

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	6410.4	12/19/19
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VERIFYING SWINE SLAUGHTER ESTABLISHMENTS MAINTAIN ADEQUATE PROCEDURES FOR PREVENTING CONTAMINATION OF CARCASSES AND PARTS BY ENTERIC PATHOGENS

I. PURPOSE

This directive instructs inspection program personnel (IPP) on how to verify that establishments effectively prevent contamination of swine carcasses and parts throughout the slaughter and dressing operation as required in 9 CFR 310.18(c). It also instructs IPP on how to verify that establishments meet the recordkeeping requirements in 9 CFR 310.18(d). The requirements in 9 CFR 310.18(c) and (d) apply to all swine slaughter establishments as per the modernization of swine slaughter inspection final rule.

KEY POINTS:

- Provides instructions to IPP on how to verify compliance with the requirements in the modernization of swine slaughter inspection final rule that apply to all swine slaughter establishments, including instructions on how to verify that:
 - *The regulatory sampling requirements are being met;*
 - *Establishments are preventing contamination throughout the slaughter and dressing process as part of their Hazard Analysis and Critical Control Point (HACCP) plans, sanitation standard operating procedures (Sanitation SOPs), or other prerequisite programs (i.e., their HACCP systems); and*
 - *Establishment sampling plans meet all requirements as per 9 CFR 310.18(c) and (d).*
- Provides instructions to IPP on how to review establishment sampling results and determine actions to be taken.

II. BACKGROUND

A. On October 1, 2019, FSIS published the final rule titled “Modernization of Swine Slaughter Inspection” [84 FR 52300](#), which made several changes to the regulations that affect all establishments that slaughter swine, regardless of the inspection system under which they operate or the age, size, or class of swine.

B. 9 CFR 310.18(c) requires all establishments that slaughter swine to develop, implement, and maintain written procedures in their HACCP systems (HACCP plan, Sanitation SOP, or Prerequisite Program) to prevent contamination of carcasses and parts by enteric pathogens, feces, ingesta, and milk throughout the entire slaughter and dressing operation.

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C. 9 CFR 310.18(c) also requires all swine slaughter establishments to determine which microbial organisms will be effective in monitoring process control and to implement sampling plans, specifically to monitor for enteric pathogens and fecal contamination. An establishment may continue to test for generic *Escherichia coli* (*E. coli*), as was previously required, as the indicator organism in its sampling procedures, if the establishment determines such testing is effective for monitoring process control.

D. Establishments may elect to respond to all 9 CFR 310.18(c) requirements in one written plan or in separate plans in their HACCP system.

E. 9 CFR 310.18(d) requires all swine slaughter establishments to maintain daily records sufficient to document the implementation and monitoring of the procedures required under 9 CFR 310.18(c).

F. FSIS has staggered the applicability dates for 9 CFR 310.18(c) and 9 CFR 310.18(d) to give small and very small establishments more time to comply with the new requirements. IPP are to verify compliance with these regulations, following the instructions in this directive, after the dates listed below for:

1. Large establishments, defined as all establishments with 500 or more employees, after December 30, 2019;
2. Small establishments, defined as all establishments with 10 or more employees but fewer than 500 employees, after January 29, 2020; and
3. Very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, after March 30, 2020.

G. VERIFYING THAT ESTABLISHMENTS PREVENT CONTAMINATION BY ENTERIC PATHOGENS, FECES, INGESTA, AND MILK THROUGHOUT THE ENTIRE SLAUGHTER AND DRESSING OPERATION

A. IPP are to verify that an establishment meets the requirements of 9 CFR 310.18(c) to prevent contamination of carcasses and parts with enteric pathogens, feces, ingesta, and milk throughout the slaughter operation in two ways, as described below.

1. IPP are to conduct the Livestock Zero Tolerance Verification Task to verify that the establishment's HACCP system is preventing carcass contamination with feces, ingesta, and milk throughout the slaughter process following the instructions in [FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations](#).
2. IPP are to conduct the applicable HACCP system verification tasks – either Slaughter HACCP Verification or Operational Sanitation SOP Verification task (depending on the location of the contamination control program(s)) following the instructions in [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#). IPP are to verify that the establishment maintains and implements the written plans required by 9 CFR 310.18(c) effectively to prevent carcass and parts contamination with enteric pathogens. IPP are to review the results of the establishment's microbiological sampling plan as part of this verification (see [Section V](#) of this directive).

