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Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness

Food Safety and Inspection Service:

Modernization of Swine Slaughter Inspection

- Welcome & Introductions to Panel
- Swine Modernization & HACCP
  followed by open question session
- Monitoring Process Controls
  followed by open question session
- New Swine Slaughter Inspection System
  followed by open question session
- Implementation
  followed by open question session

Food Safety and Inspection Service:

Modernization of Swine Slaughter Inspection

Food Safety and Inspection Service:

Modernization of Swine Slaughter Inspection

- On February 1, 2018, proposed to create a new optional 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.

- FSIS also proposed several changes to the regulations that allow swine slaughter establishments to develop sampling plans that are more tailored to their specific operations, and thus more effective in monitoring their specific process control.

- On October 1, 2019, FSIS published the final rule in the *Federal Register*.

Food Safety and Inspection Service:
HACCP Approach and HIMP

- Establishments must have an effective HACCP system
- HACCP is science-based control approach to food safety
- Focus is on preventing food safety hazards
- Responsibility belongs to the establishment with verification conducted by FSIS

Food Safety and Inspection Service:

Hazard Analysis and Critical Control Point (HACCP) Systems Overview

Food Safety and Inspection Service:

HACCP Seven Principles

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping & Documentation
7. Establish Verification Procedures

Conducting a Hazard Analysis

- Identify Reasonably Likely To Occur (RLTO) hazards at each process step
  - Biological
  - Chemical
  - Physical
- Identify preventive measures – forms the basis for CCPs
- Unique to each establishment

Food Safety and Inspection Service:

Thought Process for Hazard Analysis

- Is there a potential hazard at **this step**?
  - Biological? Chemical? Physical?
- Is it reasonably likely to occur?
  - **Yes** – CCP
  - **No** – What basis for this decision?
    - Supporting documentation
    - Prerequisite program / other supporting program

Food Safety and Inspection Service:
Prerequisite Programs

- Procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food.

- Become part of the HACCP system if used to support a decision in the hazard analysis.

- Common examples
  - Temperature control programs
  - Sanitation SOPs
  - Purchase specifications
  - Allergen control programs
  - Sanitary dressing programs
  - Antimicrobial interventions
  - Establishment sorting procedures

Food Safety and Inspection Service:
Verification Procedures

- Validation
  - Element 1: Scientific and Technical Support
  - Element 2: In-plant Validation Data (90 calendar days)
- Ongoing verification
- Reassessment
- Government verification

Questions & Discussion

Food Safety and Inspection Service:

Monitoring Process Control

Food Safety and Inspection Service:
Generic E. coli

Generic E. coli

- The 1996 PR/HACCP final rule established requirements for generic Escherichia coli (E. coli) testing for all slaughter establishments at post-chill.
- Generic E. coli is an indicator of microbial contamination

Food Safety and Inspection Service:
Salmonella Performance Standards

- Under the 1996 PR/HACCP final rule, FSIS set a *Salmonella* performance standard for market hog carcasses.

- Until 2011, FSIS routinely tested market hog carcasses for *Salmonella* to verify process control using the codified performance standard; sampling discontinued after low *Salmonella* recovery.

- With the final rule, FSIS is eliminating these performance standards
  - FSIS intends to propose new performance standards for raw pork products in 2020

Food Safety and Inspection Service:
Changes for All Swine Slaughter Establishments: Requirements for Written Sanitary Dressing Plans and Sampling

- Develop, implement, and maintain written procedures to prevent contamination
- These procedures must include microbiological sampling and analysis to assess ability to maintain process control
- Incorporate written procedures into HACCP/Sanitation SOP/Prerequisite Program
- Maintain records

Food Safety and Inspection Service:
Mandatory Changes for All Swine Slaughter Establishments: Requirements for Written Sanitary Dressing Plans and Sampling

Establishments:

Collect 2 samples: 1 Pre-evisceration and 1post-chill sample

1 per 1,000 carcasses

Minimum of once per week

Random Selection and Sampling of Carcasses

Very Low Volume Establishments:

