MSA DIRECTIVE	6410.1 Rev. 1	5/12/2022

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

I. PURPOSE

A. This directive is being reissued to provide inspection program personnel (IPP) with information regarding how to verify that cattle slaughter operations are implementing sanitary dressing and process control procedures, and that the procedures they are implementing prevent contamination of carcasses and ensure that insanitary conditions are not created.

B. In addition, this directive provides information describing how IPP are to assess the sanitary dressing and process controls cattle slaughter establishments employ in their food safety systems. Such controls are likely to include decontamination and antimicrobial intervention treatments. Establishments may verify the effectiveness of these controls by sampling and testing for microorganisms of beef manufacturing trimmings, other raw ground beef components (including head meat and cheek meat), and raw ground beef.

*KEY POINTS**:***

- *Defines Process Control Procedures*
- *Defines Sanitary Dressing*
- *Defines Contamination of Carcasses and Parts*
- *Describes the purpose of sanitary dressing and process control procedures*
- *Describes the points in the slaughter process where carcass contamination with food safety hazards, such as Escherichia coli (E. coli)* O157:H7*, are most likely to occur*
- *Describes how an establishment's failure to properly execute its sanitary dressing and process control procedures can increase the risk of contamination of carcasses and parts at various points in the slaughter operation*
- *Provides instruction to IPP regarding how to verify that cattle slaughter operations are implementing effective sanitary dressing and process control*

procedures to prevent contamination of carcasses and are properly applying decontamination and antimicrobial intervention treatments to carcasses and parts to address any contamination that may occur

- *Provides instruction to IPP on how to verify that the establishment is properly assessing any microbial testing results, including results for indicators of process control, at any point during slaughter and at subsequent trim fabrication and grinding operations. Examples of microorganisms used as indicators of process control in raw beef operations include Enterobacteriaceae, generic E. coli, E. coli O157:H7, non-O157 STECs, and Salmonella*

- *Provides information regarding slaughter food safety systems and how each aspect of the system (e.g., sanitary dressing and process control procedures, intervention treatments, product sampling, supporting documentation) is a factor to be considered when determining whether there is regulatory compliance*

- *Provides clarification regarding the differences between documenting noncompliance under PHIS task Beef Sanitary Dressing and under Operational SSOP Review and Observation*

- *Provides information regarding supervisory responsibilities.*

II. CANCELLATION

MSA Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age (November 3, 2011)

III. REASON FOR REISSUANCE

MSA is reissuing this directive to:

1. Add a definition of "Contamination of Carcasses and Parts".

2. Provide instructions related to pre rinsing hide-on cattle carcasses.

3. Provide instruction related to performing sanitary dressing verification under the Public Health Inspection System (PHIS).

4. Reformat the directive to include hyperlinks within the document and to resource documents.

5. Provide information regarding the differences in documenting

noncompliance under the PHIS Beef Sanitary Dressing task vs. the Operational SSOP Review and Observation task; and

6. Provide information regarding supervisory responsibilities.

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 Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations

V. DEFINITIONS

Process Control Procedure: A defined procedure or set of procedures designed by an establishment to provide control of those operating conditions that are necessary to produce safe, wholesome food. The procedures typically include some means of observing or measuring system performance, analyzing the results generated to define a set of control criteria, and acting when necessary to ensure that the system continues to perform within the control criteria. The procedure is likely to include planned measures that the establishment will take in response to any loss of process control. In addition, the procedures can be used as support for decisions made in the hazard analysis.

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

Contamination of Carcasses and Parts: Carcasses and parts that, based on organoleptic inspection, have been prepared, packed, or held under insanitary conditions that may have caused them to come into contact with filth, or that may have caused them to be injurious to health and are condemnable unless they can be effectively reprocessed. Contamination may occur from:

1. Substances not inherent to the species being slaughtered (e.g., volatile oils, paints, rail dust, rust, unidentifiable foreign material (UFM), condensate, poisons, or gases); or
2. Substances inherent to the species being slaughtered (e.g., digestive tract content, bile). Sanitary dressing procedures minimize this type of contamination.

NOTE: Not all contamination is directly associated with food safety. Sound judgment must be used when determining whether the conditions observed during

the slaughter process are part of the slaughter process or are present as an unavoidable consequence of the slaughter process. Evaluation on a case-by-case basis will be needed to determine whether the conditions observed have resulted in either the creation of an insanitary condition or the adulteration of product.

