

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

FSIS DIRECTIVE

6410.1

5/4/09

VERIFYING SANITARY DRESSING AND PROCESS CONTROL PROCEDURES IN SLAUGHTER OPERATIONS OF CATTLE OF ANY AGE

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL JUNE 1, 2009.

I. PURPOSE

A. FSIS has observed a number of significant adverse developments involving *Escherichia coli* O157:H7 (*E. coli* O157:H7) over the past year. They include an increased number of *E. coli* O157:H7 positive samples of ground beef and trim collected by FSIS and an increased number of recalls associated with *E. coli* O157:H7, including those specifically initiated as a consequence of human illness. These increases can be attributed, in part, to ineffective sanitary dressing and process control procedures that create insanitary conditions during slaughter. Effective sanitary dressing and process control procedures are crucial to an establishment's ability to produce a clean, safe, and wholesome product.

B. Effective sanitary dressing and process control procedures underpin the critical control points (CCPs) that prevent, eliminate, or reduce to an acceptable level food safety hazards that are reasonably likely to occur in the slaughter process. In a 2002 Federal Register Notice (67 FR 62325-62334, October 7, 2002), FSIS stated that it considers an acceptable reduction of *E. coli* O157:H7 to be a reduction to an undetectable level. In the absence of knowing and documenting whether the sanitary dressing and process control procedures are being properly implemented, the HACCP system likely would not be adequate to ensure that *E. coli* O157:H7 is reduced to an undetectable level.

C. Events such as the increase in FSIS percent positive trim and ground beef samples for *E. coli* O157:H7 are evidence that many beef slaughter HACCP systems are inadequate. The CCPs at these beef slaughter operations may no longer be capable of ensuring that they are reducing *E. coli* O157:H7 to an undetectable level. This is, in part, because the sanitary dressing and process control procedures in slaughter operations are inadequate. FSIS believes slaughter operations should more consistently focus on their sanitary dressing and process control procedures. Consequently, this directive provides off-line inspection program personnel (IPP) with information regarding how to verify that cattle slaughter operations are focusing on sanitary dressing and process control procedures and that those procedures are under control. In addition, this directive provides information describing how off-line IPP are to verify that establishments have validated their HACCP systems. It is expected that the validation

addresses the impact of the sanitary dressing and process control procedures that include the decontamination and antimicrobial intervention treatments, as well as the feedback on microbial test results from trim and ground beef sampling that the slaughter establishment receives from subsequent raw beef processing operations.

Key Points:

- Define Process Control Procedures
- Define Sanitary Dressing
- Describe the purpose of sanitary dressing and process control procedures
- Describe the points in the slaughter process where carcass contamination with food safety hazards, such as *E. coli* O157:H7, are most likely to occur
- Describe how the establishment's failure to properly execute its sanitary dressing and process control procedures can increase the risk of carcass contamination at various points in the slaughter operation
- Provide instruction on how to verify that cattle slaughter operations are implementing appropriate sanitary dressing and process control procedures to both prevent contamination of the carcass and to properly apply decontamination and antimicrobial intervention treatments to the carcass
- Provide instruction on how to verify that the establishment is properly assessing the impact of microbial testing results (e.g., Total plate counts, aerobic plate counts) including indicators of process control, at any point during slaughter and at subsequent trim fabrication and grinding operations. Examples of microorganisms used for indicators of process control in raw beef operations include: *Enterobacteriaceae*, generic *E. coli*, *E. coli* O157:H7, and *Salmonella*
- Provide information regarding the food safety system and how each aspect of the system (e.g., sanitary dressing and process control procedures, intervention treatments, product sampling, supporting documentation) are factors to be considered when determining regulatory compliance
- Provide information regarding documenting noncompliance and enforcement

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

[9 CFR 307.2\(g\) and \(m\), 310.3, 310.17\(a\), 310.18\(a\), 318.4\(b\), part 416, part 417](#)
[FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#)
[FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel](#)
[Federal Register: November 28, 1997, Volume 62, Number 229, Page 63254-63255](#)

V. DEFINITIONS

Process Control Procedure: A defined procedure or set of procedures designed by an establishment to provide control of operating conditions that are necessary for the production of safe, wholesome food. The procedures typically include observing or measuring system performance, analyzing the results to set control criteria, and taking action when necessary to ensure that the system continues to perform within the control criteria. The procedure would include planned measures taken by the establishment in response to any loss of process control. In addition, the procedure can be used as support for decisions made in the hazard analysis.

