

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

FSIS DIRECTIVE	6420.2	3/31/04
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**VERIFICATION OF PROCEDURES FOR CONTROLLING FECAL MATERIAL,
INGESTA, AND MILK IN SLAUGHTER OPERATIONS**

**NOTE: FSIS PERSONNEL ARE NOT TO IMPLEMENT THIS DIRECTIVE UNTIL
MAY 17, 2004**

Part I -- General

I. PURPOSE

This directive provides inspection program personnel with the methodology for protecting public health by verifying, documenting, and enforcing the requirement that there be no visible fecal material, milk, or ingesta on livestock carcasses at or immediately after the final rail, and for verifying that feces, ingesta, and milk are not present on head meat, cheek meat, and weasand meat. This directive also provides inspection program personnel with instructions for verifying that visible fecal material are not present on poultry carcasses entering the chill tank. It replaces FSIS Directive 6420.1 and FSIS Directive 6150.1, Revision 1, which were written before FSIS' HACCP regulation applied to all establishments.

II. CANCELLATION

FSIS Directive 6420.1
FSIS Directive 6150.1, Revision 1

III. RESERVED

IV. REFERENCES

9 CFR 307.2(g) and (m), 310.3, 310.17(a), 310.18(a), 318.4(b), 381.65(e) and 381.76(b)(3)(iv) of the regulations

FSIS Directive 5000.1, Revision 1

V. BACKGROUND

In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal or bird going to slaughter. Without care being taken in handling and dressing procedures during

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slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Once introduced into the establishment environment, the organisms may be spread from carcass to carcass or by other means. Therefore, FSIS enforces a “zero tolerance” standard for visible fecal material on poultry carcasses and no visible fecal, ingesta, or milk material on carcasses, head, cheek, weasand meat at inspected establishments that slaughter livestock.

One approach that FSIS takes to minimize the occurrence of pathogens such as *E. coli* O157:H7 on meat is to verify that feces, ingesta, and milk do not contaminate beef carcasses and parts, or if they do, that they are properly removed. FSIS is now providing instructions to inspection program personnel on how to verify that meat from heads, cheeks, and weasands - beef carcass parts that may become contaminated with feces, ingesta, or milk - are not contaminated with these substances. Meat from these parts is frequently used in ground beef products. If the meat from these parts is contaminated, it represents a way of importing pathogens, including *E. coli* O157:H7, into ground beef. FSIS is reissuing this directive as one of a number of steps that it is taking to ensure that the possibility of *E. coli* O157:H7 contamination is reduced to the extent possible.

Head meat, cheek meat, and weasand meat are parts that may not be part of the carcass at the time that the carcass passes the final rail. Thus, the verification by FSIS that these parts are not contaminated may not occur at this point in the process. Inspection program personnel are to verify that these parts are not contaminated by fecal material, ingesta, or milk at the completion of the harvesting process e.g., at the packaging step or when the product is placed into a container for storage.

FSIS has instructed inspection program personnel that they have access to the results of any testing and of any monitoring activities that are performed that may have an impact on the establishment’s hazard analysis (FSIS Directive 5000.2). Inspection program personnel must review results on at least a weekly basis.

Part II -- Livestock Fecal Material, Ingesta, and Milk Inspection

I. General

A. What are the regulatory requirements regarding fecal material, ingesta and milk for livestock carcasses and parts?

9 CFR 310.18(a) states: *Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.*

Under 9 CFR 417, a HACCP plan must include, as appropriate, critical control points that are designed to control identified food safety hazards (9 CFR 417.2(c)(2)). Because fecal material is a vehicle for pathogens, and because virtually all slaughter

establishments recognize that contamination of meat by pathogenic microorganisms from fecal material, ingesta, or milk is a food safety hazard that is reasonably likely to occur in the slaughter production process, inspection program personnel are to verify that slaughter establishments have adopted controls that they can demonstrate are effective in reducing the occurrence of pathogens, including controls that prevent contamination of carcasses with fecal contamination, milk and ingesta.