VI. BACKGROUND

A. MSA is aware that *E. coli* O157:H7 has been found in beef manufacturing trimmings, other raw ground beef components (including head meat and cheek meat), and raw ground beef. The presence of *E. coli* O157:H7 in these products 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, 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 the contamination of carcasses and parts in their food safety systems.

B. Effective sanitary dressing and process control procedures underpin the critical control points (CCPs) that an establishment has in place to prevent, eliminate, or reduce to an acceptable level food safety hazards that are reasonably likely to occur in the slaughter process and that support the HACCP system is functioning as intended. MSA believes slaughter operations should more consistently focus on their sanitary dressing and process control procedures to prevent carcass contamination and the creation of insanitary conditions in their operations.

VII. GENERAL INFORMATION

A. The following discussion provides IPP with an introduction to sanitary dressing, its importance, and how an establishment can use it to reduce *E. coli* O157:H7 to below detectable levels.

B. IPP verify that, as set out in 9 CFR 310.18(a), establishments 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, may contain pathogens, a principal objective of proper sanitary dressing and process control procedures is to reduce the potential for exposure of carcasses and parts to any food safety hazard during the removal of the hide, feet, head, gastrointestinal tract, and other internal organs. IPP need to verify that the design of the establishment's slaughter operation includes a means to measure how well the sanitary dressing and process control procedures accomplish this purpose, and that the establishment responds if the measure shows that carcasses are being exposed to food safety hazards.

C. In addition, IPP verify that in accordance with 9 CFR 416.1, each official establishment operates, and is maintained, in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. In addition, IPP verify that establishments maintain sanitary conditions as required by 9 CFR 416.1 through 416.5.

D. Thus, IPP are to verify that establishments slaughter and process cattle in a manner designed to prevent contamination from occurring at any step in the process and that responds with use of decontamination and antimicrobial intervention treatments as necessary to address any contamination that (a) may result from the implementation of the slaughter process or (b) may otherwise occur on the carcasses and parts. To meet these requirements establishments, employ practices such as:

1. Maintaining adequate separation of carcasses, parts, and viscera during dressing to prevent cross contamination.

2. Routinely cleaning and sanitizing or sterilizing equipment and hand tools that are used to remove contamination or to make cuts into the carcass.

3. 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 which could cause contamination of carcasses.

4. Frequently washing hands and aprons that come in contact with the carcass and parts; and

5. Implementing decontamination and antimicrobial intervention treatments such as washes or sprays on carcasses and parts in accordance with the limits selected by the establishment and documented to be adequate to address contamination.

E. Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other pre-requisite programs. IPP are to use the information regarding verification of these written programs that is included in Section XI.D of this document.

F. If IPP determine that the sanitary dressing and process control procedures are used to support decisions in the hazard analysis in accordance with 9 CFR 417.5(a)(1), they are to verify that establishments maintain records addressing the sanitary dressing and process control program. IPP are to assess whether

the records demonstrate that the program, as implemented, is effective, and whether the decisions made in the hazard analysis are supported on an on-going basis.

VIII. MSA 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 MSA Directive 6100.1, Ante-mortem Livestock Inspection and MSA Directive 6100.2, Post-mortem Livestock Inspection. Verification of procedures for controlling fecal material, ingesta, and milk in slaughter operations are to be conducted in accordance with MSA Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations

A. The PHIS beef sanitary dressing task is used to verify compliance with the sanitation performance standards (SPS) requirements in the slaughter operations. IPP that perform slaughter verification duties are to verify sanitary dressing and the process control procedures conducted by a cattle slaughter establishment in accordance with the instructions in this section. In addition, because verification of sanitary dressing and process control necessarily involves assessing the whole slaughter system, IPP are to evaluate the sanitary dressing and process control procedures.

B. To verify that all regulatory requirements associated with PHIS beef sanitary dressing task are met, IPP are to do the following:

1. IPP are to verify the establishment's sanitary dressing and process control procedures at the frequency indicated in PHIS. The verification is to focus on all aspects of the establishment's sanitary dressing and process control procedures.

