

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

FSIS DIRECTIVE	10,010.2	8/20/15
-----------------------	----------	---------

**VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC)
IN RAW BEEF PRODUCTS**

CHAPTER I – GENERAL

I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP) on the verification activities, other than FSIS sampling, related to *Escherichia coli* O157:H7 (*E. coli* O157:H7) and non-O157 Shiga toxin-producing *E. coli* (STEC). It includes instructions that previously appeared in FSIS Directive 10,010.1, *Verification Activities for Escherichia coli O157:H7 in Raw Beef Products*. Although FSIS is incorporating these instructions in this new directive, the Agency has not made fundamental changes to the approach IPP use when performing STEC verification activities other than FSIS sampling.

B. IPP responsible for performing HACCP verification tasks and Hazard Analysis Verification (HAV) tasks in establishments that produce raw beef products are to be provided up to three hours of official regular (01) time to read this directive. IPP are to designate any unscheduled tasks that they did not complete as “not performed” as a result of the time allotted for review of this directive. IPP are to select “Higher priority task took precedent” as the reason code.

C. New instructions concerning verification activities IPP are to perform at an establishment that has addressed hazards in a prerequisite program and its system fails to prevent the hazard will be provided in a forthcoming issuance.

KEY POINTS:

- *IPP verify HACCP regulatory requirements in establishments that produce raw beef products by performing the HACCP Verification Task and a HAV task*
- *FSIS verification activities for raw beef products are applicable to raw veal products*

NOTE: For the purposes of this directive, when the directive references raw beef, veal and not-ready-to-eat (NRTE) beef are included.

II. SIGNIFICANT CHANGES

A. The Agency is clarifying what is involved in the inspection activities that are related to consumer preparation practices and scientific support for antimicrobial treatments.

B. The one significant change in this directive is that IPP are to issue a noncompliance record (NR) to an establishment that has a written program to divert all product that FSIS samples to cooking when the establishment receives a positive FSIS sample result unless the establishment also tested the product and found it positive for STEC.

DISTRIBUTION: Electronic

OPI: OPPD

III. BACKGROUND

A. FSIS considers all raw non-intact beef and raw intact beef intended for use in raw non-intact product to be adulterated under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(1)) if it is contaminated with adulterant STEC. Adulterant STEC include *E. coli* O157:H7 and the six non-O157 STEC: O26, O45, O103, O111, O121, and O145.

B. STEC contamination is a food safety hazard during the slaughter and processing of raw intact and raw non-intact beef products. The establishment may use a multi-hurdle approach and incorporate multiple controls and preventive measures to address the pathogen in its HACCP system. Thus, the establishment may control the pathogen through one or more critical control points (CCPs) in its HACCP plan or prevent the potential pathogen from becoming reasonably likely to occur (RLTO) through preventive measures in its Sanitation Standard Operating Procedures (Sanitation SOPs) or through other prerequisite programs, or a combination of these mechanisms.

C. IPP are to be aware that an establishment producing raw beef product needs to make sure that it effectively addresses the hazard. At this time, there are few controls specific to non-O157 STEC that are not also effective against *E. coli* O157:H7. An establishment may determine that its controls or preventive measures for *E. coli* O157:H7 effectively control or prevent non-O157 STEC. Interventions validated to control *E. coli* O157:H7 should be effective in controlling the non-O157 STECs when properly implemented as described in the establishment's supporting documentation unless data such as multiple non-O157 STEC sample results indicate otherwise.

CHAPTER II – IPP HACCP VERIFICATION ACTIVITIES

I. GENERAL

IPP are to verify that establishments that produce raw intact and non-intact beef products meet HACCP regulatory requirements by performing Hazard Analysis Verification (HAV) Tasks and HACCP Verification Tasks.