Sanitary dressing: Practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat food product in a sanitary environment.

VI. BACKGROUND

A. As set out in 9 CFR 310.18(a), establishments are required to handle beef carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter. Because these sources of contamination, whether visible or not visible, may contain pathogens, a principal objective of proper sanitary dressing and process control procedures is to reduce the potential for exposure of the carcass to any food safety hazard during the removal of the hide, feet, head, gastrointestinal tract, and other internal organs. The design of the establishment's slaughter operation should include a means to measure how well the sanitary dressing and process control procedures accomplish this purpose.

B. Under 9 CFR 416.1, each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. In addition, 9 CFR 416.2 through 416.5 identify the Sanitation Performance Standards (SPS) that establishments need to meet to maintain sanitary conditions.

C. It is FSIS's expectation that establishments will slaughter and process cattle in a manner designed to prevent contamination from occurring at any step in the process and to use decontamination and antimicrobial interventions treatments as necessary to address any contamination that (a) may result from the implementation of the slaughter process or (b) otherwise occur on the carcasses. To meet this expectation, establishments may employ practices such as:

- Maintaining adequate separation of carcasses, parts, and viscera during dressing
- Routinely cleaning and sanitizing or sterilizing equipment and hand tools that are used to remove contamination or to make cuts into the carcass
- Designing and arranging equipment to prevent the contact of successive carcasses and parts with contaminated equipment, or not allowing the hide during its removal to flap or splatter, causing contamination of carcasses
- Washing frequently hands and aprons that come in contact with the carcass
- Implementing decontamination and antimicrobial intervention treatments such as carcass washes or sprays, in accordance with the limits selected by the establishment, and documented to be adequate to address contamination

D. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are necessary to prevent the creation of insanitary conditions. Establishments that fail to control these procedures and treatments create the potential for carcass contamination in their food safety systems.

VII. FSIS VERIFICATION OF SANITARY DRESSING AND PROCESS CONTROL PROCEDURES

NOTE: The verification activities addressed in this directive are to be used in conjunction with, and can be conducted simultaneously with, those addressed in FSIS Directives 6100.1, Ante-mortem Livestock inspection and FSIS Directive 6100.2, Post-mortem Livestock Inspection. Verification of procedures for controlling fecal material, ingesta and milk in slaughter operations is to be conducted in accordance with FSIS Directive 6420.2.

A. IPP that perform off-line slaughter verification duties (hereafter referred to as off line IPP) are to verify sanitary dressing and the process control procedures conducted in a cattle slaughter facility in accordance with the instructions in this section. Establishments may elect to maintain written procedures as part of the HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP) or other pre-requisite programs. Information regarding verification of these written programs is included in Section X.C. of this document.

B. PBIS procedure 06D01 encompasses a variety of regulatory Sanitation Performance Standards (SPS) designed to ensure that insanitary conditions are not being created. This will include ensuring that the sanitary dressing and process control procedure being utilized by the slaughter establishment are sufficient to prevent the

contamination of carcasses during slaughter operations. To ensure that all regulatory requirements associated with the performance of 06D01 are met, IPP are to do the following:

- 1) Every other week, during the performance of the scheduled weekly 06D01 procedure, off-line IPP are to verify the establishment's sanitary dressing and process control procedures. The verification is to focus on all aspects of the establishment's sanitary dressing and process control procedures. Once verification of sanitary dressing and process controls procedures has been completed on that day, IPP are to verify any additional SPS requirements (e.g. lighting, plumbing, rodent and pest control) in accordance with FSIS Directive 5000.1, as time allows.

NOTE: Off-line IPP are to evaluate the sanitary dressing and process control procedures in relation to the food safety system and not just one step of the process.