2. When the information gathered suggests that the establishment has lost process control, IPP are to determine whether the establishment has taken measures to bring the process back under control. Examples of measures an establishment may take include cleaning of contaminated equipment, removing excessive mud on cattle via washes, or additional checks to verify the process is back under control. If the supervisor determines that it is necessary, IPP are to perform additional verification of the sanitary dressing and process control procedures to verify that the establishment has brought the process back under control. In such circumstances, it may be necessary for IPP to use the beef sanitary dressing task more frequently than once every other week. The following are examples of the types of findings that can indicate a loss of control:

a. A comparison of the results of current and previous IPP reviews indicates that there has been an increase in contamination. For example, has there been a recent cluster of contamination events following a period of substantial compliance?

b. Evidence that contamination events are not being effectively prevented (e.g., receiving input regarding verification activities that demonstrate IPP are finding contamination or observing improper dressing procedures more frequently than expected); and

c. Input from MSA personnel when there is an increase in positive pathogen results in raw beef manufacturing trimmings or raw ground beef samples, from either MSA or establishment microbiological testing, beyond what is expected, explained, and documented under conditions in which effective sanitary dressing and process controls are implemented.

C. IPP are to gather information using the questions in Section IX.C.Parts 1-10 of this directive to assist them in determining whether an establishment's slaughter operation meets the requirements of 9 CFR 416. The questions provided at each point in Section IX.C.Parts 1-10 below, are not all-inclusive and may vary depending on the type of slaughter operation being conducted. A response to one of the questions in Section IX.C.Parts 1-10 that suggests loss of control does not automatically mean that there is regulatory noncompliance or a system failure.

D. When verifying the establishment's food safety system as set out in MSA Directive 5000.1, 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 those CCPs or programs.

E. IPP are to gather information using the methodology outlined in Section IX of this directive to assist in the determination of regulatory noncompliance and document noncompliance in accordance with the instructions in Section XI of this directive.

IX. POTENTIAL CONTAMINATION POINTS IN THE SLAUGHTER PROCESS

A. 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 are to determine the best sequence for verification based on the specific observations made at a given time.

B. The purpose of identifying and addressing vulnerable points in this directive is to help IPP focus on these points to verify that contamination events are effectively prevented. When contamination occurs, IPP are to verify that the establishment takes steps to minimize recurrence (9 CFR 416.1), and that the establishment effectively addresses the reconditioning of the contaminated carcasses (9 CFR 310.18).

C. 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, MSA personnel are to follow good employee hygiene practices to ensure that their verification activities do not result in cross contamination of the carcasses.

1. **Live receiving/holding**

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

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

i. What measures, if any, does the establishment take to reduce the pathogen load on in-coming animals? For example:

1. Does the establishment take measures, such as periodic cleaning of the unloading areas and pens to reduce the contamination of animals?

2. Has the establishment elected to conduct cattle washing? If so, do they monitor the process to ensure that washing is adequate to minimize contaminants?

3. Does the establishment use water mist to reduce airborne dust and dirt particles in the holding area?

4. Has the establishment elected to utilize a "mud-scoring" system (i.e., a system to quantify the amount of mud on live animals) to identify cattle that may present an increased likelihood of contamination during hide removal?

5. What measures, if any, does the establishment take to determine the incoming bacterial load on animals?

6. 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?

2. **Sticking**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at sticking include, but are not limited to:

i. 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:

1. Does the establishment use the smallest cut possible to accomplish bleeding?

2. 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?

c. 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. **Hide removal (manual and mechanical)**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at hide removal include, but are not limited to:

    i. 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:

        1. Has visible contamination been removed at the cut line?

            a. Does the establishment wash the hide on carcass before skinning?

            b. Is excess water on the hide handled in a way that would prevent contamination of the carcass during skinning? (e.g., Is the establishment preventing pooling water in the flanks of a carcass placed on a skinning cradle)

            NOTE: Rinsing a hide on carcass, before skinning, has been shown to increase the microbial load on the final carcass. While rinsing hide on carcasses is not prohibited, the establishment must take all necessary steps to prevent rinse water from contaminating the carcass during skinning. Additionally, the establishment should determine if hide rinsing is a step in the process. If hide rinsing is identified as a step in the process, any potential hazards associated with the step must be addressed through the hazard analysis as described in Sections X. A. Part 4 of this directive.