II. PERFORMING THE HAV TASK

A. IPP are to use the instructions in Table 1 when performing Raw Intact and Raw Non-Intact HAV Tasks.

TABLE 1: STEPS IN PERFORMING THE HAZARD ANALYSIS VERIFICATION (HAV) TASK IN RAW INTACT AND RAW NON-INTACT BEEF PRODUCTS

Step	Description	Verification Questions	Regulatory Citation (9 CFR)
Step 1	Review flowchart and compare to production process. Determine whether the establishment has identified the product's intended use (see Chapter II, Section III of FSIS Directive 10,010.1).	<ul style="list-style-type: none">Has the establishment described all of the steps of each process and product flow?	417.2(a)(2)
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry	<ul style="list-style-type: none">Has the establishment addressed possible hazards from STEC in its hazard	417.2(a)(1), 417.5(a)(1)

	<p>Hazards and Controls Guide available on FSIS's website and Chapter IV, Section IV of this directive. Become familiar with any prerequisite programs the establishment uses as preventive measures support hazard analysis decision that STEC is not reasonably likely to occur (NRLTO) for the specific product type.</p>	<p>analysis?</p> <ul style="list-style-type: none"> • If the establishment has determined that STEC is RLTO in the product, has the establishment implemented at least one CCP designed to control STEC? • Has the establishment identified non-O157 STEC in its hazard analysis as NRLTO because its preventive measures for <i>E. coli</i> O157:H7 are adequate for non-O157 STEC? If so, does the establishment receive multiple non-O157 STEC positives that call this decision-making into question? • If the establishment has not considered possible hazards from STEC, or is not controlling it through its HACCP plan or preventing it through its Sanitation SOP or prerequisite program, do IPP contact the DO so the DO can take enforcement action? • Does the establishment use the instructional or disclaimer statement as a control or CCP to address STEC? <p>NOTE: This represents noncompliance with 417.5(a)(1) (See Chapter IV).</p>	<p>417.2(a)(1) 417.2(c)(2)</p> <p>417.2(a)(1), 417.5(a)(1)</p> <p>417.5(a)(1)</p>
<p>Step 3</p>	<p>For each hazard that the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. <i>If no hazards are reasonably likely to occur, skip to step 4.</i> See Chapter IV, Section IV of this</p>	<ul style="list-style-type: none"> • If the establishment considers STEC a hazard RLTO, has the establishment included one or more CCPs to control the hazard either at that step or a later step? • Is the establishment's HACCP plan designed to 	<p>417.2(c)(2)</p> <p>417.5(a)(2)</p>

	<p>directive.</p>	<p>ensure that it includes the monitoring procedures and frequencies that it uses to monitor the CCPs?</p> <ul style="list-style-type: none"> • If the establishment has included its antimicrobial intervention control measures as a CCP, has the establishment incorporated the critical operating parameters* (e.g., carcass and product coverage) into its written monitoring procedures? <p>*Critical parameters are those parameters (e.g., carcass or product coverage, temperature, concentration, contact time) of an intervention that must be met in order for the intervention to operate effectively and as intended.</p> <p>NOTE: IPP are to use the information in Attachment 1 to assist them in reviewing the establishment’s scientific support for antimicrobial treatments that establishments apply as part of a CCP, Sanitation SOP, or other prerequisite program.</p> <ul style="list-style-type: none"> •If the establishment performs STEC testing, does the establishment have support for its sampling and testing procedures and the frequency for the procedures? <p>NOTE: IPP are to be aware that establishments are not required to use the same sample analysis procedures as FSIS. However, IPP are to be aware that the regulations require the establishment to maintain documents that support its verification activities (including sampling</p>	<p>417.2(c)(4)</p> <p>417.2(c)(2), 417.5(a)(2)</p> <p>417.2(c)(4)</p> <p>417.5(a)(2)</p>
--	-------------------	---	--