B. What are the general responsibilities of inspection program personnel?

1. In each establishment slaughtering livestock, the activities of inspection program personnel include checks to determine whether the establishment is producing carcasses, head, cheek, and weasand meat that are not contaminated with fecal material, ingesta, or milk. (See 9 CFR 307.2(g), 310.3, 310.17(a), 310.18(a), and 318.2(b) and (d).)

NOTE: This directive does not affect the disposition of livestock carcasses and carcass parts observed during post-mortem inspection to have pathological conditions. It provides additional instructions on decision making involving noncompliances with regulatory requirements in slaughter establishments (part 310; see also 9 CFR 312.6(a) and 318.2(b) and (d)).

II. On-line inspection program personnel

A. What are the on-line inspection activities?

1. On-line inspection program personnel verify removal of contamination during examination of carcasses and parts as part of post-mortem inspection.

a. When on-line inspection program personnel find feces, ingesta, or milk, they should stop the slaughter line for carcass reexamination and rework by the establishment unless:

i. the establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, and

ii. the IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.

b. On-line inspection program personnel who retain a carcass for veterinary disposition are not to authorize establishment trimming until after disposition by a veterinary medical officer.

c. On-line inspection program personnel are to notify off-line inspection program personnel when they believe that:

i. an establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or

ii. an establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of contaminated carcasses for post-mortem inspection at the rail inspection station indicates failure to control dressing processes).

d. If the on-line head inspector finds contamination, the establishment must remove the contamination before the head can be passed. If the on-line inspector repeatedly finds contamination, he or she is to notify off-line inspection program personnel. The off-line inspection program personnel are to perform verification activities to determine whether the establishment's process and sanitary dressing procedures are controlling contamination during the head meat production process.

e. If the on-line inspector finds contamination on weasand meat during the harvesting step, the establishment must remove the contamination before the weasand meat can be passed. If the on-line inspector repeatedly finds contamination, he or she is to notify the off-line inspection program personnel. The off-line inspection program personnel are to perform verification activities to determine whether the establishment's process and sanitary dressing procedures are controlling contamination during the weasand meat production process.

III. Verification Procedures

A. For off-line inspection personnel, what is the frequency for verifying that carcasses, head, cheek, and weasand meat are not contaminated with fecal material, ingesta or milk?

Off-line inspection program personnel verify the adequacy of the establishment's procedures to ensure that carcasses are not contaminated with fecal material, ingesta, or milk by the post-mortem rail inspection station, and that head, cheek, and weasand meat are not contaminated with fecal material, ingesta, or milk at the completion of the harvesting process, at the frequency determined by the scheduling of 03J01/03J02 procedures, and when notified by on-line inspection program personnel of a problem.

B. What are the off-line inspection program personnel responsibilities in livestock slaughter establishments?

1. When verifying that carcasses are free of fecal material, ingesta, and milk, off-line inspection program personnel are to select carcass units at the post-mortem rail inspection station for examination on-line, at or after the post-mortem rail inspection station (see Attachment 2 for selection of carcass units.). This inspection should occur before the final wash. In situations, such as those related to worker safety, the IIC should develop appropriate procedures with establishment management for this inspection to be properly conducted.

2. When verifying that head, cheek, and weasand meat are free of fecal material,

ingesta, and milk, inspection program personnel are to select product at the end of the harvesting process, after all of the establishment controls and interventions. This verification may occur at the time of packaging or when the product is placed in a container for storage. 9 CFR 417.5(a)(2) requires that the establishment maintain a written HACCP plan, including decisionmaking documents associated with the selection and development of the CCPs and critical limits, and documents that support both the monitoring and verification procedures selected and the frequency of those procedures. Because the establishment is required to have documents to support the monitoring procedures (amount of product examined), inspection program personnel should examine the same amount of product as the establishment has listed in the HACCP plan for the monitoring procedure. If the establishment does not have documents supporting the monitoring procedure and frequency, there is noncompliance with 9 CFR 417.5(a)(2).

