UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

6420.5

10/17/16

VERIFYING POULTRY SLAUGHTER ESTABLISHMENTS MAINTAIN ADEQUATE PROCEDURES FOR PREVENTING CONTAMINATION WITH FECES AND ENTERIC PATHOGENS

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL MONDAY, NOVEMBER 28, 2016.

I. PURPOSE

This directive instructs inspection program personnel (IPP) how to verify that establishments effectively prevent contamination of poultry carcasses (other than ratites) throughout the slaughter and dressing operation as required in <u>9 CFR 381.65</u>(f) and (g). This directive contains instructions previously found in FSIS Notice 64-14, *Modernization of Poultry Slaughter Inspection: Verifying an Establishment's Procedures for Preventing Contamination by Enteric Pathogens and Fecal Material,* and FSIS Directive 6410.3 *Verifying Sanitary Dressing and Process Control Procedures by Off-Line Inspection Program Personnel (IPP) in Poultry Slaughter Operations.* FSIS will no longer assign the Poultry Sanitary Dressing Verification task in the Public Health Information System (PHIS). This directive also supersedes instructions relating to poultry fecal contamination verification (Chapters III., IV., and V.) of <u>FSIS Directive 6420.2</u>, *Verification of Procedures for Controlling Fecal Material, Ingesta and Milk Contamination.* Lastly, this directive clarifies that the recordkeeping and sampling requirements in <u>9 CFR 381.65(g)</u> are applicable to poultry establishments that slaughter under a religious exemption.

KEY POINTS

- Verifying establishments prevent contamination with feces and enteric pathogens throughout the slaughter process as part of the slaughter HACCP system
- Verifying establishments meet zero tolerance requirements for feces on poultry carcasses entering chilling system.
- Reviewing poultry slaughter establishment sampling results.

II. CANCELLATION

FSIS Directive 6410.3, Verifying Sanitary Dressing and Process Control Procedures by Off-Line Inspection Program Personnel (IPP) in Poultry Slaughter Operations, 7/17/12

III. BACKGROUND

A. <u>9 CFR 381.65(f)</u> requires all establishments that slaughter poultry other than ratites to develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller.

B. <u>9 CFR 381.65(g)</u> requires establishments that slaughter poultry other than ratites to develop,

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implement, and maintain written procedures to prevent contamination with enteric pathogens and feces throughout the slaughter process. FSIS verifies that establishments implement procedures to prevent contamination, rather than relying only on reconditioning and reprocessing procedures at the end of the line to remove contamination which could have been prevented earlier. Because any digestive tract contents can be a source of enteric pathogens, FSIS establishments are required to implement slaughter process.

C. <u>9 CFR 381.65(g)</u> also requires poultry slaughter establishments to determine which microbial organisms will be effective in monitoring process control and implement their own sampling plans, specifically for enteric pathogens and fecal contamination. An establishment may test for generic *E. coli*, as was previously required, as its indicator organism in its sampling procedures if the establishment determines such testing is effective for monitoring its ability to maintain process control.

D. The regulations require poultry slaughter establishments to incorporate the above written procedures into their Hazard Analysis Critical Control Point (HACCP) plan or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite program. The HACCP plan, Sanitation SOP, and prerequisite programs together are also called the "HACCP system". Establishments may elect to respond to all of the requirements (<u>9 CFR 381.65</u>(f), (g), and (h)) in one written program or in separate programs in their HACCP system. However, as outlined in <u>81 FR 7289</u>, if an establishment produces product associated with an outbreak or has failed to meet a pathogen reduction performance standard for *Salmonella* or *Campylobacter* and has not addressed those hazards in its HACCP plan, the establishment would need to reassess its HACCP plan for that product to determine whether the HACCP plan needs to be modified to address the hazard (<u>9 CFR 417.3(b)</u>). Thus, the establishment, to maintain an adequate HACCP system, will have to address the pathogen in its HACCP plan, rather than through a prerequisite program like the Sanitation Standard Operating Procedures.

E. The above requirements in <u>9 CFR 381.65(f)</u>, (g), and (h), including the recordkeeping and sampling requirements, apply to poultry establishments that slaughter poultry under any of the exemptions based on religious dietary laws in <u>9 CFR 381.11</u> through <u>9 CFR 381.14</u>.