<p>Step 5</p>	<p>Review prerequisite programs and other supporting programs, including written programs, records, and employee activities. Verify the implementation of prerequisite programs.</p>	<ul style="list-style-type: none"> • Does the establishment use prerequisite programs to support hazard analysis decision-making? • Does the establishment's antimicrobial intervention preventive measures on incoming raw materials incorporate the critical operating parameters (e.g., product or carcass coverage) identified in the establishment's scientific support? <p>NOTE: IPP are to use the information in Attachment 1 to assist them in reviewing the establishment's scientific support for antimicrobial treatments that establishments apply as part of a CCP, Sanitation SOP, or other prerequisite program.</p> • If the establishment has incorporated its antimicrobial intervention preventive measures or other STEC preventive procedures in a prerequisite program, does the establishment implement the antimicrobial intervention or other STEC preventive measures according to its supporting documentation? • If the establishment has determined that its prerequisite programs for <i>E. coli</i> O157:H7 adequately prevent non-O157 STEC, does the establishment implement its preventive measures according to its support? • Are the prerequisite programs consistently being implemented as written? 	<p>417.5(a)(1)</p> <p>417.5(a)(1)</p> <p>417.5(a)(1)</p> <p>417.5(a)(1)</p> <p>417.5(a)(1)</p> <p>417.5(a)(1)</p>
----------------------	--	---	--

		<ul style="list-style-type: none"> Do the prerequisite programs support the establishment's hazard analysis decision-making on an ongoing basis? 	
Step 6	Review other supporting documentation.	<ul style="list-style-type: none"> Does the establishment use data concerning customary consumer preparation practices information in conjunction with its purchase specifications and its own preventive measures employed during further processing as part of a prerequisite program to support its hazard analysis decisions? Do the establishment's hazard analysis decision-making documents describe the basis for the establishment's determination that these practices constitute customary preparation? 	<p>417.5(a)(1)</p> <p>417.5(a)(1)</p>
Step 7	Review establishment validation documents, including scientific supporting documents and validation data.	<ul style="list-style-type: none"> Does the in-plant validation data show that the establishment can implement its CCPs and prerequisite programs consistent with the scientific support to effectively control or prevent STEC? <p>NOTE: Until January 4, 2016 (large establishments) or April 4, 2016 (small and very small establishments), if IPP find the in-plant validation data inadequate, they are not to cite the lack of in-plant validation</p>	417.4(a)(1)

		data as the only reason for the documentation of noncompliance.	
Step 8	Verify reassessment requirements. Check the most recent signature and date for each HACCP plan.	<ul style="list-style-type: none"> • If an establishment that identifies non-O157 STEC in its hazard analysis as NRLTO because its preventive measures for <i>E. coli</i> O157:H7 are adequate for non-O157 STEC receives a non-O157 STEC positive result, has the establishment reassessed its HACCP plan and documented the reassessment? • Has the establishment reassessed its HACCP plan when information (e.g., repetitive ongoing positive STEC results) indicates the HACCP plan is no longer adequate? 	417.3(b), 417.4(a)(3) 417.4(a)(3)

III. PERFORMING THE HACCP VERIFICATION TASK

IPP are to use the instructions provided in [FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*](#), and in Table 2 when performing Raw Intact and Raw Non-Intact HACCP Verification Tasks.

TABLE 2: STEPS IN PERFORMING THE HACCP VERIFICATION TASK IN RAW INTACT AND RAW NON-INTACT BEEF PRODUCTS

Step	Description	Verification	Regulatory Citation (9 CFR)
Step 1	Select the product type and specific production.	<ul style="list-style-type: none"> • IPP are to review the list of products, to ensure all product types are selected over time. 	None
Step 2	Verify the monitoring requirements.	<ul style="list-style-type: none"> • If the establishment has included its antimicrobial intervention control measures as a CCP, IPP are to verify that the establishment implements the procedure as 	417.2(c)(4)