Collect 1 post-chill sample

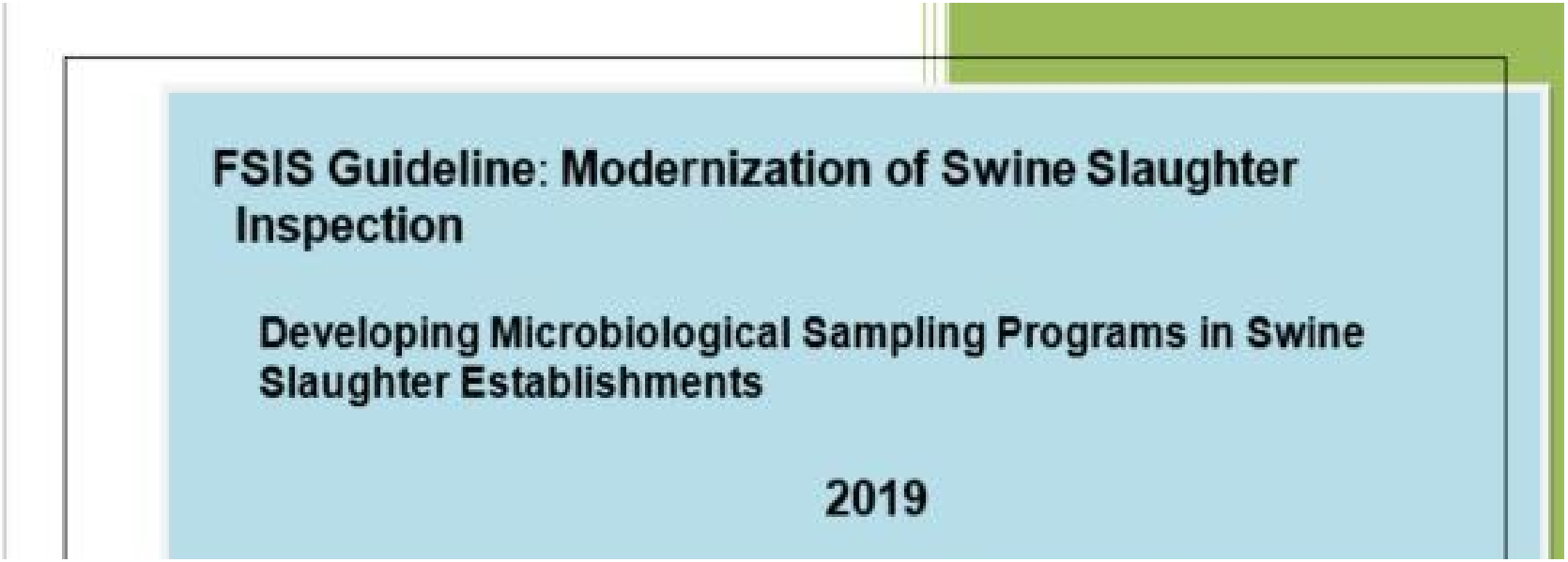
Starting June 1 of every year

Minimum of 13 samples

Random Selection and Sampling of Carcasses

Food Safety and Inspection Service:

Sampling Guideline to Assist Establishments



The guideline does not impose new regulatory requirements

Generic *E. coli* is a 'Safe Harbor'