IV. VERIFYING THAT ESTABLISHMENTS PREVENT CONTAMINATION BY ENTERIC PATHOGENS AND FECAL MATERIAL THROUGHOUT ENTIRE SLAUGHTER AND DRESSING OPERATION

A. IPP are to verify that an establishment meets the requirements of <u>9 CFR 381.65</u>(f) and (g) to prevent contamination with enteric pathogens and feces throughout the slaughter operation in two main ways, which are described further below:

- 1. IPP are to perform the Poultry Zero Tolerance task to verify that the establishment's HACCP system is preventing carcasses contaminated with feces from entering the chilling system. (See Section V below.)
- 2. When IPP verify the establishment's food safety system meets HACCP requirements in accordance with the instructions in FSIS <u>Directive 5000.1</u>, *Verifying an Establishment's Food Safety System,* they are to verify that the establishment implements the written programs required by <u>9 CFR 381.65(f)</u> and <u>381.65(g)</u> effectively to prevent contamination with feces and other sources of enteric pathogens. IPP are also to verify that the establishment meets the applicable recordkeeping requirements of <u>9 CFR 381.65(h)</u>. IPP are also to review the results of the establishment's microbiological sampling program as part of this verification. (See Section VI below.)
- B. IPP are to document any regulatory noncompliances they observe during these verification activities as

described in Section VII below.

C. IPP are also to consider their findings from these two verification activities together with other findings to evaluate whether the establishment is effectively implementing the components of its HACCP system to ensure that poultry are slaughtered under sanitary conditions. If the overall pattern of inspection findings suggest that the establishment is not maintaining sanitary conditions throughout the slaughter process, IPP are to consult with their supervisor as described in Section VII, G below.

V. VERIFYING THAT ESTABLISHMENTS PREVENT CARCASSES CONTAMINATED WITH FECES FROM ENTERING THE CHILLING SYSTEM

A. IPP assigned to establishments that operate under any poultry slaughter inspection systems are to perform scheduled and unscheduled Poultry Zero Tolerance Verification tasks as described below to verify that the establishment is preventing carcasses with fecal material from entering the chiller (<u>9 CFR</u> <u>381.65(f)</u>).

- Each day, IPP are to conduct at least two (eight for NPIS) fecal contamination checks for each evisceration line for every shift (i.e., the number of checks per day will total at least 2 x number of shifts x number of lines) and as scheduled by the Public Health Veterinarian (PHV). IPP are to schedule directed tasks in PHIS as needed above the routine number of Poultry Zero Tolerance Verification Tasks assigned by PHIS to document the correct number of fecal contamination checks each shift.
- Each fecal contamination check by IPP consists of selecting and examining 10 poultry carcasses after the final wash and before the chilling tank, to verify that the establishment's process produces product free of visible fecal contamination. Results of the checks help determine whether the written procedures for preventing carcasses with feces <u>9 CFR 381.65(f)</u> from entering the chiller are effective.
- 3. IPP are to examine each 10-bird sample set at the pre-chill re-inspection station using the inspection procedure in Attachment 1 to examine each carcass. To ensure consistency, IPP are to identify feces according to the identification guidelines for feces in Attachment 1.
- 4. If IPP observe feces on any of the 10 birds in a set, IPP are to notify the establishment and document noncompliance with <u>9 CFR 381.65(f)</u> as described in Section VII below.
- 5. If IPP observe ingesta on a carcass during the fecal contamination check, IPP are to notify establishment personnel and verify that the ingesta is removed from the affected carcass. IPP are not to document noncompliance for this finding. However, IPP are to consider the possible sources of the ingesta contamination when performing the additional verification activities below.

VI. VERIFYING THE ESTABLISHMENT'S WRITTEN PROGRAMS TO PREVENT CONTAMINATION WITH FECES AND ENTERIC PATHOGENS

A. IPP are to verify that establishments maintain and implement written programs to prevent contamination of carcasses with feces and enteric pathogens throughout the slaughter process, as required by 9 CFR <u>381.65</u>(f) and (g). IPP are to be aware of how the establishment has included such written programs in its HACCP system and verify implementation of those programs when performing the applicable food safety verification tasks – either Slaughter HACCP Verification or Operational Sanitation SOP Verification tasks in accordance with the instructions in FSIS <u>Directive 5000.1</u>.

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 with feces or ingesta. IPP are to verify that the establishment's procedures are not regularly or systematically allowing contamination to occur. IPP are also to consider recent findings during FSIS verification activities or establishment monitoring procedures that might suggest that increased contamination could be occurring in a certain location in the slaughter process and pay particular attention to those possible sources of contamination when observing establishment operations. If IPP observe potential insanitary conditions other than contamination with feces or ingesta, they are to refer to the instructions on verifying sanitation regulatory requirements in Chapter II of FSIS Directive 5000.1. When they observe the slaughter operation, IPP are to:

- 1. Observe carcasses at various points on the slaughter line for evidence of frequent or recurring contamination with visible ingesta or feces;
- Observe the contact surfaces and operation of establishment equipment (e.g., venter, opener) to verify the equipment appears to be adjusted correctly for the bird size or other factors and is not routinely contributing to fecal and or ingesta contamination of the carcasses;
- Observe establishment employees to verify that they are consistently preventing contamination of carcasses during dressing tasks and that they respond appropriately to correct visible contamination when it does occur;
- 4. Observe establishment employees implementing the procedures for preventing contamination with enteric pathogens and feces, including any monitoring, recordkeeping, or sampling activities that the establishment uses to document control of contamination during the slaughter process; and
- 5. Verify that establishments use reconditioning, reprocessing, or antimicrobial intervention treatments effectively to address any contamination that occurs during the slaughter process.
- C. IPP are to review establishment microbiological sampling records to verify that the establishment:
 - 1. Collects and analyzes microbiological samples as described in its written sampling program;
 - 2. Meets sampling locations and frequencies requirements of 9 CFR 381.65(g);
 - 3. Considers the overall levels of microbial contamination as well as the reduction in contamination between pre- and post-chill as indicators of process control;
 - Uses microbiological sampling results to monitor its ability to maintain process control as required in <u>9 CFR 381.65(g)</u>. IPP are to verify that establishments monitor and assess sampling results at preand post-chill locations;
 - 5. Takes actions to restore or improve process control when sampling results indicate problems with establishment's slaughter HACCP system; and
 - 6. Maintains daily records documenting the implementation and monitoring of its procedures to prevent contamination by enteric pathogens and fecal material throughout the slaughter process including records documenting the results of its sampling plan (<u>9 CFR 381.65(h)</u>). IPP are to verify that the establishment's test results are recorded in a manner that allows the analysis of test results to determine process control over time and identify situations that may indicate a loss of control. IPP are to verify that the establishment:

- a. Makes these records available for IPP to review and retains these records for one year; and
- b. Implements appropriate controls to ensure integrity of electronic data if records are maintained on computers.

D. 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.
- 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 which reduce the overall effectiveness of the establishment's system.
- 3. Sampling results show a trend of rising contamination over a relatively long period of time. Normal seasonal or weather-related changes can produce trends of more or less contamination on incoming birds, which may be reflected in establishment sampling results. However, if microbiological contamination increases from previous years or begins to deviate from an establishment's established seasonal pattern, this may indicate gradual decline of system effectiveness over time.
- 4. Other sampling programs begin to show significantly worse results. These could include FSIS carcass sampling results or FSIS or establishment sampling results from downstream products such as poultry parts and comminuted poultry products that originate from the establishment's slaughtered carcasses. Abnormal results of these other sampling programs may indicate that increased contamination is occurring during slaughter.

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

E. If IPP have questions about whether the establishment's records indicate it is maintaining process control, IPP should consult their supervisor.

F. If IPP observe that the establishment's written programs do not meet the requirements described above or the establishment's slaughter process is not consistently preventing carcasses or parts from becoming contaminated with feces or ingesta, they are to document noncompliance as described in Section VII below.

VII. 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 programs to prevent carcasses from becoming contaminated with feces or enteric pathogens during slaughter.

B. If IPP observe feces on a carcass during the Poultry Zero Tolerance task, they are to:

- Document noncompliance with <u>9 CFR 381.65(f)</u> and consider whether the noncompliance is associated with any previous noncompliances according to the instructions in Chapter V of <u>FSIS</u> <u>Directive 5000.1</u>;
- 2. Perform a Slaughter HACCP Verification task to verify that the establishment performs corrective actions for the affected product in accordance with <u>9 CFR 417.3(a)</u>;

C. IPP are to document noncompliance with the applicable Sanitation SOP requirements in <u>9 CFR 416</u> or HACCP requirements in <u>9 CFR 417</u> if they observe that:

- 1. Establishment employees are not implementing the establishment's procedures to prevent contamination, including sampling procedures, as written;
- 2. The establishment does not have records to document the implementation and monitoring of its procedures;
- 3. The establishment does not respond to findings of visible fecal contamination or sampling results as described in their HACCP plan, Sanitation SOPs or other prerequisite program; or
- 4. The establishment does not perform and document corrective actions when they identify product that has become contaminated with feces or ingesta.

D. IPP are to document noncompliance with the applicable regulatory citation from <u>9 CFR 381.65</u> if they observe that:

- The establishment has not developed written procedures to prevent carcasses contaminated with feces from entering the chilling system or has not incorporated those procedures into the HACCP system (<u>381.65(f)</u>); or
- 2. The establishment has not developed written procedures to prevent carcasses from becoming contaminated with feces or enteric pathogens throughout the slaughter process, if those procedures do not include microbiological sampling, or if the establishment has not incorporated those procedures into the HACCP system (<u>381.65(g)</u>).