		<p>written.</p> <ul style="list-style-type: none"> If the establishment has determined that its CCPs for <i>E. coli</i> O157:H7 adequately control non-O157 STEC, IPP are to verify the establishment implements its procedures according to its support. 	417.5(a)(2)
Step 3	Verify the verification requirements.	<ul style="list-style-type: none"> If the establishment performs STEC testing, IPP are to: <ul style="list-style-type: none"> --Observe the establishment's employee collecting the sample and determine whether the sampling procedures are being performed as written. --Review sample results (including any non-O157 STEC results the establishment conducts in addition to <i>E. coli</i> O157:H7) and verify that the establishment takes corrective actions in response to positive results that meet the requirements of 9 CFR 417.3 (see step 5). 	417.4(a)(2)
Step 4	Verify the recordkeeping requirements.	<ul style="list-style-type: none"> IPP are to review sampling records to determine whether the establishment collected the number of samples at the frequency documented in its program. 	417.5(a)(3)
Step 5	Verify the corrective action requirements. See Chapter III, Sections I and II for more information.	<ul style="list-style-type: none"> IPP are to verify that the establishment: <ul style="list-style-type: none"> --Has included corrective actions as part of its HACCP plan and --Takes corrective action in response to STEC positive results from establishment or FSIS testing. 	417.3

Step 6	Verify the pre-shipment review requirements. See Chapter III, Section III and Chapter IV of this directive for more information.	<ul style="list-style-type: none"> • IPP are to verify that product which bears an instructional or disclaimer statements is only being sent to an official establishment for further processing. 	417.5(c)
Step 7	Consider the implications of any noncompliance. See Chapter III, Section I.B. for more information.	<ul style="list-style-type: none"> • IPP are to document noncompliance and consider the findings in the context of the establishment's food safety system as instructed in Chapter V of FSIS Directive 5000.1. 	

CHAPTER III – IPP RESPONSIBILITIES RELATED TO POSITIVE STEC SAMPLE RESULTS

I. IPP RESPONSIBILITIES WHEN AN ESTABLISHMENT RECEIVES A POSITIVE STEC SAMPLE RESULT FROM FSIS, ANOTHER FEDERAL ENTITY, OR STATE

A. Verify the corrective action requirements (Step 5 in Table 2):

1. IPP are to verify that products that tested positive for STEC from FSIS or establishment testing received appropriate disposition.
2. IPP are to verify that the establishment transporting presumptive positive or positive product to another site for appropriate disposition has met all corrective action requirements by verifying that the establishment maintained:
 - a. Records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;
 - b. Control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);
 - c. Control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1); and

NOTE: IPP are to be aware that a voluntary instructional “For Cooking Only” statement is not a sufficient control.

- d. Records showing that presumptive positive or positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred.
3. If the positive product is shipped to another official establishment for disposition (e.g., cooking), IPP at that establishment are to verify that the receiving establishment adequately addresses the pathogen in the product. Specifically, IPP are to verify that the establishment:

- a. Documents the receipt of presumptive positive or positive product, as required under 9 CFR 417.5;
 - b. Maintains control of the product; and
 - c. Addresses the receipt of adulterant STEC in its hazard analysis, flow chart, and HACCP plan, so that the positive product will receive an adequate lethality treatment to destroy the pathogen.
4. If an establishment ships adulterated product to a renderer or landfill operation, IPP are to routinely verify the establishment denatures the product before the product leaves the establishment (9 CFR 314.3).
 - a. There may be situations when an establishment may want to move product to a renderer or landfill without denaturing the product before the product leaves the establishment;
 - b. In these situations, the establishment must put the request in writing, describe the controls it will use in its request, and obtain permission from the DO; and
 - c. IPP are to verify that the establishment follows the procedures agreed upon with the DO.
5. Generally, an establishment may not ship positive or presumptive positive product through a cold storage facility because the establishment that produced the product must maintain control of it during shipment. Ownership is typically passed once the cold storage facility holds the product. However, there may be circumstances in which either the producing or receiving establishment can ship positive or presumptive positive product through a cold storage facility. In this situation, IPP are to verify that the producing establishment maintains:
 - a. Control of the product while it is in transit (e.g., through company seals) or ensure such product moves under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);
 - b. Records identifying the cold storage facility and how the products will be controlled while stored in the cold storage facility;
 - c. Records identifying the official establishment, renderer, or landfill that received the product; and
 - d. Records that show that the product received proper disposition, including documentation evidencing proper disposal of the product from the official establishment where disposition occurred or from the renderer or landfill where disposition occurred.
6. When verifying adequate corrective actions in response to a non-O157 STEC positive from FSIS testing, IPP are to first determine whether the establishment identified non-O157 STEC as a hazard in its hazard analysis.
 - a. If the establishment identified non-O157 STEC, IPP are to verify that the establishment takes corrective action in accordance with 9 CFR 417.3(a).