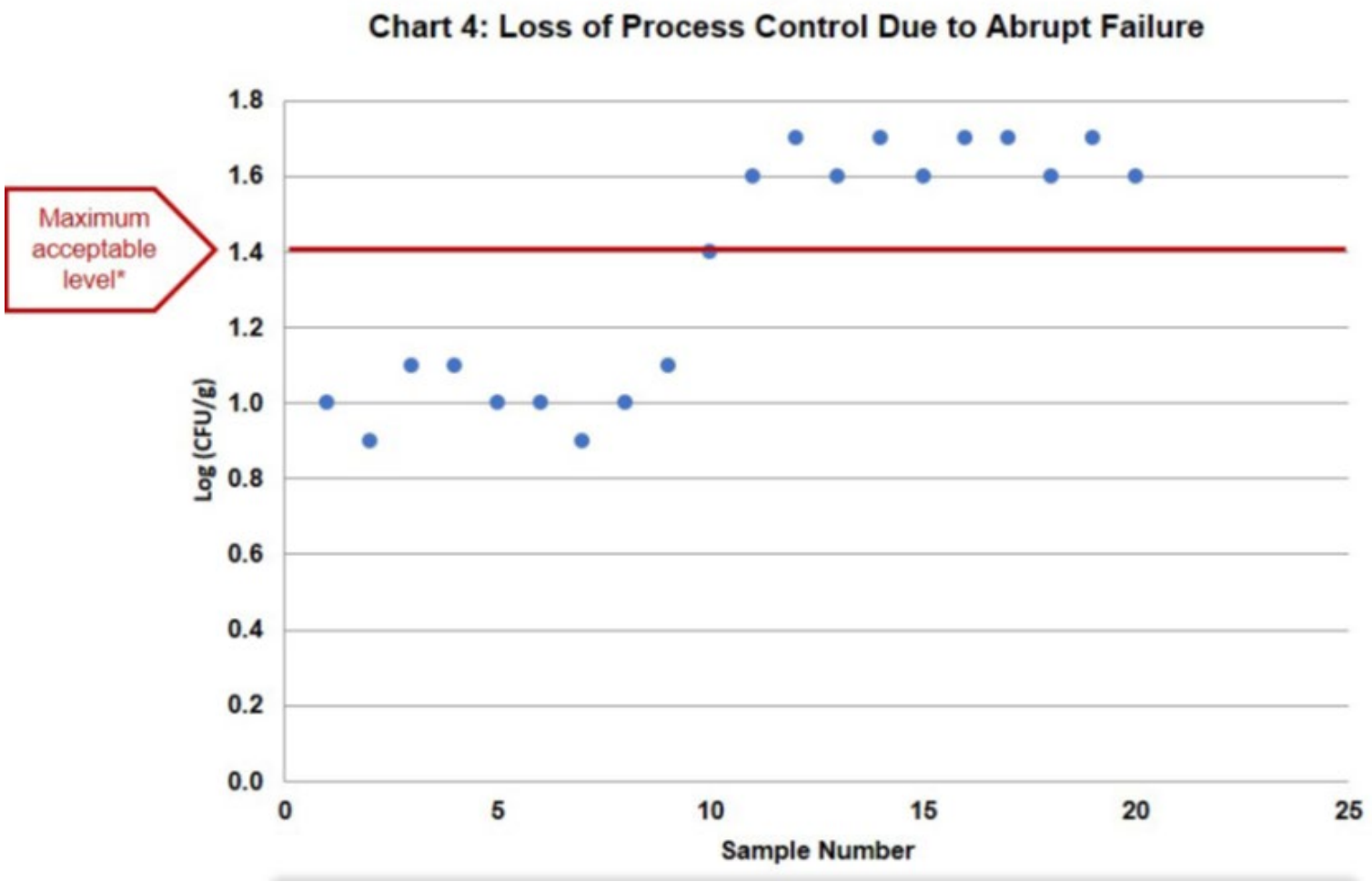
- Establishments can continue to use generic *E. coli*

Types of Indicator Organisms

✓ ***Aerobic Plate Counts***

✓ *Enterobacteriaceae*
✓ Generic *E. coli*
✓ Total coliforms

Food Safety and Inspection Service:
Loss of Process Control Example



Food Safety and Inspection Service:
Actions in Response to Loss of Process Control

- Establishments must define actions to take in response if the test results exceed the limit
- Delineate actions, who will take them, how they will be documented, and how verified
- Investigate root cause and deploy corrective actions

Questions & Discussion

Food Safety and Inspection Service:

The New Swine Slaughter Inspection System

Food Safety and Inspection Service:
Key Elements of NSIS

(1) Requires establishment personnel to sort and remove unfit animals before FSIS ante-mortem inspection and to trim and identify defects on carcasses and parts before FSIS post-mortem inspection;