3. When off-line inspection program personnel are only verifying the adequacy of the establishment procedures of ensuring carcasses and head, cheek, or weasand meat are not contaminated with fecal contamination, milk, or ingesta, they are to document the findings using the 03J01 procedure. If this verification is done in conjunction with verifying the HACCP regulatory requirements (monitoring, verification, recordkeeping, corrective action, and reassessment), the findings should be recorded using either the 03J01 or 03J02 procedure code, as appropriate. When off-line inspection program personnel find fecal contamination, milk, or ingesta on carcasses or head, cheek, or weasand meat, inspection program personnel should verify that the establishment implements corrective action that meets the requirements of 417.3. Inspection program personnel are to verify that the establishment implements corrective action to:

- a. identify and eliminate the cause of the deviation,
- b. ensure that the CCP is under control after the action is taken
- c. establish measures to prevent recurrence
- d. ensure that no product that is injurious to health enters commerce.

NOTE: 9 CFR 417.5(a)(2) requires the establishment to support the monitoring frequency in its HACCP plan. If the establishment has supporting documentation for the monitoring procedure and frequency, and fecal material, ingesta, or milk is observed on carcasses or head, cheek, or weasand meat, inspection program personnel should verify that the establishment has ensured that all product back to the last acceptable check is unadulterated before allowing the product to enter commerce. Inspection program personnel can review the monitoring records and the corrective action records, and observe the establishment isolating affected product, when verifying that the establishment is meeting corrective action regulatory requirements. This verification would be part of a HACCP 01 or 02 procedure. If the establishment does not have

supporting documents for the monitoring procedure and frequency, there is noncompliance with 417.5(a)(2).

C. How do off-line inspection program personnel determine compliance?

1. If off-line inspection personnel are verifying that the process is controlling fecal material, ingesta, or milk contamination during the carcass production process, these personnel should:

- a. determine the expected slaughter volume for that day,
- b. determine the number of carcass units based on daily slaughter volume (see attachment 2),
- c. randomly select the appropriate number of carcass,
- d. examine the selected carcass units using the technique that on-line inspection program personnel use at the post-mortem rail inspection station,
- e. identify foreign material as fecal material or ingesta only when both the color and texture characteristics are identifiable (see Attachment 3), and
- f. identify foreign material as milk only when both the color and consistency characteristics are identifiable (see attachment 3).

2. If off-line inspection program personnel are verifying that the process is controlling fecal material, ingesta, or milk contamination during the head meat, cheek meat, or weasand meat production process, they are to:

- a. review the HACCP plan to determine the amount of head, cheek, or weasand meat to select for examination, and
- b. examine all outer surfaces of the product selected for fecal material, ingesta, or milk.

Part III -- Poultry Fecal Contamination Inspection

I. General

A. What are the regulatory requirements regarding poultry fecal contamination?

9 CFR 381.65(e) states: *Poultry carcasses contaminated with visible fecal material shall be prevented from entering the chilling tank.*

Under 9 CFR 417, a HACCP plan must include, as appropriate, critical control points that are designed to control identified food safety hazards (§ 417.2(c)(2)). Because fecal material is a vehicle for pathogens, and microbiological contamination is a food

safety hazard that can be expected to occur in the production process, an establishment must control the occurrence of pathogens on product, including preventing poultry carcasses contaminated with visible fecal material from entering the chilling tank.

NOTE: This directive provides instructions for conducting verification activities to determine whether an official establishment is complying with 9 CFR 381.65(e). This directive does not affect the disposition of poultry carcasses observed to have pathological conditions during post-mortem inspection or reinspection (9 CFR 381.76 and 381.91).

II. Verification Procedures

A. What is the frequency for performing fecal contamination checks?

Each day, inspection program personnel are to conduct at least two fecal contamination checks for each evisceration line for every shift (i.e., the number of checks will total at least 2 x number of shifts x number of lines).

B. What is the inspection verification methodology?

Each fecal contamination check by inspection program personnel in a poultry slaughter establishment consists of selecting and examining 10 poultry carcasses, after the final wash and before the chilling tank, to verify that the establishment's process is producing carcasses free of visible fecal material.

If inspection program personnel are only conducting the 10-bird check to verify that the establishment's process is producing carcasses free of visible fecal material, they are performing procedure 03J01.

If inspection program personnel are verifying other HACCP regulatory requirements in conjunction with the 10-bird check, inspection program personnel can be performing the 03J01 or 03J02 procedure.