- b. If the establishment did not identify non-O157 STEC in its hazard analysis or does not have controls for *E. coli* O157:H7 that would also address non-O157 STEC, IPP are to verify that the establishment takes corrective action in accordance with 9 CFR 417.3(b).
7. When verifying compliance with 9 CFR 417.3(b) in response to a non-O157 STEC positive from FSIS testing, IPP are not to expect the establishment to initiate a testing program for non-O157 STEC if it does not already have one at this time. IPP are to verify that the establishment has reassessed its HACCP system for non-O157 STEC or maintains support demonstrating that its existing controls or preventive measures for *E. coli* O157:H7 effectively control or prevent the non-O157 STEC. IPP are to evaluate whether the establishment properly implemented existing controls and preventive measures, including sanitary dressing procedures.

B. Consider the implications of any noncompliance based on the positive FSIS result (Step 7 in Table 2):

1. IPP are to document a noncompliance record (NR) for the confirmed positive result from FSIS testing, as described below. IPP are to take the following into consideration when issuing NRs:
 - a. If FSIS finds the product to be positive for non-O157 STEC or *E. coli* O157:H7, and the establishment also tested the product, IPP are to check establishment test results to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7 or non- O157 STEC.
2. IPP are not to issue an NR in response to the positive FSIS result if both of the following are true:
 - a. The establishment held the product or maintained control of the product (e.g., the establishment moved the product off-site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results; and
 - b. FSIS and the establishment found the product positive for either *E. coli* O157:H7 or non-O157 STEC. Testing can find the product positive for different adulterant STEC.
3. IPP are to issue a NR to establishments that have a written program to divert all product that FSIS samples to cooking unless the establishment also tested the product and found it positive for STEC.
4. If FSIS finds the product positive, and the establishment testing found that the product was negative (or the establishment did not perform testing), then IPP are to issue an NR (cite 9 CFR 301.2 and 9 CFR 417.4(a)) because the establishment's HACCP system was inadequate resulting in adulterated product being produced.
5. If IPP find that the establishment did not hold or maintain control of the product, he or she is to issue an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review (step 6 in Table 2) following availability of all relevant test results, as set out in 9 CFR 417.5(c). IPP are to immediately contact the District Office (DO). If the results are confirmed positive for adulterant STEC, the DO is to take appropriate administrative action and contact the Recall Management and Technical Analysis Staff (RMTAS) and Office of Investigation, Enforcement and Audit (OIEA), Compliance and Investigation Division (CID), Regional Director. As appropriate, FSIS will request a recall or detain the product. OIEA, CID RD, in consultation with Headquarters, will consider whether additional enforcement actions or sanctions are necessary.
6. IPP are to verify, after the establishment has implemented its corrective action, that the establishment implements corrective actions that meet the applicable requirements in 9 CFR

- 417.3, including ensuring the product receives appropriate disposition (see step 5 in Table 2).
7. For FSIS positive results from follow-up samples from raw non-intact products and raw intact products intended for raw non-intact use, IPP are to:
 - a. Link noncompliance (e.g., previous FSIS STEC results, sanitary dressing, antimicrobial intervention implementation), as appropriate; and
 - b. Cite 9 CFR 417.3(a) on the NR because the establishment's corrective actions were not implemented or not effective (i.e., failed to prevent the recurrence of a positive result).
 8. If IPP find noncompliance with 9 CFR 314.3, they are to document it in accordance with FSIS Directive 5000.1. In situations where the establishment has not properly moved the product, IPP also are to notify the DO through supervisory channels.
 9. If IPP have concerns about the adequacy of the HACCP system, they are to discuss their concerns with their supervisors.