NOTE: IPP are to be aware that establishments that develop new procedures to prevent contamination of carcasses and parts with enteric pathogens, feces, ingesta, and milk throughout the slaughter operations and any establishment that implements sampling procedures in accordance with 310.18(c) and incorporates those procedure into their HACCP system, has 90 days to validate those new procedures consistent with the time period for validating other changes.

B. IPP are to verify that the establishment meets the applicable recordkeeping requirements of 9 CFR 310.18(d).

C. IPP are to document any regulatory noncompliances they observe during these verification activities as described in [Section VI](#) of this directive.

D. IPP are to consult with their supervisor as described in [Section V.I](#) of this directive when the overall pattern of inspection findings suggests that the establishment is not effectively implementing the components of the HACCP system to maintain sanitary conditions throughout the slaughter process.

IV. VERIFYING THE ESTABLISHMENT'S WRITTEN PLANS TO PREVENT CONTAMINATION WITH ENTERIC PATHOGENS, FECES, INGESTA, AND MILK

A. IPP are to review and verify that swine slaughter establishments maintain and implement written plans to prevent contamination of carcasses and parts with enteric pathogens, feces, ingesta, and milk throughout the slaughter process, as required by 9 CFR 310.18(c), as part of routine HACCP and sanitation verification tasks in accordance with the instructions in [FSIS Directive 5000.1](#).

B. IPP are to observe the slaughter operation and establishment records to verify that the establishment's slaughter process is in control and preventing contamination of carcasses and parts with enteric pathogens, feces, ingesta, and milk. IPP are to verify that the establishment's procedures are not regularly or systematically allowing such contamination to occur. When IPP observe the slaughter operation, they are to:

1. Observe carcasses at various points on the slaughter line for evidence of frequent or recurring contamination with visible feces, ingesta, or milk (color and consistency described in the [Attachment](#) to this directive);
2. Observe the contact surfaces and operation of establishment equipment (e.g., opener, carcass splitter) to verify the equipment appears to be adjusted correctly for the size of the swine or other factors and is not routinely contributing to fecal, ingesta, or milk contamination of the carcasses and parts;
3. Observe establishment employees to verify that they are consistently preventing contamination of carcasses during the dressing process and that they respond appropriately to remove visible contamination when it does occur;
4. Observe establishment employees implementing the procedures for preventing contamination with enteric pathogens, feces, ingesta, and milk, including any monitoring, recordkeeping, or sampling activities that the establishment uses to document control of contamination during the slaughter process;
5. Verify that establishments use reconditioning, trimming, or antimicrobial intervention treatments effectively to address any incidental contamination that occurs during the slaughter process;
6. Consider if recent noncompliance record (NRs) or problems found during FSIS verification activities or establishment monitoring procedures suggest that increased contamination is occurring at a certain location in the process and pay particular attention to that location and possible sources of contamination; and

7. Document noncompliance findings as described in [Section VI](#) of this directive.

V. VERIFYING THE ESTABLISHMENT'S WRITTEN SAMPLING PLAN

A. IPP are to review establishment microbiological sampling records (during the Review of Establishment Data task) as instructed in [FSIS Directive 5000.2](#), *Review of Establishment Testing Data by Inspection Program Personnel* to verify that the establishment collects and analyzes microbiological samples as described in its written sampling plan and at the required locations and frequencies per 9 CFR 310.18(c). If the establishment has a waiver of 310.18(c) for sampling location or frequency, IPP are to verify the establishment is meeting the parameters associated with the alternative provisions as listed in the waiver letter.

B. IPP are to verify that for each day of swine slaughter, the establishment's sampling plan describes the procedures for collection and analysis of samples.