(2) Requires establishment personnel to identify animals or carcasses, that they have sorted and removed for disposal before FSIS inspection, with a unique tag, tattoo, or similar device, and to develop, implement, and maintain written procedures in their HACCP system to ensure that animals and carcasses sorted and removed for disposal do not enter the human food supply and are properly disposed of according to 9 CFR part 314;

(3) Requires establishments to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal;

Food Safety and Inspection Service:
Key Elements of NSIS

(4) Requires establishment personnel to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (e.g., African swine fever, classical swine fever, or Nipah virus encephalitis);

(5) Shifts Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which allows for up to two offline verification inspectors per line per shift and reduces the number of online inspectors to a maximum of three per line per shift;

(6) requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the new definition of ready-to-cook (RTC) pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor which is suitable for cooking without need of further processing; and

(7) Revokes maximum line speeds.

Food Safety and Inspection Service:
NSIS: Ante-Mortem

NORMAL PEN 	NORMAL PEN 
NORMAL PEN 	SUBJECT PEN 
NORMAL PEN 	US SUSPECT PEN

REJECT PEN (FOR HEALTHY ANIMALS THAT DON'T MEET ESTABLISHMENT SPECIFICATIONS. THESE ANIMALS WILL GO TO ANOTHER OFFICIAL ESTABLISHMENT FOR SLAUGHTER UNDER FSIS INSPECTION.)

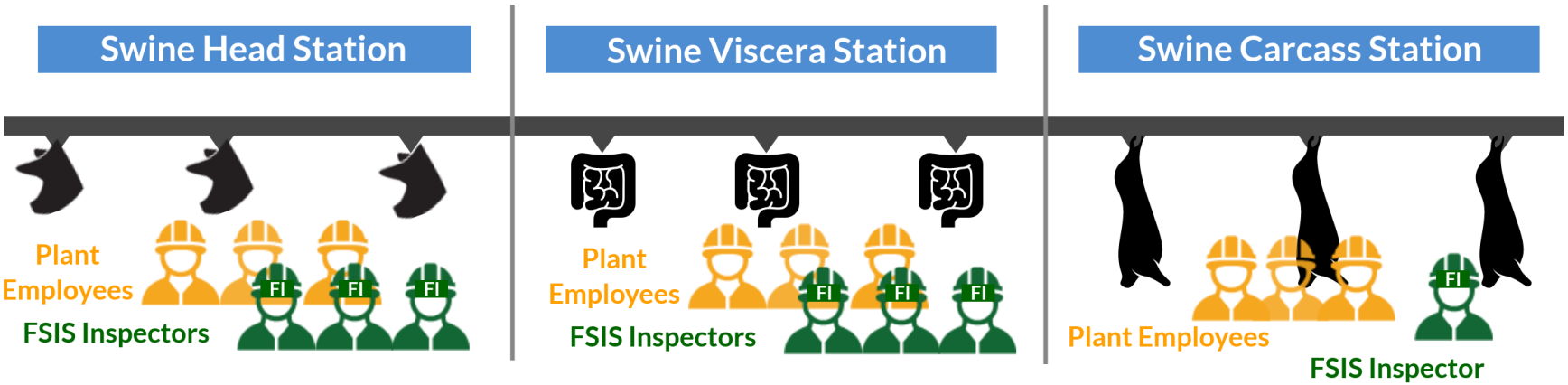
Food Safety and Inspection Service:
Traditional: Post-Mortem

Off-Line Inspection Protocol

In practice, there is typically one FSIS inspector to conduct off-line inspection tasks. There is also one FSIS PHV to supervise inspectors and inspect for animal disease conditions. A PHV supervises inspectors and inspects for animal disease conditions.

On-Line Inspection Protocol

For traditional swine inspection, there are up to **seven FSIS inspectors total.** The below graphic illustrates an example of how a line might look.



- FSIS food safety inspectors (FI) direct plant employees to make cuts and trim defects. FSIS food safety inspectors are the only personnel responsible for inspection.