II. IPP RESPONSIBILITIES WHEN AN ESTABLISHMENT HAS A POSITIVE STEC SAMPLE RESULT FROM ITS OWN TESTING

A. When performing the HACCP verification task (step 3 in Table 2), IPP are to review the records associated with any STEC testing conducted by an establishment (see [FSIS Directive 5000.2 Review of Establishment Testing Data by Inspection Program Personnel](#)). If IPP find presumptive positive or confirmed positive STEC results in the testing records, they are to verify that the establishment is implementing corrective actions (step 5 in Table 2). When an establishment tests product, a presumptive positive or positive result alone does not warrant a NR. IPP are only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions in accordance with its HACCP system to meet the requirements in 9 CFR 417.3.

B. IPP are to verify that the establishment addresses the product as if it had tested positive if an establishment is only performing screening tests (e.g., a presumptive positive) and does not follow up with additional testing to determine whether STEC is isolated from the product. The establishment cannot use negative results for a second screening test for STEC as a means to support food safety because a screening test is not a conclusive (specific) test for the pathogen.

C. When performing a HACCP verification task (step 3 in Table 2 above), IPP are to verify that establishment employees conducting sampling for STEC do not sample sterile product that could not be contaminated with STEC (e.g., product taken from the interior of a carcass). If IPP observe such sampling, they are to document noncompliance with 9 CFR 417.4(a)(2) on an NR in accordance with the instructions in [FSIS Directive 5000.1](#).

D. If establishment records show testing of trim and other raw ground beef components for STEC, but the establishment never finds any positives, IPP are to notify the DO. In addition, if establishment records show multiple positives for STEC in its own testing, evidencing a potential systemic problem, IPP are to notify the DO. The DO is to schedule an Enforcement, Investigations and Analysis Officer (EIAO) to review the establishment's trim and other raw ground beef components sampling and testing methods for trim for STEC.

III. ESTABLISHMENTS CONDUCTING PRE-SHIPMENT REVIEW FOR PRODUCT THAT IS NOT AT THE PRODUCING ESTABLISHMENT

When performing a HACCP verification task (step 6 in Table 2), IPP are to be aware that Agency policy allows establishments to conduct pre-shipment review when the product is at locations other than at the

producing establishment, provided the product does not leave the control of the producing establishment. Some establishments analyze samples for STEC while they are moving the product, but the product is still under the establishment's control. IPP are to be aware that the Agency provides establishments the flexibility to move their product before pre-shipment review when the establishment is conducting testing for STEC and maintains control of the product (e.g., through company seals or FSIS control).

CHAPTER IV – VERIFICATION PROCEDURES INVOLVING INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING STEC

NOTE: See Attachment 2 and 3 for corresponding flow charts.

I. GENERAL

This chapter provides instructions for IPP for verifying an establishment's use of instructional or disclaimer statements during HACCP verification and HAV tasks.

II. INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING STEC

A. An instructional statement concerning STEC is a statement that addresses how the product is to be prepared or handled to ensure that the pathogen is eliminated or reduced to below detectable levels. If an official establishment labels product with the phrase "for further processing" without further qualification, this phrase is not an instructional statement. It is a statement of limited use.

B. Examples of instructional statements concerning STEC in raw ground beef components, raw beef patty components, and raw ground beef products may include, "for full lethality treatment," "for cooking only," or "for further processing into RTE products that will receive a full lethality treatment." "Cooking" is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate *E. coli* O157:H7. "Full lethality treatment" may be cooking or another process that eliminates *E. coli* O157:H7, such as fermentation or salt curing.

C. A disclaimer statement concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were not used in the production of the product. An example of a disclaimer statement concerning *E. coli* O157:H7 is, "product has not been tested for *E. coli* O157:H7."

D. Imported product, product for export, and product to be sent to a State-inspected establishment may not bear either an instructional or a disclaimer statement.

NOTE: A statement that the establishment does not intend to use the product in ground product or other non-intact product is not an instructional or disclaimer statement (e.g., "not intended for grinding" or "not intended for raw ground"). These types of statements **may not be used at all** on product labels.