        2. 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?

        3. What measures does the establishment use to limit cross contamination of carcasses during hides removal? For

example:

a. Does the establishment minimize the possibility that contaminants can become airborne from splattering or flapping of the hide?

b. 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?

c. Is the establishment maintaining clean hands and garments of the employees handling the hide and the carcass; and knives and other equipment contacting the de-hided carcass?

d. 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)?

c. 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. **Bunging**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at bunging include, but are not limited to:

i. What measures does the establishment take to ensure that carcass contamination does not occur? For example:

1. Is the establishment putting plastic bags and ties on the bung in a sanitary manner?

2. 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)?

3. 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?

5. **Brisket opening**

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

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at brisket opening include, but are not limited to:

i. What measures is the establishment taking to prevent the introduction of contamination into the carcass at this point in the process? For example:

1. Is the establishment cleaning and sanitizing the brisket saw and knife between each carcass and ensuring that the gastrointestinal tract is not punctured?

2. 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)?

ii. 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?

6. **Head removal**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at head removal include, but are not limited to:

i. What measures has the establishment implemented to ensure that contamination of heads, equipment, and employees does not occur? For example:

1. Are heads removed in a manner that avoids contamination with digestive tract contents or specified risk materials (SRM)?

2. Is the establishment adequately washing heads, including thoroughly flushing the nasal cavities and mouth, before washing the outside surfaces?

3. Does the establishment limit the splashing of water when washing heads to prevent cross contamination and to limit airborne contaminants?

4. Does the establishment properly maintain and clean knives?

5. 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)?

c. 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?

7. **Rodding the weasand (esophagus)**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing

and process control procedures at the point of rodding the weasand include, but are not limited to:

i. What measures does the establishment take to prevent the introduction of contamination into the carcass during this point in the process? For example:

1. Does the establishment have a means to close the esophagus to prevent leakage of rumen contents?

2. Do employees maintain proper employee hygiene practices (e.g., wash hands and arms often enough to prevent contamination of the carcass)?

3. Do employees change or sanitize the weasand rod between each carcass?

c. Is the weasand cleaned and chilled quickly to limit contamination and pathogen multiplication?

d. 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?

8. **Evisceration**

a. 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.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at evisceration include, but are not limited to:

i. What measures does the establishment take to prevent contamination of the viscera during removal? For example:

1. Do establishment employees remove visible contamination from the area to be cut (e.g., by trimming), before the cut is made?

2. Is the uterus removed in a manner that prevents contamination of the carcass and viscera?

c. What measures does the establishment implement to ensure that employees do not contaminate carcasses during evisceration? For example:

i. Do employees properly use knives to prevent damage (i.e., puncturing) to the paunch and intestines?

ii. Is contamination removed in a timely manner and in accordance with accepted reconditioning procedures?

iii. 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?

9. **Carcass splitting**

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

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at splitting include, but are not limited to:

i. What measures does the establishment take to prevent the split carcass from becoming contaminated? For example:

1. Is the establishment cleaning and sanitizing the saws and knives between each carcass?

2. Does the establishment allow for adequate distance between carcasses (i.e., limit carcass-to-carcass contact)?

ii. 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?

iii. Does the establishment address the removal of spinal cord in accordance with 9 CFR 310.22?

10. **Head and Cheek Meat Processing**

a. 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.

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

i. What measures does the establishment take to ensure that head meat/cheek meat is safe to use in raw beef? For example:

1. Does the establishment properly maintain and clean knives?

2. Does the establishment utilize measures sufficient to prevent cross contamination of heads?

3. 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)?

4. Is head and cheek meat quickly chilled to limit pathogen multiplication?

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?

X. ESTABLISHMENT INTERVENTIONS

A. General

1. The following discussion informs IPP on assessing the measures implemented by an establishment to reduce *E. coli* O157:H7 to below detectable levels.

2. How well the establishment performs its slaughter dressing procedures has a direct bearing 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. MSA 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:

a. Documentation that supports that the food safety system at slaughter, including sanitary dressing procedures coupled with all intervention treatments is effective under the actual conditions that apply in its operation; or

b. The establishment has reassessed its system in response to any new or revised procedures or interventions that have been implemented and has determined that no changes are necessary.