This graphic is for illustrative purposes only. Each establishment is configured differently and the number of FSIS inspection personnel will vary per plant.

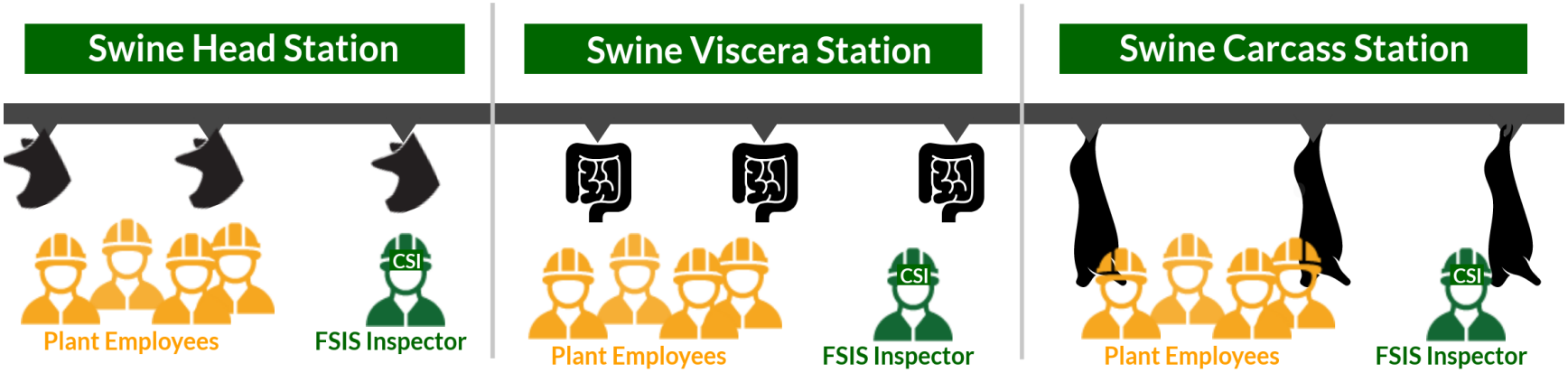
Food Safety and Inspection Service:
NSIS: Post-Mortem

Off-Line Inspection Protocol

In the proposal we state that up to **one public health veterinarian (PHV)** and **two FSIS inspectors** are **off-line.** A PHV supervises inspectors and inspects for animal disease conditions.

On-Line Inspection Protocol

For modernized swine inspection, there are up to **three FSIS inspectors total.** The below graphic illustrates an example of how a line might look.



- Plant employees are required to sort carcasses and parts and trim dressing defects and contamination (i.e., hair, bruises, feces, ingesta and milk) before the carcasses and parts are presented to an FSIS on-line inspector for post-mortem inspection.

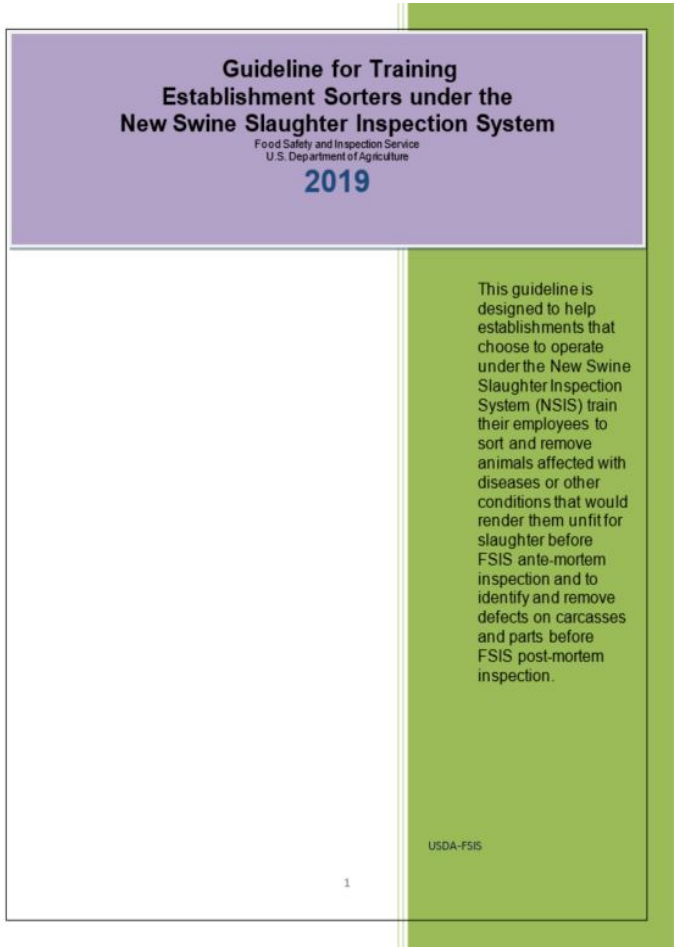
- FSIS consumer safety inspectors (CSI) are the only personnel responsible for inspection.