III. TYPES OF PRODUCTS THAT CAN BEAR INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING STEC

A. IPP are to be aware that establishments can only place these statements on product for use at other official establishments. When the Labeling and Program Delivery Staff (LPDS), Office of Policy and Program Development (OPPD), approves the use of instructional labeling statements, LPDS specifies that establishments can only use such statements on products destined for official establishments that ensure that these products receive adequate lethality treatment.

B. When conducting a General Labeling task, IPP are to verify that the establishment has received sketch approval from LPDS. If IPP find that the establishment does not have sketch approval, IPP are to document noncompliance on an NR and cite 9 CFR 412.1(a).

C. When performing a HACCP verification task (step 6 in Table 2), IPP are to verify that the product that bears an instructional statement is only being sent to an **official** establishment for further processing.

D. When performing a HACCP verification task (step 5 in Table 2), IPP are to be aware that establishments may label product with instructional statements (e.g., “for cooking only”) if the establishment has not tested the product for STEC.

E. IPP are to be aware that positive product can bear instructional statements. However, an instructional or disclaimer statement is not a control for movement of positive product. The establishment is required to move product under controls and maintain records showing that the product received proper disposition (see Chapter III, Section I.A.2.)

F. Establishments’ use of instructional or disclaimer statements is optional.

IV. IPP VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT PLACE INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING *E. COLI* O157:H7 ON THE LABELING OF RAW GROUND BEEF PRODUCTS, RAW GROUND BEEF COMPONENTS, OR RAW BEEF PATTY COMPONENTS

A. When performing a HAV task, IPP are to verify that:

1. The instructional or disclaimer statement is not being used as a control or CCP to address STEC;
2. The establishment has not used the instructional or disclaimer statement to justify its determination that STEC is not a hazard reasonably likely to occur in the production of these products; and
3. The establishment’s HACCP plan for products that bear a disclaimer statement includes a validated intervention for STEC. A disclaimer statement that indicates that the product has not been tested for STEC implies that the pathogen may be a food safety hazard reasonably likely to occur in the product in the absence of adequate controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address STEC in the HACCP plan. In this situation, the HACCP plan may be determined inadequate (9 CFR 417.6).

B. If the establishment places a “for cooking only” or “for full lethality treatment” statement on the product and ships it to outside establishments, IPP, while performing the HAV task, are to verify that the hazard analysis shows how the shipping establishment is ensuring that the product will go only to establishments that cook it or that provide other full lethality treatment. IPP are to verify that the shipping establishment has controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that it does not intend for cooking, IPP are to verify that the establishment has controls in place to segregate product intended for cooking from product not intended for cooking.

C. If IPP find that the establishment’s use of instructional statements does not meet the criteria in Section IV. A.1., 2., or 3., or that the establishment’s use of disclaimer statements does not meet the criteria in Section IV. A. 1., 2., or 4. of this chapter, they are to document the noncompliance on an NR as described in [FSIS Directive 5000.1](#), Chapter V, using the appropriate HAV task and the appropriate regulatory citation (usually, 9 CFR 417.5(a)(1)).

D. If an establishment labels product with an instructional or disclaimer statement and does not send it to an official establishment for further processing to destroy the pathogen, IPP are to document the noncompliance on an NR. IPP are to initiate a regulatory control action (9 CFR 500.2(a)) if the product is still at the official establishment or contact the District Recall Officer (DRO) through supervisory channels. Noncompliance exists because the product is misbranded. IPP are to be aware that establishments can only place these statements on product for use at other official establishments where the establishment

will treat the product in a way to address STEC.

V. VERIFICATION ACTIVITIES IPP CONDUCT AT ESTABLISHMENTS RECEIVING RAW GROUND BEEF COMPONENTS, RAW BEEF PATTY COMPONENTS, OR RAW GROUND BEEF PRODUCTS WITH INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING STEC

A. When performing a HACCP verification task to verify that the HACCP requirements are met for products produced using incoming products with an instructional or disclaimer statement, IPP are to verify that an establishment that receives such incoming products:

1. Has addressed the use of incoming product with disclaimer statements in its HACCP plans as if the products may be contaminated with STEC; or
2. Is following any instructional statements on the incoming products and cooking product to a sufficient temperature and for a sufficient period of time to eliminate or reduce STEC to below detectable levels.