3. 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.

4. 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 determination that it's SOP, GMP, or other prerequisite program will prevent the creation of insanitary conditions and the occurrence of contamination, including E. coli O157:H7 contamination, during the slaughter and dressing operation needs to include as part of its hazard analysis data and information concerning these prerequisite programs that support that judgment. Unless the establishment demonstrates that the measures implemented through the SOP, GMP or other prerequisite program coupled with the decontamination and antimicrobial intervention treatments will achieve the anticipated effect under actual in-plant conditions, MSA will view the effectiveness of the food safety system as theoretical.

5. Establishments can demonstrate the effectiveness of 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, an establishment may elect to demonstrate that their 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 interventions to show that the anticipated reduction has occurred.

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. MSA Verification of Establishment Interventions

1. Once per month when conducting the Slaughter HACCP task in accordance with the methodology in MSA Directive 5000.1, 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, they are to review the establishment's interventions, supporting documentation, and testing records and consider questions such as the following:

    a. Is the establishment effectively using sanitary dressing procedures to minimize contamination and thereby preventing the creation of insanitary conditions?

    b. Has the establishment considered the level of contamination that may be on the incoming animals?

    c. Has the establishment used that information as a measure to demonstrate that its interventions can address the expected contamination load?

    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), to demonstrate that its CCPs achieve the intended reduction in organisms?

    f. Does the establishment evaluate testing results, including generic *E. coli* and *Salmonella* on carcasses, *E. coli* O157:H7 on

beef manufacturing trimmings or other raw beef components, and *E. coil* O157:H7 and *Salmonella* on raw ground beef, to help determine how the results impact the operations?

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 are to be recorded and is that documentation available for MSA review?

h. 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 IPP have concerns that the establishment's interventions, as implemented, do not achieve the intended reduction in organisms (e.g., *E. coli* O157:H7), they are to contact their supervisor who may contact the Central Office (CO) and request that an EIAO conduct a Food Safety Assessment (FSA). The CO will consider IPP findings based on food safety concerns and risk to the product and prioritize the FSA as necessary.

XI. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. Using the information gathered during MSA verification, IPP are to determine whether noncompliance exists. IPP are to use the information gathered during their verification activities as prompts to direct them to points in the slaughter process where further observation may be necessary. Examples of observations that could indicate that sanitary dressing procedures are not being properly implemented, and where insanitary conditions are being created because of the loss of process control include but are not limited to:

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; failure to effectively prevent the contamination of carcasses and parts; or failure to remove such contaminants before final inspection.

3. Establishment or MSA microbial sampling results from carcasses, beef manufacturing trimmings or other raw ground beef components trim

(including head meat and cheek meat), or raw ground beef that indicate increasing microbial contamination of carcasses or parts with generic E. coli, Salmonella, or E. coli O157:H7.

4. Increased contamination on carcasses because of environmental conditions (e.g., weather or season), 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 IPP indicating increased incidents or frequency of carcass contamination.

8. Feedback from in-plant processing IPP indicating an increase in positive *E. coli* O157:H7 test results, in testing done by either MSA or the establishment of beef manufacturing trimmings, other raw ground beef components trim (including head meat and cheek meat), or raw ground beef.

9. Notification through the CO that the establishment may be implicated in supplying *E. coli* O157:H7 positive beef to another establishment or in an illness- related recall action.

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, IPP are to consider how all the information they have gathered relates to the food safety system.

B. IPP are to document noncompliance using PHIS Beef Sanitary Dressing task code when an insanitary condition has been created as the result of the ineffective implementation of the sanitary dressing procedures.

C. Specifically, IPP are to:

1. Cite 9 CFR 310.18(a) to address the contamination of the carcass and cite any SPS regulation that is appropriate to the situation 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 therefore the creation of an insanitary condition; and

2. Review any available NRs on file for trends. Link them as necessary in accordance with the instructions in MSA Directive 5000.1 to document that a trend of noncompliance is occurring.

NOTE: As indicated in MSA Directive 5000.1 noncompliance with SPS requirements can be linked to Sanitation SOP or HACCP noncompliance's if the causes of the noncompliance are the same.