This graphic is for illustrative purposes only. Each establishment is configured differently and the number of FSIS inspection personnel will vary per plant.

Food Safety and Inspection Service:
Establishment Sorting

- **Ante-mortem**
  - Food Safety Conditions removed and identified for disposal: Dead, Moribund (Dying), Central Nervous System (CNS) Disorders, Pyrexia (Body Temp. > 106 degrees F)
  - Other ante-mortem abnormalities are sorted to “Subject” Pen for inspection by FSIS Public Health Veterinarian.
- **Post-mortem**
  - Food Safety Conditions marked for disposal of carcass and parts: Septicemia, Toxemia, Pyemia, Cysticercosis.
  - All other diseases or abnormal conditions marked for trimming and disposal of affected parts or carcass depending on nature, degree, or extent.
- **Foreign Animal Diseases**
  - Establishments are required to report animals showing signs of foreign or reportable animal diseases to FSIS PHV for examination. For example: Foot and Mouth Disease, Hog Cholera, African Swine Fever.

Food Safety and Inspection Service:
Sorter Guideline


Guideline for Training
Establishment Sorters under the
New Swine Slaughter Inspection System
Food Safety and Inspection Service
U.S. Department of Agriculture
2019

This 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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The guideline is provided to assist swine slaughter establishments. It does not impose new regulatory requirements.

Food Safety and Inspection Service:
RTC Pork Product

- Under NSIS, establishments will have the flexibility to design and implement measures to
- address OCP defects that are best suited to their operations.

- They will also be responsible for determining the type of records that will best document that they are meeting the RTC pork product definition.

- The records will be subject to review and evaluation by FSIS offline inspectors (9 CFR 310.26(d)(1)).

Food Safety and Inspection Service:
RTC Pork Product

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

Questions & Discussion

Food Safety and Inspection Service:

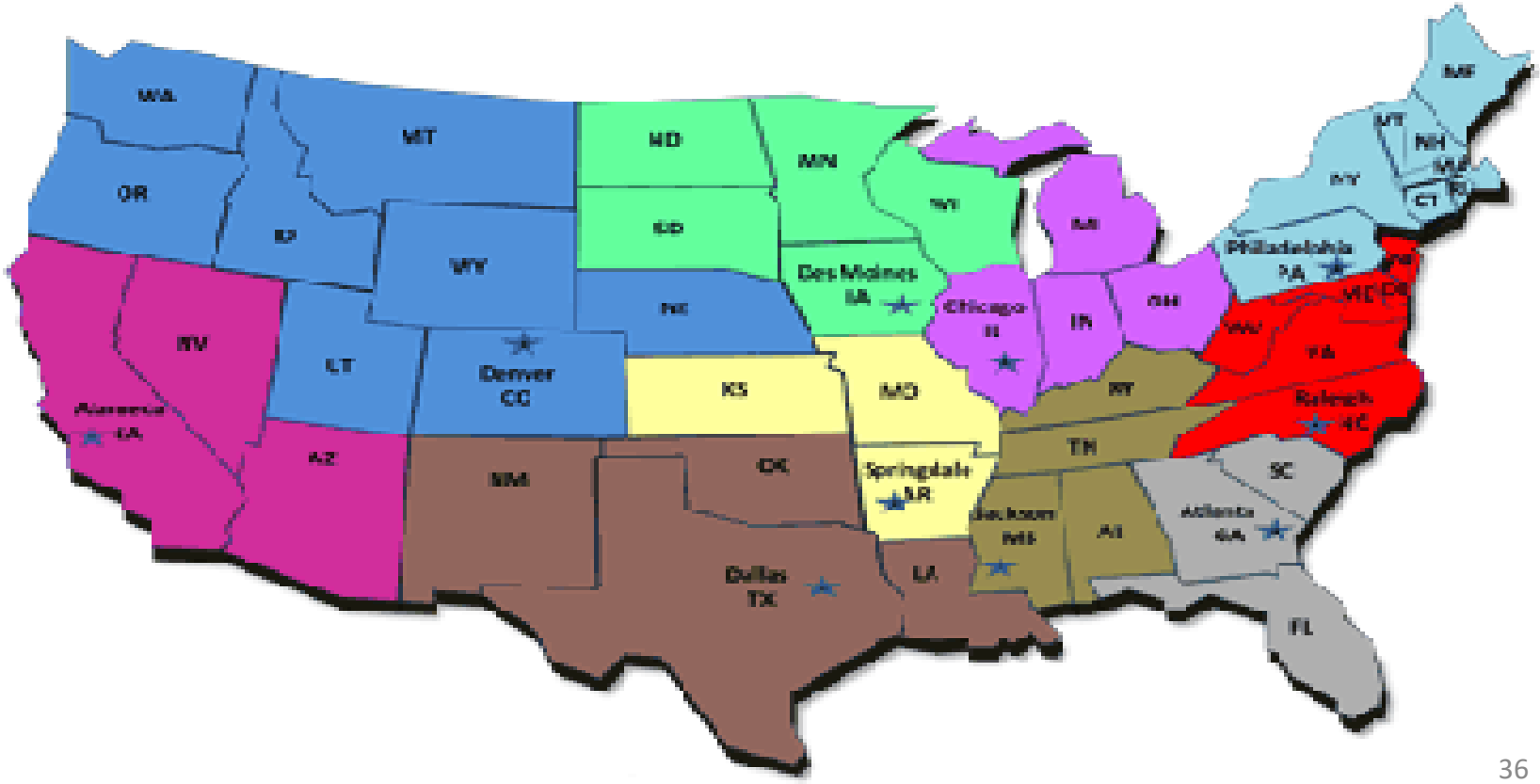
Implementation

Food Safety and Inspection Service:
Dates

- The final rule will become effective on December 2, 2019.
- The portion of the final rule that requires all hog slaughter establishments to develop and implement written sanitary dressing plans and sampling programs to monitor process control for enteric pathogens by establishment size will be applicable as follows:
- In large establishments, defined as all establishments with 500 or more employees, on **Dec. 30, 2019**;
- In small establishments, defined as all establishments with 10 or more employees but fewer than 500 employees, on **Jan. 29, 2020**; and
- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million: 180 days, on **March 30, 2020**.

Food Safety and Inspection Service:
Dates

- All market hog establishments will initially have until **March 30, 2020** to notify FSIS of their intent to operate under the NSIS. Establishments that do not notify FSIS of their intent within that period will be deemed to have chosen to continue operating under traditional inspection.



Food Safety and Inspection Service:
Current Waiver Status

Waiver	Status
Market Hog line speed, decreased numbers of inspectors, generic *E. coli* testing, 9 CFR 310.25(a) and (b) for OCP defects	Establishments operating under HIMP or HIMP like system must choose to convert to NSIS or Traditional inspection system by **3/30/2020**. May continue to use the sampling frequency and location in their generic *E. coli* sampling waiver until FSIS announces new criteria. Waivers for line speed, decreased numbers of inspectors, and OCP defects evaluation end on **3/30/2020**.
Market Hog generic *E. coli* testing (9 CFR 310.25(a))	Establishments with waivers for alternative sampling frequency and location in their generic *E. coli* sampling program may continue until FSIS announces new criteria.