1. In a very low volume (VLV) establishment (i.e., an establishment that annually slaughters 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), the sampling plan needs to describe collection and analysis of at least one post-chill sample per week of operation starting June 1 of each year. An establishment would not be able to follow the VLV swine sampling options described 9 CFR 310.18(c)(1)(i) if the establishment annually slaughters:
 - a. More than 20,000 total head per year of swine; or
 - b. More than 20,000 total head per year of all livestock species combined; or
 - c. A combination of livestock that exceeds 6,000 cattle, or 6000 sheep, or 6000 goats but less than 20,000 total head (e.g., 5,000 swine and 6,001 cattle).

NOTE: If after testing 13 consecutive weekly samples, a VLV establishment can demonstrate that it is effectively maintaining process control, the establishment can modify its sampling plan to collect samples less frequently or discontinue sampling.

2. In all other establishments, the sampling plan needs to describe collection and analysis of two samples per every 1,000 carcasses.
 - a. If an establishment "hot-bones" carcasses, the sampling plan needs to include two samples per every 1,000 carcasses, one sample at pre-evisceration and one sample after the final wash location.
 - b. If an establishment chills carcasses (or halves or quarters), the sampling plan needs to include two samples per every 1,000 carcasses, one sample at pre-evisceration and one sample at post-chill.

NOTE: Relative to 2a. and 2b., the two samples do not need to be taken from the same carcass.

C. IPP are to verify that the sampling plan includes a sampling frequency of:

1. One post-chill sample per week of operation starting June 1 each year in VLV establishments; or
2. Two samples (one at pre-evisceration and one after the final wash (hot-bones) or post-chill) per every 1,000 carcasses.

D. IPP are to verify that sampling of the predominant species is conducted in accordance with 9 CFR 310.18(c)(1) or [9 CFR 310.25](#). If the establishment slaughters cattle or other livestock in a greater number than swine, the sampling frequency and location requirements in 9 CFR 310.18(c) do not apply.

E. IPP are to verify the sampling is conducted by sponge or excision of tissue from the ham, belly, and jowl areas (9 CFR 310.18(c)(1)).

F. IPP are to verify that the establishment considers the overall levels of microbial contamination as well as the reduction in contamination between pre- and post-chill as indicators of process control, and that the establishment takes action to restore or improve process control when sampling results indicate problems with the establishment's slaughter HACCP system.

G. IPP are to verify that the establishment maintains daily records documenting the implementation and monitoring of its procedures to prevent contamination of carcasses and parts by enteric pathogens, feces, ingesta, and milk throughout the slaughter process, including records documenting the results of its sampling plan (9 CFR 310.18(d)). IPP are to verify that the establishment's test results are recorded in a manner that facilitates analysis to determine whether the establishment maintains process control over time and allows for the identification of situations that may indicate a loss of control. IPP are to verify that the establishment:

1. Makes these records available for IPP to review and retains these records for one year ([9 CFR 417.5\(a\)\(3\)](#)); and
2. Implements appropriate controls to ensure integrity of electronic data if records are maintained on computers.

NOTE: When an establishment elects to include the sampling plan in a HACCP plan or Sanitation SOP, the recordkeeping requirements for those plans ([9 CFR 417.5\(a\)\(1\)](#) or [9 CFR 416.16](#)) also apply to the sampling records.

H. When reviewing establishment sampling results, IPP are to consider that a well-controlled process will normally show small to moderate variation around the desired result over time and may occasionally produce results well outside the normal range through random statistical variation. However, trends in sampling results that indicate increasing variation or rising contamination levels can be signs that the establishment is not maintaining process control. IPP are to look for trends, such as:

1. Sampling results exceed the establishment's normal variation or upper control limit by a relatively large amount several times in quick succession. This may indicate rare but significant variations from the normal performance of the establishment's system that overwhelm the control measures in place.
2. Sampling results begin to regularly exceed the establishment's normal variation or upper control limit by a relatively small amount. This may indicate frequent or ongoing loss of control in one part of the establishment's slaughter system that is partially compensated for by controls in other parts of the system. Alternately, this could indicate systemic changes that reduce the overall effectiveness of the establishment's system.
3. Sampling results show a trend of rising values over a relatively long period of time. Normal seasonal or weather-related changes can produce trends of more or less contamination on incoming swine, which may be reflected in establishment sampling results. However, if

microbiological contamination increases from previous years or begins to deviate from an establishment's typical seasonal pattern, this may indicate gradual decline of system effectiveness over time.

