otherwise reconfigure their evisceration lines in order to make room for more innovative, automated equipment
- Allows establishments to operate at faster line speeds, if they are able to also maintain process control by preventing fecal contamination and meeting microbial performance measures.

Food Safety and Inspection Service:
Proposed Changes for All Swine Slaughter Establishments

- 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.

- Remove the current requirements to test carcasses for generic *E. coli* to monitor process control 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, thus more effective in monitoring their specific process control than the current generic E. coli criteria.

- Remove the codified *Salmonella* pathogen reduction performance standards for swine.

Food Safety and Inspection Service:
Proposed Changes for All Swine Slaughter Establishments

- 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.
  - 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.
- Allow establishments to substitute alternative sampling locations and alternative sampling frequencies,

Food Safety and Inspection Service:
Proposed Changes for All 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 includes food contact surfaces, reuse water, and equipment, including knives, in edible food production departments before slaughter operations begin.
  - This is a new and novel proposed requirement that we may extend to other species in subsequent rulemaking, depending on comments and whether we are able to finalize and implement the requirements.

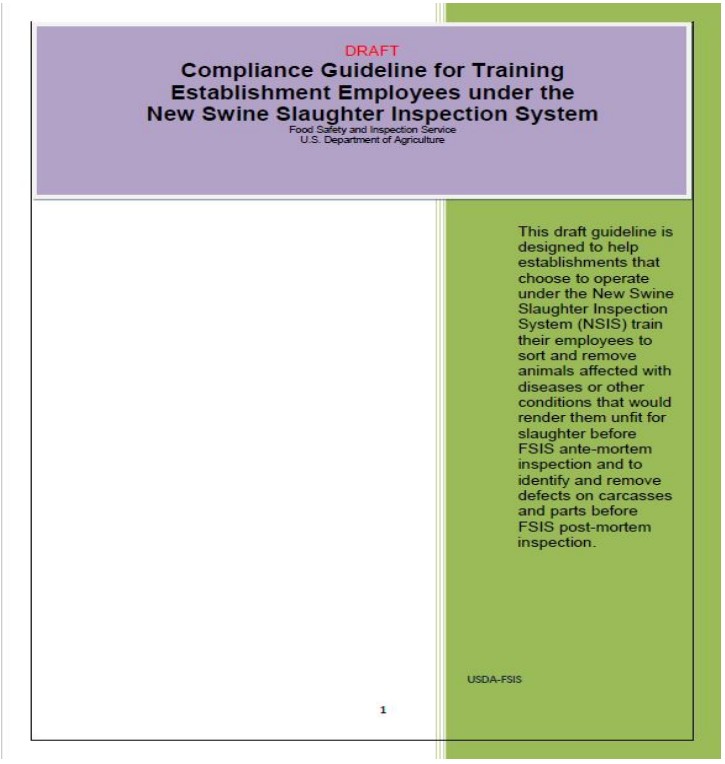
- These procedures must include sampling and analysis of food-contact surfaces in the pre-operational environment for microbial organisms to ensure that the surfaces are sanitary and free of enteric pathogens.

- The sampling frequency must be adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment.

Food Safety and Inspection Service:
Draft Compliance Guidance

- FSIS has developed two draft compliance guides on sorting and sampling.

- The compliance guides are posted on https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules.



DRAFT

Compliance Guideline for Training Establishment Employees under the New Swine Slaughter Inspection System

Food Safety and Inspection Service
U.S. Department of Agriculture

This draft guideline is designed to help establishments that choose to operate under the New Swine Slaughter Inspection System (NSIS) train their employees to sort and remove animals affected with diseases or other conditions that would render them unfit for slaughter before FSIS ante-mortem inspection and to identify and remove defects on carcasses and parts before FSIS post-mortem inspection.

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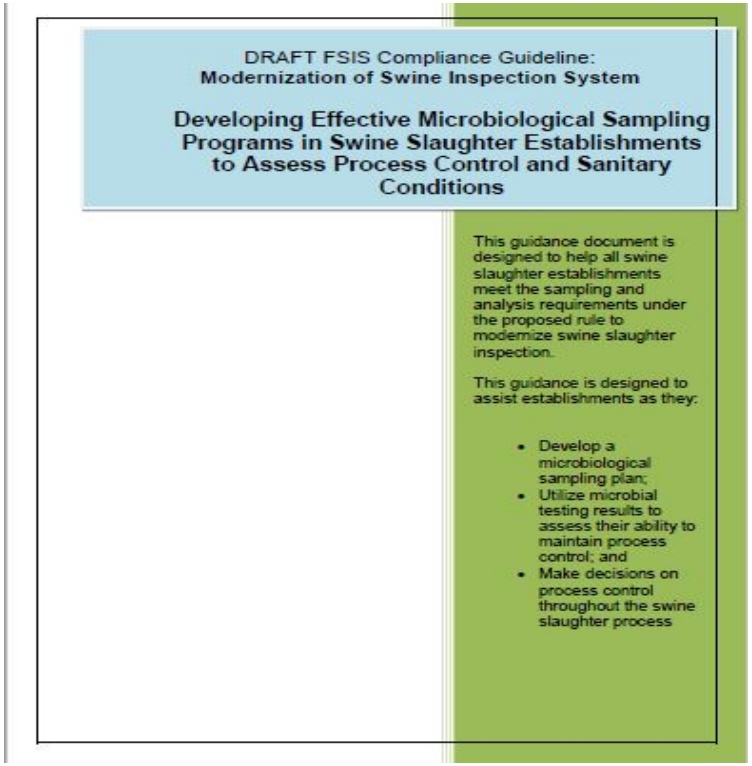

DRAFT FSIS Compliance Guideline:
Modernization of Swine Inspection System

Developing Effective Microbiological Sampling Programs in Swine Slaughter Establishments to Assess Process Control and Sanitary Conditions

This guidance document is designed to help all swine slaughter establishments meet the sampling and analysis requirements under the proposed rule to modernize swine slaughter inspection.