- 2) On the alternate week, during the performance of the scheduled weekly 06D01 procedure, off-line IPP are to focus their verification on one or more of the SPS requirements (e.g., lighting, plumbing, rodent and pest control) in accordance with FSIS Directive 5000.1. Once verification of the SPS requirements has been the completed on that day, IPP are to verify as many of the aspects of the establishment's sanitary dressing and process control procedures, in accordance with this directive, as time allows.
- 3) Based on the information gathered while conducting the verification methodology presented in this directive (e.g. increased numbers of positive *E. coli* testing results or Zero Tolerance findings; feedback from on-line FSIS personnel regarding carcass contamination; repeated or on-going loss of process control), off-line IPP may believe there is evidence of systemic conditions that affect sanitary dressing and process control. They may perform a focused verification of the sanitary dressing and process control procedures more frequently than once every other week if it is determined to be necessary by supervisory personnel. An additional 06D01 procedure can be performed as an unscheduled procedure in lieu of a scheduled 04C03 procedure. If the 04C03 procedure has already been replaced with an 08S procedure, the unscheduled 06D01 is to be conducted in lieu of a scheduled 01C02.

C. Off-line IPP are to gather information using the questions in Section VIII, Parts A-J of this directive to assist them in determining whether an establishment's slaughter operation meet the requirements of 9 CFR 416 and are not creating insanitary conditions that result in product adulteration. The questions provided at each point in Section VIII, Parts A-J below, are not all-inclusive, and may vary depending on the type of slaughter operation being conducted (e.g., a high-speed line vs. bed/cradle dressing operation).

NOTE: a negative or adverse response to one question is not an automatic indication of regulatory noncompliance or of a system failure. When making determinations of regulatory compliance (i.e., the prevention of the creation of insanitary conditions), IPP performing off-line duties are to consider how the information they have gathered relates to the food safety system. This could include:

- information regarding sanitary dressing and process control procedures; decontamination and antimicrobial intervention treatments;
- feedback to the slaughter operation on its effectiveness relative to microbial testing on carcasses, trim, or ground beef;
- the adequacy of the training of plant employees for their assignment to particular points in the process because appropriate performance by establishment personnel is necessary for adequate process control.

D. When the information gathered suggests that the establishment has lost process control, off-line IPP may need to increase the frequency of their verification of sanitary dressing and process control procedures, based on sound professional judgment and with in-input from the immediate supervisor. The following examples can indicate a loss of control:

- A comparison of findings between current, and previous, off-line IPP reviews that indicates an increase in contamination. For example, has there been a recent cluster of contamination events following a period of substantial compliance?
- Evidence that contamination events are not being effectively prevented (e.g. Receiving in-input regarding on-line verification activities that demonstrates that on-line IPP are finding contamination, or observing improper dressing procedures, more frequently than expected).
- In-input from supervisory personnel when there is an increase in positive pathogen results in trim or ground beef samples, from either FSIS or establishment microbiological testing, beyond what is expected, explained, and documented under conditions in which effective sanitary dressing and process controls are implemented.

E. When verifying the establishment's food safety system as set out in FSIS Directive 5000.1, off-line IPP are to determine whether the establishment has CCPs or other written programs that address any of the potential contamination points identified below in this directive, and verify that the establishment properly executes such CCPs or other programs.

F. Off-line IPP are to gather information using the methodology outlined in Section VIII of this directive to assist in the determination of regulatory noncompliance and document noncompliance in accordance with the instructions in Section X of this

directive.

VIII. POTENTIAL CONTAMINATION POINTS IN THE SLAUGHTER PROCESS

FSIS has identified, through both scientific literature review and best practice guidance created by industry, the points in the slaughter process where carcasses are most vulnerable to contamination. The steps listed in this directive are not all-inclusive but are those that are most frequently associated with carcass contamination. The steps listed in the directive are in a sequential order (start to finish) for ease of presentation only. IPP are not required to verify them in that same sequential order and should determine the best sequence for verification based on the specific observations made at a given time.

The purpose of identifying and addressing these vulnerable points in this directive is to help off-line IPP focus on these points to verify that contamination events are effectively prevented and that the slaughter process is completed in a timely manner prior to chilling the carcass. Delays in chilling, such as power outages, equipment failure, or holding carcasses for extended periods prior to reconditioning to remove visible contamination, could cause pathogens to multiply. When contamination occurs, off-line IPP are to verify that the establishment takes steps to minimize recurrence, and that the establishment effectively addresses the reconditioning of the contaminated carcasses.