4. Other sampling plans begin to show significantly worse results. These could include FSIS carcass sampling results or FSIS or establishment sampling results from downstream products, such as pork parts and comminuted pork products that originate from the establishment's slaughtered carcasses. Abnormal results of these other sampling plans may indicate that increased contamination is occurring during slaughter.

NOTE: Establishment sampling results, by themselves, even those showing a negative trend, do not necessarily indicate noncompliance, as long as records indicate that the establishment takes effective action to maintain or restore process control when required.

I. If IPP have questions about whether the establishment's records or an observable trend in sampling results indicate the establishment is maintaining process control, IPP are to consult their supervisor.

J. If IPP observe that the establishment's written plans do not meet the requirements described above or the establishment's slaughter process is not consistently preventing carcasses or parts from becoming contaminated with enteric pathogens, feces, ingesta or milk, they are to document noncompliance as described in [Section VI](#) of this directive. If IPP observe that the establishment's written plans meet the requirements described above and the slaughter process is consistently preventing carcasses or parts from becoming contaminated with enteric pathogens, feces, ingesta, and milk, IPP are to document compliance with the appropriate routine HACCP, Sanitation SOP, Livestock Zero Tolerance, or Review of Establishment Data task.

VI. DOCUMENTING NONCOMPLIANCE

A. IPP are to consider their findings from the verification tasks described above in the overall context of the establishment's control of the slaughter process and the effectiveness of the establishment's plans to prevent carcasses and parts from becoming contaminated with enteric pathogens, feces, ingesta, or milk during slaughter.

B. If IPP observe feces, ingesta, or milk on a carcass, head, cheek, or weasand meat during the Livestock Zero Tolerance verification task, in addition to following the instructions in [FSIS Directive 6420.2](#), they are to:

1. Document noncompliance with 9 CFR 310.18(a) and consider whether the noncompliance is associated with any previous noncompliances according to the instructions in Chapter V – Documentation and Enforcement of [FSIS Directive 5000.1](#); and
2. If there is a critical limit deviation, perform a Slaughter HACCP verification task to verify that the establishment performs corrective actions for the affected product in accordance with [9 CFR 417.3\(a\)](#).

C. IPP are to document noncompliance with the applicable Sanitation SOP requirements in [9 CFR part 416](#) or HACCP requirements in [9 CFR part 417](#) if they observe that:

1. Establishment employees are not implementing the establishment's procedures to prevent contamination, including sampling procedures, as written. IPP are also to cite 9 CFR 310.18(c);

2. The establishment does not have records to document the implementation and monitoring of its procedures. IPP are also to cite 9 CFR 310.18(d);
3. The establishment does not respond to findings of visible contamination or sampling results as described in its HACCP plan, Sanitation SOPs or other prerequisite program; or
4. The establishment does not perform and document corrective actions (when required by [9 CFR 416.15, 9 CFR 417.3](#)) when they identify product that has become contaminated with enteric pathogens, feces, ingesta, or milk.

D. IPP are to document noncompliance with 9 CFR 310.18(c) if they observe that the establishment has not developed written procedures to prevent carcasses or parts from becoming contaminated with enteric pathogens, feces, ingesta, or milk, throughout the slaughter process, if those procedures do not include microbiological sampling, or if the establishment has not incorporated those procedures into its HACCP system.

E. Using the appropriate task based on how the establishment has incorporated its procedures in its HACCP system to prevent or minimize contamination by enteric pathogens, feces, ingesta, or milk contamination at steps throughout slaughter operations (i.e., HACCP, or Sanitation SOP task as outlined in [FSIS Directive 5000.1](#)), IPP are to document noncompliance (citing the regulation in parentheses below) if they observe that:

1. The establishment does not have necessary support for its sampling plan to show that its testing is effective in determining whether the system is preventing pathogens ([417.5\(a\)\(1\)](#));
2. The establishment does not include support for testing for indicator organisms ([417.5\(a\)\(1\)](#));
3. The establishment is not, at a minimum, conducting microbiological sampling at the required location(s) or frequency according to the establishment's size and production volume (9 CFR 310.18(c));
4. The establishment does not maintain sample integrity, (e.g., randomness and handling of samples) (9 CFR 310.18(c));
5. The establishment is not maintaining daily records to document the implementation and monitoring of its written procedures (9 CFR 310.18(d));
6. The establishment does not make records available for FSIS review or does not retain records for one year (9 CFR 310.18(d)); or
7. The establishment does not conduct corrective actions to address findings of visible fecal, ingesta, or milk contamination as required by HACCP ([9 CFR 417.3](#)), Sanitation SOPs ([9 CFR 416.15](#)), or other prerequisite programs, described in [FSIS Directive 5000.1 \(9 CFR 417.5\)](#).