This guidance is designed to assist establishments as they:

- Develop a microbiological sampling plan;
- Utilize microbial testing results to assess their ability to maintain process control; and
- Make decisions on process control throughout the swine slaughter process

Food Safety and Inspection Service:
Market Overview

In 2016, there were approximately 612 swine slaughter establishments under Federal Inspection that slaughtered approximately 118 million hogs.

- 40 establishments (5 Large HIMP, 22 Large, 13 Small) exclusively slaughtered market swine, were considered high volume, and account for over 92% of production.

- 572 establishments (1 large, 92 Small, 479 Very Small) slaughtered a variety of swine sub classes, were a mix of high and low volume, and account for less than 8 percent of production.

Food Safety and Inspection Service:
PRIA for Modernization of Swine Slaughter Inspection
Voluntary Costs: Overview of NSIS

- This analysis estimates the increase in costs associated with the NSIS.
  - Overall, the annualized cost of the NSIS is roughly $17.02 million, assuming a 3 percent discount rate over 10 years.

- These costs are a result of:
  - Increased establishment labor needs associated with online sorting, which has an annualized cost of roughly $16.62 million, assuming a 3 percent discount rate over 10 years.
  - Increased establishment labor costs associated with ready-to-cook standards, which has an annual cost of $399 thousand.

- These cost increases are incurred by the 22 large and 13 small high volume establishments expected to voluntarily convert to the NSIS.

- The 5 large HIMP establishments that have already incurred the increase in costs associated with the NSIS are not included in this portion of the cost analysis.

Food Safety and Inspection Service:
PRIA for Modernization of Swine Slaughter Inspection Mandatory Costs: Overview

- This analysis also estimates the increase in costs associated with the mandatory requirements of the proposed rule.
  - Overall, the annualized cost of the mandatory requirements is roughly $881 thousand, assuming a 3 percent discount rate over 10 years.

- These costs are associated with:
  - Establishing and implementing written sanitary dressing plans, which has an annualized cost of $1.5 million, assuming a 3 percent discount rate over 10 years;
  - Modernizing process control sampling programs for microbial organisms, which has an annualized cost savings of $756 thousand, assuming a 3 percent discount rate over 10 years; and
  - Sampling the slaughter environment for microbiological contamination, which has an annual cost of $81 thousand.

- The mandatory costs of the proposed rule are expected to apply to all 612 swine slaughter establishments.

Food Safety and Inspection Service:
PRIA for Modernization of Swine Slaughter Inspection Benefits

This analysis also estimates the quantified economic value of the proposed rule's expected health benefits and benefits from increasing industrial efficiency.

- The hog risk assessment estimates that if the 35 establishments expected to convert to NSIS do so, the NSIS would reduce the number of human illnesses attributed to products derived from market hogs by an average of about 2,533 *Salmonella* illnesses annually. Such a decrease in illnesses has a potential cost reduction of $9.33 million annually.

- Based on the Evaluation of HACCP Inspection Models Project for Market Hogs report, the HIMP establishments' average line speed was approximately 12.5 percent faster than comparable establishments. Assuming all 35 establishments expected to adopt NSIS increase their line speeds by this amount, industry benefits would increase by roughly $47.33 million annually.

Food Safety and Inspection Service:
PRIA for Modernization of Swine Slaughter Inspection
Expected Budgetary Impacts

This analysis estimates the changes in the Agency's budgetary requirements associated with the NSIS.

- Overall, the NSIS is expected to reduce Agency budgetary needs by roughly $6.38 million annually, assuming a 3 percent discount rate over 10 years.

- These changes take into consideration:
  - Changes to Agency staffing, which has an annual cost reduction of $6.67 million.
  - Training Agency staff on NSIS methods, which has an annualized cost of $68 thousand, assuming a 3 percent discount rate over 10 years.
  - Converting Food Inspectors (FIs) into Consumer Safety Inspectors (CSIs), which has an annualized cost of $229 thousand, assuming a 3 percent discount rate over 10 years.

- These changes occur at the 22 large and 13 small high volume establishments expected to voluntarily convert to the NSIS.

Food Safety and Inspection Service:
PRIA for Modernization of Swine Slaughter Inspection Net Costs and Benefits

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)	

Food Safety and Inspection Service:
Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

- Consistent with E.O. 13771, we have estimated that this proposed rule would yield cost savings of approximately $24.97 million, not including health benefits, consistent with E.O. 13771 criteria.

- Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

Food Safety and Inspection Service: Comments

- Comments on the rule may be submitted online via the Federal eRulemaking Portal, available at http://www.regulations.gov;

- by mail sent to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza III, Mailstop 3782, Room 8-163A, Washington, D.C. 20250-3700;

- or by hand or courier delivery to Patriots Plaza III, 355 E St. SW., Room 8-163A, Washington, D.C. 20250-3700. All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-0017.

- The comment period will end on May 2, 2018.