NOTE: When IPP conduct routine verification at the following points in the slaughter process, personal safety is paramount. Verifications are to be conducted from a safe vantage point, especially at the sticking and rodding locations. In addition, when conducting routine verifications, FSIS personnel are to follow good employee hygiene practices in order to ensure that their verification activities do not result in cross contamination of the carcasses.

A. Live receiving/holding

This is the point where cattle arrive at the establishment and are held prior to slaughter. There is an increased potential for contamination with enteric pathogens such as *E.coli* O157:H7 and *Salmonella* during this time due to their presence on the hide and in feces of cattle. Transportation to the slaughter facility, handling during transport and unloading, and interaction with other cattle may cause stress and increased shedding of pathogens.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at live receiving/holding include, but are not limited to:

- 1) What measures, if any, does the establishment take to reduce the pathogen load on in-coming animals? For example:
 - a. Does the establishment take measures, such as periodic cleaning of the

unloading areas and pens to reduce the contamination of animals during unloading and holding?

- b. Has the establishment elected to conduct cattle washing? If so, do they monitor the process to ensure that contamination is minimized?
 - c. Does the establishment use water mist as a means to reduce airborne dust and dirt particles in the holding area?
 - d. Has the establishment elected to utilize a “mud-scoring” system (i.e., a system to quantify the amount of mud on live animals) in order to identify cattle that may present an increased likelihood of contamination during hide removal?
- 2) What measures, if any, does the establishment take to determine the incoming bacterial load on animals?
- 3) Does the age or type of cattle received (e.g. veal calves) represent a concern related to pathogen load, and does the establishment consider that concern?

B. Sticking

This is the point in the process where the animal is bled. Regardless of the slaughter method, it is important for the establishment to minimize contamination of the carcass during any cut conducted at this step.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at sticking include, but are not limited to:

- 1) What measures does the establishment use to ensure that contamination of the carcass underlying the hide does not occur during the initial cut? For example:
 - a. Does the establishment use the smallest cut possible to accomplish bleeding?
 - b. Does the establishment use a one knife system whereby the hand and the knife are cleaned and the knife is sanitized between sticking each carcass, or elect to use a two knife system (i.e., one knife is being used while one knife is being sanitized) and the hand is cleaned between sticking each carcass?
- 2) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

C. Hide removal (manual and mechanical)

This is the point in the process where the hide is removed from the animal. Hides are a significant source of contamination (e.g., dust, dirt, feces, mud). It is important to maintain sanitary conditions when handling the hide.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at hide removal include, but are not limited to:

- 1) What measures does the establishment use that minimizes the likelihood of contamination of the carcass during the opening of the hide (other than sticking)? For example:
 - a. Has visible contamination been removed at the cut line (e.g., with air knives or by steam vacuuming)?
 - b. Does the establishment remove the udder in a manner to prevent contamination of the carcass with milk, as well as to prevent contamination of the exposed carcass by the hide, or by a soiled knife or employee hand?

- 2) What measures does the establishment use to limit cross contamination of carcasses during hide removal? For example:
 - a. Does the establishment have shields between the carcasses and hide puller to minimize potential contamination?
 - b. Does the establishment minimize the possibility that contaminants can become airborne from splattering or flapping of the hide by severing or removing the switch on the tail when hide pullers are used?
 - c. Do mechanical hide pullers pull the hide away from the carcass (e.g., downward or backward and not upward), thereby reducing the potential for contamination to drip, splatter, or flap onto the carcass or employees handling de-hided carcasses?
 - d. Does the exterior side of the hide touch, slap, or flap the carcass when being removed, potentially allowing the dirty exterior side to touch the carcass?
 - e. Is the establishment maintaining clean mechanical hide puller contact points with the hide, hands and garments of the employees handling the hide and the carcass, and knives and other equipment contacting the de-hided carcass?
 - f. Do employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled

hands, tools, or garments)?