F. If IPP observe that the establishment's slaughter process is regularly allowing enteric pathogens, feces, ingesta, or milk to contaminate carcasses and parts, they are to:

1. Document noncompliance with 9 CFR 310.18(c) and consider whether the noncompliance is associated with any previous noncompliances according to the instructions in Chapter V of [FSIS Directive 5000.1](#);

2. Perform the appropriate food safety verification task (HACCP or Sanitation SOP) to verify that the establishment performs corrective actions for the affected product in accordance with [9 CFR 417.3](#) or [9 CFR 416.15](#); and
3. Consider the establishment's identified cause for this and other recent contamination findings and observe establishment operations at those specific points during subsequent verification tasks to verify the establishment's corrective actions have been effective in restoring process control.

G. IPP are to consider whether the overall pattern of inspection findings suggest that the establishment is not maintaining sanitary conditions throughout the slaughter HACCP system. For example, if an establishment has repetitive HACCP or Sanitation SOP noncompliances for multiple aspects of the slaughter system, or if the establishment's corrective actions in response to findings of enteric pathogens or visible feces, ingesta, or milk contamination are consistently ineffective, it may indicate systemic problems with the establishment's HACCP system, and may indicate that the establishment is slaughtering swine under insanitary conditions. IPP are to discuss such situations with their immediate supervisor to evaluate the need to take an enforcement action as described in [FSIS Directive 5000.1](#), Chapter V – Documentation and Enforcement.

VII. QUESTIONS

IPP are to refer questions regarding this directive to their supervisor. Follow-up questions can be sent to the Office of Policy and Program Development (OPPD) through [askFSIS](#). OPPD can also be reached by telephone at 1-800-233-3935.

When submitting a question through [askFSIS](#), use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 6410.4**.

Question Field: Enter your question being sure to include as much detail as possible.

For questions regarding verification of preventing fecal material contamination:

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Slaughter/Livestock** from the drop-down menu.

For questions regarding microbiological testing procedures:

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling/General** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

Identification of Contaminants for Swine

To verify carcasses and parts are free of feces, ingesta, or milk contamination known to be vectors for pathogens that represent food safety hazards, inspection program personnel (IPP) are to first identify the contamination, as instructed in [FSIS Directive 6420.2](#). Feces, ingesta, or milk can be identified by color, texture, and consistency.

The actual appearance of feces and ingesta reflect the diet, age of the animal, type of animal (functioning rumen; non-ruminant), and regional feeding practices. Therefore, the descriptions below are guidelines and are not absolute. The Public Health Veterinarian-Inspector-In-Charge (PHV-IIC) in each official establishment is the final arbiter regarding any disputed findings of feces, ingesta, or milk representing zero-tolerance noncompliance.

A. Livestock Feces and Ingesta

IPP are to identify foreign material as feces or ingesta based on two factors: color and texture.

Basic Criteria for Identification of Feces on Swine Carcasses	
Color	Yellow, green, tan, or brown.
Texture	May include identifiable grain particles or fibrous plant material.
Size	The size or quantity of feces or ingesta is largely unimportant in identifying fecal or ingesta contamination. However, as size decreases, color and texture become more difficult to discern.

NOTE: Bile is a contaminant on carcasses and parts per 9 CFR 310.18 but is not counted as a zero-tolerance defect.

B. Milk

IPP are to identify foreign material as milk based on two factors: color and consistency.

Milk, if present, tends to be found on the midline, during or after removal of mammary glands (udder) from lactating animals.

Criteria for Identification of Milk on Swine	
Color	Clear to white to light yellow.
Consistency	Watery to ropy or curdy.