1. Inspection program personnel are to:

a. randomly select 10 carcasses and

b. examine the selected carcasses off line, at either:

i. the same location as prechill testing, in an establishment inspected under the finished product standards (9 CFR 381.76(b)(3)(iv)(d)(ii)), or

ii. the inspection station where Acceptable Quality Level (AQL) testing is conducted in a plant under traditional inspection.

2. Inspection program personnel are to check for visible fecal material, using the following inspection procedure:

a. Outside back. While holding the carcass, with the back of the carcass toward the observer and starting at the hock area, observe the hocks, back part of the legs, tail area, back of the carcass, and top side of the wings.

a. Outside front. Turn the carcass and observe the bottom side of the wings, breast, and front part of the legs.

b. Inside. Observe the inside surfaces of the carcass and the abdominal flaps and fat.

c. Neck flap area. Observe the neck flap and the thoracic inlet area.

3. As inspection program personnel examine the carcasses, they should seek answers to the following questions:

a. If contamination is observed on carcasses or parts during the fecal contamination check, is the color, consistency, and composition characteristics of feces identifiable (see attachment 1)?

b. If contamination is observed on a carcass or part during the fecal contamination checks, and the characteristics of feces are not identifiable, are the characteristics for ingesta identifiable (see attachment 1)?

If fecal contamination is observed during the fecal contamination check, inspection program personnel should notify the establishment and verify that the corrective action requirements of 9 CFR 417.3 are met. The noncompliance should be documented as described in FSIS Directive 5000.1, Revision 1, Chapter IV.

If inspection program personnel were performing the 03J01 procedure when the observation was made, the 03J02 procedure should be performed.

If ingesta is observed during the fecal contamination check, the establishment should be notified of the finding. The ingesta should be removed from the bird. There would be no noncompliance documented for this finding.

Part IV. Documentation

A. How do off-line inspection program personnel document the verification check results when performing the 03J01 procedure?

1. Off-line inspection program personnel are to mark the 03J01 procedure as performed on the Procedure Schedule each time they perform this verification, if during this verification procedure they do not observe any fecal material on any of the poultry carcasses and no fecal material, ingesta or milk on livestock carcasses or on head, cheek, or weasand meat.

2. When inspection program personnel find identifiable fecal material on poultry carcasses, or fecal material, ingesta, or milk on livestock carcasses or on head, cheek, or weasand meat during this verification, the monitoring trend indicator should be marked.

3. When off-line inspection program personnel find any HACCP regulatory noncompliance while performing the 03J01 procedure, he or she is to perform the 03J02 procedure on that specific production. All regulatory requirements should be verified while performing this procedure, including the corrective action requirement.

B. How do inspection program personnel document the verification check results when performing an 03J02 procedure?

1. If inspection program personnel are performing an 03J02 procedure and they do not observe any fecal material on any of the poultry carcasses; or they do not observe any fecal material, ingesta, or milk on livestock carcasses or head, cheek, or on weasand meat during this verification, and no other regulatory noncompliance is observed, the 03J02 procedure is marked as performed on the Procedure Schedule.

2. If they find identifiable fecal material on any poultry carcass, or fecal material, ingesta, or milk on any carcass or head, cheek, or weasand meat when performing an 03J02 procedure, inspection program personnel are to notify the establishment and complete this procedure before completing the FSIS Form 5400-4, Noncompliance Record (NR) documentation.

a. There is no need to perform another 03J02 procedure as all requirements, including corrective action, can be verified as part of the procedure that inspection program personnel are performing.

b. When the 03J02 procedure is complete, document all noncompliances on an (NR) using the appropriate trend indicator.

c. If the only noncompliance observed was the fecal material, ingesta, or milk contamination, the monitoring trend would be used for that noncompliance.

Part V. ENFORCEMENT

A. What is the enforcement methodology?

1. If inspection program personnel find repeated fecal material noncompliances and determine that these findings are from the same cause, the NRs should be linked. If the findings do not show the same cause, the NRs should not be linked. When linking NRs, inspection program personnel are to follow the methodology set out in FSIS Directive 5000.1, Revision 1, Chapter IV, Enforcement, CSIs, Part VI, Linking NRs. Also, when inspection program personnel have concerns about whether the documented fecal findings evidence a systemic problem, the IIC should review all relevant records including generic *E. coli* results, compliance with HACCP requirements, Sanitation SOP compliance, Sanitation Performance Standard compliance, Salmonella test results, and any other microbiological testing results.