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

1. The establishment is not properly implementing its written procedures (<u>381.65(g)</u>);

- The establishment does not have necessary support for its sampling program to show that its testing is effective to determine whether the system is preventing pathogens (<u>417.5(a)(1)</u>);
- 3. The establishment does not include support for testing for indicator organisms (417.5(a)(1));
- 4. The establishment is not, at a minimum, conducting microbiological sampling at the required location or frequency according to the establishment's size and production volume (<u>381.65(g)</u>);
- 5. The establishment does not maintain sample integrity, (e.g. randomness and handling of samples) (<u>381.65(g)</u>);
- The establishment is not maintaining daily records to document the implementation and monitoring of its written procedures (<u>381.65(h)</u>);
- The establishment does not make records available for FSIS access or does not retain records for one year (<u>381.65(h)</u>); and
- If the establishment does not conduct corrective actions to address findings of visible fecal contamination as required by HACCP (<u>9 CFR 417.3</u>), Sanitation-SOPs (<u>9 CFR 416.15</u>) or other prerequisite program (<u>9 CFR 417.5</u>).

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

- Document noncompliance with <u>9 CFR 381.65(g)</u> and consider whether the noncompliance is associated with any previous noncompliances according to the instructions in Chapter V of <u>FSIS</u> <u>Directive 5000.1</u>;
- 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 <u>9 CFR 417.3</u> or <u>9 CFR 416.15</u>;
- 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 to restore process control; and

G. IPP are to consider whether the overall pattern of inspection findings suggests that the establishment is not maintaining sanitary conditions throughout the slaughter HACCP system. For example, if an establishment has repetitive associated HACCP or SSOP noncompliances for multiple aspects of the slaughter system, or if the establishment's corrective actions in response to findings of visible fecal contamination are consistently ineffective, it may indicate systemic problems with the establishment's slaughter HACCP system, and may indicate that the establishment is slaughtering poultry 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.

VIII. QUESTIONS

IPP are to refer questions regarding this directive to their supervisor. Follow up questions regarding the verification of written procedures to prevent visible fecal material throughout the slaughter operations can be sent to the Policy Development Staff (PDS) through <u>askFSIS</u>. Refer follow up questions regarding verification of microbiological testing procedures to the Risk and Innovations Management Staff (RIMS)

through <u>askFSIS</u>. PDS and RIMS can also be reached by telephone at 1-800-233-3935.

When submitting a question through <u>askFSIS</u>, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter FSIS Directive 6420.5

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 PDD General from the drop-down menuCategory Field:Select Slaughter/Poultry from the drop-down menu

For questions regarding microbiological testing procedures:

Product Field:Select Sampling from the drop-down menu.Category Field:Select General from the drop-down menuPolicy 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.

John

Assistant Administrator Office of Policy and Program Development

Inspection Procedure for Examining Carcasses Offline

To conduct the PHIS Poultry Zero Tolerance Verification task, IPP are to examine each 10-bird sample set at the pre-chill re-inspection station. To ensure consistency, IPP are to use the inspection procedure described below to examine each carcass and identify feces according to the identification guidelines for feces in Attachment 2.

- a. Outside back: While holding the carcass, with the back of the carcass toward the inspector and starting at the hock area, observe the hocks, back part of the legs, tail area, back of the carcass and top side of the wings;
- b. Outside Front. Turn the carcass and observe the bottom side of the wings, breast, and front part of the legs;
- c. Inside: Observe the inside surfaces of the carcass and the abdominal flaps and fat; and
- d. Neck Flap Area: Observe the neck flap and the thoracic inlet area.

Identification of Feces for Poultry

To determine whether an establishment is preventing poultry carcasses with visible fecal material from entering the chilling tank (as required by <u>9 CFR 381.65(f)</u>), inspection program personnel who examine carcasses must be able to properly identify feces.

Three factors—color, consistency, and composition—are essential in identifying fecal material on the inside or outside of poultry carcasses.

• The color of feces ranges from varying shades of yellow to green, brown, and white.

The consistency of feces is characteristically semi-solid to a paste.

- The composition of feces may or may not include plant material. Inspection program personnel must take care to distinguish feces from ingesta.
- The color of ingesta varies with the diet.
- The consistency of ingesta is characteristically solid or granular; digestive fluids sometimes are present.
- The composition of ingesta is identifiable plant material.

<u>9 CFR 381.65(f)</u> does not apply to ingesta. However, inspection program personnel who find ingesta during fecal contamination checks are to notify establishment management to remove ingesta from affected carcasses.)