- 3) What measures does the establishment have in place to allow for adequate distance between carcasses throughout the slaughter dressing process to minimize carcass-to-carcass contact and cross contamination?
- 4) Are wash cabinets used at this, or any, point in the slaughter process? If so, what measures does the establishment take to ensure the cabinets do not spread contamination to adjacent carcasses? For example:
 - a. Does the establishment have measure in place to control overspray of water from the cabinet?
 - b. Does the establishment take measures to address conditions such as open abscesses, septic bruises, or the presence of parasites and parasitic lesions before carcasses enter the cabinet?
 - c. Does the establishment address pooling of water around anus of the carcass prior to dropping the bung?
 - d. Does the establishment take measures to ensure that carcasses with excessive contamination do not cross contaminate other carcasses (i.e., create an insanitary condition)?
 - e. Does the establishment take measures to ensure that carcasses identified with U.S. Suspect or Retained tags, and which are to be removed from the slaughter line at a further point in the process, do not enter the cabinets unless measures are in place to prevent cross contamination of equipment or other carcasses?

NOTE: U.S. Suspects are to be washed in these cabinets only with permission of the PHV, and in consideration of whether the design of the cabinet prevents cross contamination of other carcasses.

- 5) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

D. Bunging

This is the point in the slaughter process where a cut is made around the rectum (i.e., terminal portion of the large intestine) to free it from the carcass, and then it is tied off to prevent spillage of fecal material.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at bunging include, but are not limited to:

- 1) What measures does the establishment take to ensure that carcass contamination does not occur? For example:
 - a. Is the establishment putting plastic bags and ties on the bung in a sanitary manner?
 - b. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?
- 2) Does the establishment employ any validated decontamination or antimicrobial intervention treatment that is effective in reducing presence or counts of microbial contaminants at this point in the process?

E. Brisket opening

This is the point in the process where the brisket is split (i.e., cut along the centerline).

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at brisket opening include, but are not limited to:

- 1) What measures is the establishment taking to prevent the introduction of contamination into the carcass at this point in the process? For example:
 - a. Is the establishment cleaning and sanitizing the brisket saw and knife between each carcass, and ensuring that the gastrointestinal tract is not punctured?
 - b. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?
- 2) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

F. Head removal

This is the point in the slaughter process where the head is removed from the carcass. It is important to maintain sanitary conditions because cross contamination can occur if the head comes into contact with insanitary heads, equipment, and employee handling.

Questions that off-line IPP should consider when verifying sanitary dressing and

process control procedures at head removal include, but are not limited to:

- 1) What measures has the establishment implemented to ensure that contamination of heads, equipment, and employees does not occur? For example:
 - a. Are heads removed in a manner that avoids contamination with digestive tract contents or specified risk materials (SRM)?
 - b. Is the establishment adequately washing heads, including thoroughly flushing the nasal cavities and mouth before washing the outside surfaces?
 - c. Does the establishment limit the splashing of water when washing heads in order to prevent cross contamination and to limit airborne contaminants?
 - d. Does the establishment properly maintain and clean knives?
 - e. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?
- 2) If a head wash cabinet is used at this point in the slaughter process, what measures does the establishment use to ensure that excessively contaminated heads do not enter the cabinet, that the equipment holding the head does not contaminate the head, or that spray from the cabinet does not spread contamination to adjacent heads?
- 3) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

G. Rodding the weasand (esophagus)

This is the point in the process where the establishment uses a metal rod to free the esophagus (weasand) from the trachea and surrounding tissues. Weasand meat may be salvaged from the remainder of the gastrointestinal tract for use in raw ground beef production. Typically, the weasand is closed (i.e., tied) to prevent rumen spillage. It is important, at this point in the process, that contamination is not transferred from the exterior of the carcass to the interior or onto the weasand. In addition, if, during the rodding process, the gastro-intestinal tract is punctured, it can cause contamination of the carcass interior and exterior with ingesta content.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at the point of rodding the weasand include, but are not limited to:

- 1) What measures does the establishment take to prevent the introduction of contamination into the carcass during this point in the process? For example:
 - a. Does the establishment have a means to close the esophagus to prevent leakage of rumen contents?
 - b. Do employees maintain proper employee hygiene practices (e.g., wash hands and arms often enough to prevent contamination of the carcass)?
 - c. Do employees change or sanitize the weasand rod between each carcass?
- 2) Is the weasand cleaned and chilled quickly to limit contamination and pathogen multiplication?
- 3) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