2. The IIC will make a determination as to whether the findings show that there have been isolated incidents of fecal material noncompliance, or if the findings evidence a systemic problem with the slaughter food safety system. When making this determination, the IIC should seek answers to questions such as:

- a. What is the rate of noncompliance?
- b. Has the establishment implemented meaningful preventive measures?
- c. Has the rate of noncompliance decreased?
- d. Does the generic *E. coli* testing indicate a problem with the sanitary dressing procedures or sanitation in the establishment?
- e. Are there indications that other parts of the HACCP system are not appropriately designed to prevent food safety hazards?
- f. Is the establishment doing any other testing that is relevant (e.g., testing for customers)? If so, what are the results of that testing?
- g. Are all parts of the HACCP system being implemented as designed?
- h. Are there indications that the establishment's antimicrobial interventions are not operating as intended?
- i. Do the establishment's microbiological testing program results have spikes that might indicate problems with sanitation? If so, does the establishment implement corrective actions to eliminate these problems?

3. If the IIC determines that repetitive findings of fecal material, ingesta, and milk represent a developing trend, the NRs would be linked to document that the slaughter process is not effective in preventing contamination of carcasses. This situation can lead to a determination that the food safety system is inadequate. If so, the IIC is to follow the methodology set out in FSIS Directive 5000.1, Revision 1, Chapter IV, Enforcement, Rules of Practice to determine the appropriate enforcement action.

If inspection program personnel have questions regarding this directive they are to

contact the Technical Service Center.

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Identification of Feces for Poultry

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

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

- The color of feces ranges from varying shades of yellow to green, brown, and white.
- The consistency of feces is characteristically semi-solid to a paste.
- The composition of feces may or may not include plant material.

Inspection program personnel must take care to distinguish feces from ingesta.

- The color of ingesta varies with the diet.
- The consistency of ingesta is characteristically solid or granular; digestive fluids sometimes are present.
- The composition of ingesta is identifiable plant material.

(Section 381.65(e) does not apply to ingesta. However, inspection program personnel who find ingesta during fecal contamination checks should notify establishment management to remove ingesta from affected carcasses.)

Livestock Carcass Examination

Based on the expected slaughter volume for that day (number of animals), determine the number of carcass units to be examined, using the following table. If carcasses are split, each half carcass is ½ of a carcass unit (so select two times as many half-carcasses).

<u>number of animals</u>	<u>number of carcass units</u>
100 or fewer	2
101 to 250	4
251 to 500	7
more than 500	11

- a. Select the carcass units randomly.
- b. Examine the selected carcass units using the technique that inspection program personnel use at the post-mortem rail inspection station (Part II, II., B., 2).

Off-line inspection program personnel should verify that carcasses are not contaminated with fecal material, ingesta or milk by the post-mortem rail inspection station.

Identification of Contaminants for Livestock

In determining whether an establishment has prevented the contamination of or removed contaminants from carcasses or carcass parts, inspection program personnel assigned to verify that the sanitary dressing procedures must be able to properly identify feces, ingesta, or milk.

A. Feces and Ingesta

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

- The color of fecal or ingesta contamination is yellow, green, or brown, in the case of cattle;

tan to dark brown, in the case of swine; and

brown to black, in the case of sheep and goats.
- Fecal or ingesta contamination has a fibrous or plant-like texture. Sheep and goat feces and ingesta may be tarry. Swine feces and ingesta may include identifiable grain particles.

Inspection program personnel should identify foreign material as feces or ingesta only when they are able to identify both color and texture, as described above. In and of itself, size is unimportant in identifying fecal or ingesta contamination. However, as size decreases, color and texture become more difficult to discern.

B. Milk

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

- The color of milk ranges from clear to white to light yellow.
- The consistency of milk ranges from watery to ropy or curdy.

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