D. If an establishment has elected to include sanitary dressing and process control procedures in its HACCP plan or Sanitation SOP, GMP, or other prerequisite program, failure to implement those procedures as written could also result in noncompliance. IPP are to verify the implementation of the procedures using the verification methodology in MSA Directive 5000.1 and document any noncompliance's observed in accordance with the instructions in MSA Directive 5000.1

E. IPP are to use the Beef Sanitary Dressing task code to document noncompliance, citing the appropriate SPS regulation when the IIC determines that there is evidence that an insanitary condition has interfered with the inability of the IPP to adequately perform the inspection procedures.

F. Isolated occurrences of contamination (e.g., fecal, specks, grease) observed during the verification of process control procedures is not automatic evidence that the establishment has failed to maintain sanitary dressing. Contamination on carcasses before to the final rail is typically the result of an insanitary condition caused by ineffective sanitary dressing procedures. When there is contamination on carcasses before the final rail, the establishment still has the opportunity to implement measures to address the contamination before presenting the carcass for final inspection. IPP are to evaluate incidental occurrences of contamination as they relate to the overall slaughter system to determine whether the establishment has failed to prevent the creation of insanitary conditions. If IPP determine that the establishment has failed to prevent the creation of an insanitary condition, they are to document their observations using the Beef Sanitary Dressing task, citing 9 CFR 310.18(a). In addition, IPP are to document noncompliance when the establishment is not implementing its sanitary dressing procedures, or that the procedures are ineffective in preventing the creation of ongoing systematic insanitary conditions.

G. IPP are not to use the PHIS Operational SSOP Review and Observation task unless the establishment has elected to include its sanitary dressing procedures and process control procedures in its Sanitation SOP.

H. IPP are to verify compliance with 9 CFR 310.18(a) by observing that the

establishment's slaughter procedures are adequate to ensure that carcasses presented for inspection are not contaminated. IPP conduct this verification at the MSA final rail inspection station prior to carcass washing (i.e., after the establishment has had an opportunity to implement all its sanitary dressing procedures). If IPP observe fecal, ingesta, or milk during the performance of zero tolerance verification, they are to document the noncompliance using the HACCP slaughter task in accordance with the instructions in MSA Directive 6420.2 Chapter 1 Section III Part E. If IPP observe other kinds of contamination (e.g., rail dust, grease smears) on carcasses *after* the final carcass wash, noncompliance may be documented using the Operational SSOP Review and Observation task.

XII. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. "Supervisory personnel" refers to any MSA personnel that supervise IPP who conduct verification activities in cattle slaughter operations.

B. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with MSA statutory authority and Agency policy, and that duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.

C. MSA supervisory personnel are to discuss the key points identified in this directive with IPP. In addition, supervisory personnel are to discuss the potential contamination points in the slaughter process addressed in this directive to ensure that IPP understand their role in verifying whether the establishment is initiating measures designed to prevent the creation of insanitary conditions by preventing the contamination of carcasses.

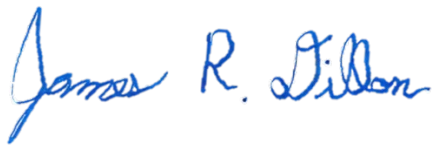
D. MSA supervisory personnel are to emphasize that IPP are to verify that establishments have documentation, in accordance with 9 CFR 417.5(a)(1), sufficient to support any food safety decisions that they make based on the implementation of sanitary dressing and process control procedures.

E. Supervisors are to discuss how sanitary dressing and process control procedures have an impact on *E. coli* O157:H7 testing results of beef manufacturing trimmings, other raw ground beef components such as trim (including head meat and cheek meat), or raw ground beef. Supervisors are to emphasize that IPP in the slaughter areas are to conduct a purposeful evaluation of the establishment's sanitary dressing and process control procedures and are to correlate with IPP in processing areas whenever poor implementation of the procedures could lead to positive results in beef manufacturing trimmings, other raw ground beef components trim (including head meat and cheek meat), or raw ground beef testing results.

F. Supervisory personnel are to ensure that IPP are correctly applying the inspection methodology, are making informed decisions, are properly documenting findings, and are taking the appropriate enforcement actions as instructed in this directive.

XIII. QUESTIONS

Refer questions through supervisory channels.



James R. Dillon, DVM, MPH
Director, Texas State Meat and Poultry Inspection Program
Department of State Health Services