Food Safety and Inspection Service:
Current Waiver Status

Waiver	Status
Market Hog alternative kidney presentation for increased line speed and generic *E. coli* testing (9 CFR 310.1(b)(3) and 310.25(a)	Establishment with waiver for line speed associated with alternative kidney presentation ends on **12/31/2020**. However, may continue to use the sampling frequency and location in their generic *E. coli* sampling waiver until FSIS announces new criteria.
Market Hog handling of bruised parts and generic *E. coli* testing waivers (9 CFR 310.14 and 310.25(a))	Establishments with waiver for handling bruised parts ends on **12/31/2020**. However, may continue to use the sampling frequency and location in their generic *E. coli* sampling waiver until FSIS announces new criteria.

Food Safety and Inspection Service:
Waivers

As described in the final rule, FSIS will consider possible waivers in the future

- HOLD - Do not apply for a waiver now
- FSIS will issue a *Federal Regis*ter Notice announcing the criteria for waivers

Food Safety and Inspection Service: *Salmonella* Initiative Program Waivers

Salmonella Initiative Program participation required

Possible Waivers to Inform Future Rulemaking:

- Sampling Frequency
- Alternative Carcass Sampling Sites (alternative to ham, belly, jowl)
- Alternative Sampling Locations (pre-evisceration, post-chill)
- Lymph Node Incision

Food Safety and Inspection Service:

NSIS Opt-in Requests

To opt-in, establishments must submit a request in writing to the District Office with an estimated date that they expect to be operational. District management will begin a dialogue with establishment management to ensure they understand their responsibilities under NSIS including:

- Sorting and removing unfit animals before FSIS ante-mortem inspection and to trim and identify defects on carcasses and parts before FSIS post-mortem inspection
- Identifying animals that they have sorted and removed for disposal and to ensure that animals sorted and removed for disposal are properly disposed of

Food Safety and Inspection Service:

NSIS Opt-in Requests (cont.)

- Maintaining records to document the total number of animals and carcasses sorted and removed per day
- Submitting annual worker safety attestations

The FSIS in-plant supervisor will monitor establishment progress in meeting its estimated operational date by ensuring:

- The establishment is in compliance with facilities requirements
- Establishment personnel have been trained in carcass sorting and disposition
- Has processes in place to maintain records to document animals and carcasses sorted and removed

Food Safety and Inspection Service:

NSIS Opt-in Requests (cont.)

- The opt-in period for priority conversion for establishments closes on March 30, 2020
- Establishments who opt-in subsequent to March 30, 2020 will be “lower” priority for conversion by Districts than establishments that notified of conversion by March 30, 2020

Food Safety and Inspection Service:

Staffing Analysis

Once the District Office receives the opt-in request, District management will need to:

- Assess DO resources
  - Verify current in-plant staffing
  - Determine new staffing under NSIS based on new line configurations
- Coordinate with HR on recruitment and hiring announcements, as needed

Food Safety and Inspection Service:

Training

- Schedule NSIS training for CSIs and PHVs
  - Review leave schedules to ensure staffing coverage
  - Ensure district train the trainer is available to deliver training
- Schedule IM training (4 weeks) for inspection program personnel, as needed
- Track training and completion

Food Safety and Inspection Service:

NSIS Plant Conversion Complete

Once an establishment is staffed with trained employees and the establishment has met all requirements for sorting, record-keeping, etc., implementation/conversion is complete.

The District Offices will:

- Update internal tracking documents with the conversion date
- Provide notification to HQ of establishment conversion date
- Make any necessary changes in the Public Health Information System for assignments and for inspection verification purposes
- Verify HACCP program reassessments for termination of redundant waivers issued prior to the publication of the final rule

Questions & Discussion

Thank you.