H. Evisceration

This is the point in the process where the removal of the viscera (e.g., the edible offal that includes the heart, intestines, paunch, liver, spleen, and kidneys when presented with viscera) occurs. If the viscera are not handled properly, or if employee hygiene practices are not being followed, contamination of the carcass and edible offal can occur.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at evisceration include, but are not limited to:

- 1) What measures does the establishment take to prevent contamination of the viscera during removal? For example:
 - a. Do establishment employees remove visible contamination from the area to be cut (e.g., by trimming or by using air knives or by steam vacuuming) before the cut is made?
 - b. Is the uterus removed in a manner that prevents contamination of the carcass and viscera?
- 2) What measures does the establishment implement to ensure that employees do not contaminate carcasses during evisceration? For example:
 - a. Do employees properly use knives to prevent damage (i.e., puncturing) to the paunch and intestines?

- b. Is contamination removed in a timely manner and in accordance with accepted reconditioning procedures?
 - c. Are footbaths, and separate footwear, being used by employees on moving evisceration lines to prevent footwear from contaminating other parts of the operation?
- 3) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

I. Carcass splitting

This is the point in the process where carcasses are split vertically into two halves.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at splitting include, but are not limited to:

- 1) What measures does the establishment take to prevent the split carcass from becoming contaminated? For example:
 - a. Is the establishment cleaning and sanitizing the saws and knives between each carcass?
 - b. Does the establishment allow for adequate distance between carcasses (i.e., limit carcass-to-carcass contact)?
- 2) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?
- 3) Does the establishment address the removal of spinal cord in accordance with 9 CFR 310.22?

J. Head and Cheek Meat Processing

This is the point in the process where the meat is removed from the head and cheek. This meat can be used in the production of raw beef products, including ground beef. It is important for the establishment to maintain sanitary conditions.

Questions that off-line IPP should consider when verifying sanitary dressing and process control procedures at head meat/cheek meat processing include, but are not limited to:

- 1) What measures does the establishment take to ensure that head meat/cheek

meat is safe to use in raw beef? For example:

- a. Does the establishment properly maintain and clean knives?
 - b. Does the establishment utilize measures sufficient to prevent cross contamination of heads?
 - c. Do employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g. touching the head with soiled hands, tools, or garments)?
- 2) Is head and cheek meat quickly chilled to limit pathogen multiplication?
 - 3) Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

IX. VALIDATED INTERVENTIONS

A. General

The following discussion provides an introduction to validation for off-line IPP:

1. How well the establishment performs its slaughter dressing procedures directly bears on whether the decontamination and antimicrobial intervention treatments in place in an operation will have their intended effects. When contamination overwhelms the decontamination and antimicrobial intervention treatments, reduction of *E.coli* O157:H7 may no longer meet the standard of reduction to an undetectable level. FSIS will have questions about the establishment's ability to support that the food safety system is having the effect that the hazard analysis anticipates, unless the establishment has:

- validated its food safety system at slaughter, including sanitary dressing procedures coupled with all intervention treatments) to be effective under the actual conditions that apply in its operation; or,
- the establishment has reassessed its system in response to any changes that have occurred since the last time it validated its food safety system and determined that no changes were necessary

2. In accordance with the requirements of 9 CFR 417.4(a)(1), an establishment that has CCPs designed to control contamination during the slaughter and dressing operation, is to validate the individual CCPs to ensure that they are effective in preventing, eliminating, or reducing pathogens to an undetectable level under the establishment's operating conditions. Until establishments demonstrate that the interventions employed at each CCP will achieve the anticipated effect under actual in-

plant conditions, the effectiveness of the CCP is theoretical, and it can not be considered adequately validated.

3. Importantly, to meet the requirements of 9 CFR 417.5(a)(1), an establishment's hazard analysis must include all documentation that supports the decisions made for the food safety system. Thus, an establishment whose hazard analysis makes the judgment that its SOP, GMP, or other prerequisite program will prevent contamination during the slaughter and dressing operation needs to include as part of its hazard analysis data and other information that support that judgment. Unless these establishments demonstrate that the measures implemented through the SOP, GMP or other prerequisite program coupled with the decontamination and antimicrobial intervention treatment will achieve the anticipated effect under actual in-plant conditions, FSIS will view the effectiveness of the food safety system as theoretical and not adequately validated for that operation.

4. Establishments can validate their individual decontamination and antimicrobial intervention treatments by ensuring that the interventions used to control hazards at the CCP are implemented in a manner that is consistent with the parameters of any scientific, peer-reviewed, published studies, or challenge studies being used as support for decisions in their hazard analysis. For both the individual treatments, and the food safety system, one mechanism available to an establishment to demonstrate that the controls achieve their intended effect is testing a representative sample of carcasses for microbial indicators of process control using non-pathogenic indicator organisms. The testing would occur prior to, and after, the application of the controls to show that the anticipated reduction has occurred. Off-line IPP can assess whether the results of this testing are reflective of those reported in the supporting documents.

NOTE: In establishments that elect to test for the pathogen of concern, finding only sporadic positives can be an indication that the system is functioning as designed and is effective. However, failure to find any positives may be an indication that the sampling and testing methods are not sufficient to detect the pathogen of concern and therefore may be failing to provide vital feedback on the food safety system.

B. FSIS Verification of Validated Interventions

1. Once per month when conducting the 03J01 procedure in accordance with the methodology in FSIS Directive 5000.1, off-line IPP are to consider the food safety system when verifying that the establishment is meeting its responsibility to reduce *E.coli* O157:H7 to an undetectable level. In addition, off-line IPP are to review the establishment's interventions, supporting documentation, and testing records and consider questions such as the following:

- a) Has the establishment considered the level of contamination that may be on the incoming animals?
- b) Has the establishment used that information as a measure to demonstrate that

its interventions are capable of addressing the expected contamination load?

- c) Is the establishment effectively using sanitary dressing procedures as a means to minimize contamination and thereby preventing the creation of insanitary conditions?
- d) Has the establishment demonstrated that its interventions, as applied within their day-to-day operations, are effective under actual in-plant conditions?
- e) Does the establishment use some form of Statistical Process Control (SPC), such as ongoing testing of carcasses for an indicator organism (i.e., prior to and post application of interventions) to demonstrate that its CCPs achieve the intended reduction in organisms?
- f) Does the establishment assess the impact of microbial testing results on their operation, including generic *E. coli* and *Salmonella* on carcasses, *E. coli* O157:H7 on trim, and *E. coli* O157:H7 and *Salmonella* on ground beef?
- g) When the establishment conducts multiple operations (e.g., slaughter and processing/trim manufacture in one facility), does the establishment have documentation that describes how and when communication between the production departments regarding slaughter/dressing performance and trim testing results is to be recorded?
- h) Does the establishment explain how the communication documentation is made available to the IIC for review?
- i) Does the establishment describe how that information will be used to investigate, and to adjust, the food safety system to ensure that the food safety system is adequate to control *E. coli* O157:H7?

2. When off-line IPP have concerns that the establishment's interventions, as implemented, are not validated or that they do not achieve the intended reduction in organisms (e.g., *E. coli* O157:H7), they are to contact the District Office (DO) and request that an EIAO conduct a Food Safety Assessment (FSA). The DO will consider off-line IPP findings based on food safety concerns and risk to the product and prioritize the FSA as necessary.

X. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. Using the information gathered during FSIS verification (see Sections VII, VIII and IX.B of this directive), off-line IPP are to determine whether noncompliance exists. Off-line IPP should use any findings, such as those listed below, as prompts to direct them to points in the slaughter process where sanitary dressing procedures are not being properly implemented, and insanitary conditions are being created as a result of the loss of process control:

- 1) Repeated or ongoing noncompliance related to contamination of carcasses with feces, milk, or ingesta at the final rail (i.e. zero tolerance);
- 2) Repeated or ongoing loss of process control resulting in failure to prevent contamination of carcasses or parts with fecal material, urine, bile, hair, dirt, or foreign matter or failure to effectively remove such contaminants before final inspection;
- 3) Establishment or FSIS microbial sampling results from carcasses, trim (including head meat and cheek meat), or ground beef that indicate high or increasing microbial contamination of carcasses or parts with generic *E.coli*, *Salmonella*, or *E.coli* O157:H7;
- 4) Increased contamination on carcasses due to environmental conditions (e.g., weather or season), age of animals (e.g. veal calves), or by other factors affecting the condition of incoming animals that have not been addressed by the establishment;
- 5) Inappropriate design or use of facilities, equipment, or utensils for the type or size of beef slaughtered;
- 6) Results of any establishment programs designed to prevent insanitary conditions during dressing procedures that may not support decisions made in the hazard analysis;
- 7) Feedback from on-line IPP and IIC indicating increased incidents or frequency of carcass contamination (i.e., increased contamination may be an indication that the slaughter line speed is too fast);
- 8) Feedback from in-plant processing IPP and IIC indicating an increase in positive *E.coli* O157:H7 test results, either FSIS or establishment results, in non-intact trim or ground beef;
- 9) Feedback via STEPS notification that the establishment may be implicated in supplying *E.coli* O157:H7 positive beef to another establishment or in an illness-related recall action;

B. Off-line IPP are to document noncompliance using 06D01 procedure code when an insanitary condition has been created as the result of the ineffective implementation of the sanitary dressing procedures.

NOTE: When seeking answers to the example questions listed throughout this directive, a negative or adverse response to one question is not an automatic indication of regulatory noncompliance or a system failure. When making determinations of regulatory compliance and process control, off-line IPP are to consider how all the

information they have gathered relates to the food safety system.

Specifically, off-line IPP are to:

- 1) document the creation of an insanitary condition using the 06D01 procedure code, and the “p”-- “product based “ noncompliance result code;
- 2) cite 9 CFR 310.18(a) to address the contamination of the carcass and also cite appropriate SPS regulation to address the creation of the insanitary condition. For example, cite 9 CFR 416.5 if improper employee hygiene practices have resulted in contamination of the carcass; and
- 3) review either the NR file in the government office, or the NRs in PBIS. Link them as necessary in accordance with the instructions in FSIS Directive 5000.1 in order to document that a trend of noncompliance is occurring.

NOTE: As indicated in FSIS Directive 5000.1, Chapter IV, Enforcement, noncompliances with SPS requirements can be linked to Sanitation SOP or HACCP noncompliances if the causes of the noncompliances are the same.

C. If an establishment has elected to include sanitary dressing procedures in their Sanitation SOP, HACCP plan, a GMP or other prerequisite program, failure to implement those procedures as written could also result in documentation of noncompliance. Off-line IPP are to verify the implementation of the procedures using the verification methodology in FSIS Directive 5000.1 and document any noncompliances observed in accordance with the instructions in FSIS Directive 5000.1, Chapter IV, Enforcement.

D. Off-line IPP are to use the 06D01 procedure code to document noncompliance, citing the appropriate SPS regulation when the IIC determines there is evidence that the insanitary condition created has resulted in the inability of the on-line IPP to adequately perform the inspection procedures. The IIC may require a line speed reduction in accordance with 9 CFR 310.1(b)(1).

NOTE: Isolated occurrences of fecal contamination, observed during the verification of process control procedures, is not automatic evidence that the establishment has failed to maintain sanitary dressing. When there is evidence that the sanitary dressing or process control procedures have created an insanitary condition, off-line IPP are to document noncompliance. In addition, noncompliance is to be documented when there is documentation, by either the establishment or FSIS, which supports that the establishment is not implementing its sanitary dressing procedures, or that the procedures are ineffective in preventing the creation of ongoing systematic insanitary conditions and the adulteration of product.

XI. DATA ANALYSIS

PBIS tracks the inspection activities used to verify an establishment's food safety system. Directive 5000.1 Verifying an Establishment's Food Safety System states that Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration (DAIG) will analyze PBIS data and on inspection activities on a biannual basis. The analysis will include Sanitation Performance Standard (SPS) procedures. The final report will identify trends in noncompliance by activity.

Refer questions regarding this directive to the Policy Development Division through *askFSIS* at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development