B. If IPP find that the establishment has not met the criteria in paragraph A., they are to document the noncompliance on an NR as described in [FSIS Directive 5000.1](#), Chapter V, using the HACCP verification task and the appropriate regulatory citation (usually 9 CFR 417.5(a)(1) with the recordkeeping noncompliance classification indicator).

NOTE: IPP can verify the requirements as part of a routine scheduled HACCP verification task or, if found during performance of another task, add a directed HACCP verification task to document a noncompliance.

C. IPP are to apply a regulatory control (i.e., [U.S. Retain tag](#)) to any product produced from these incoming products when product is not going to be subjected to a lethality step as expected for product bearing an instructional or disclaimer statement.

D. If IPP retain product, they are to document the noncompliance on an NR as described in [FSIS Directive 5000.1](#), Chapter V, using the HACCP verification task and the appropriate regulatory citation (usually 9 CFR 417.5(a)(1)). IPP are to notify the DO through supervisory channels of the conditions observed in association with the use of instructional or disclaimer statements.

VI. VERIFICATION ACTIVITIES FOR PRODUCT SENT TO WAREHOUSES OR BROKERS

If IPP observe breaking bulk or repackaging of product bearing instructional or disclaimer statements at an identification warehouse, they are to:

1. Contact the DO immediately through their Frontline Supervisor (FLS) (see [FSIS Directive 12,600.1](#), *Voluntary Reimbursable Inspection Services*); and
2. Detain the product as directed (see [FSIS Directive 8410.1](#), *Detention and Seizure*).

NOTE: Failure of an identification warehouse to adhere to the provisions of its application for service could result in the District Manager withdrawing that service (see [FSIS Directive 12,600.1](#)).

VII. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,010.2**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Sampling – E. coli O157:H7** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

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

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, appearing to read "David Joseph". The signature is fluid and cursive, with a prominent loop at the end.

Assistant Administrator
Office of Policy and Program Development

CRITICAL OPERATING PARAMETERS FAMILIARIZATION

IPP are to use the examples provided in this attachment to assist them in reviewing the establishment's scientific support for antimicrobial treatments that establishments apply as part of a critical control point (CCP), Sanitation SOP, or other prerequisite program.

EXAMPLE:

FSIS test results show that the percent positive for STEC in trim produced from veal appear to be higher than trim produced from other cattle slaughter classes. Following up on these results, FSIS conducted a review of Food Safety Assessments (FSAs) and onsite visits to veal slaughter establishments to identify concerns unique to veal slaughter. The results of the review indicate a common deficiency. Specifically, veal slaughter establishments, in applying their antimicrobial interventions, failed to achieve carcass coverage because of the practice of suspending carcasses from the rail system with both hind limbs on a single hook (see Figure 2). Because of this practice, spray interventions did not reach all parts of the carcasses. Carcass coverage –ensuring that the entire carcass surface is treated -- is necessary for the intervention to operate effectively. As a result of the incomplete carcass coverage, interventions were likely less effective than intended, and this ineffectiveness may have contributed to the production of products contaminated with STEC.

In addition, during on-site visits to beef fabrication establishments, FSIS found that those establishments, when applying their antimicrobial intervention, also failed to achieve product coverage. Reasons for inadequate application of the antimicrobial intervention to all product surfaces included the stacking of products and the folding of longer pieces, particularly loins (Figures 3 and 4). These actions prevented antimicrobial sprays from reaching all product surfaces. Additionally, establishment personnel failed to address these actions by adjusting the conveyor belt timing, properly designing spray applications, and ensuring that product was single-stacked and lying flat so that all product surfaces received the antimicrobial spray. Product coverage – ensuring that all of the product is treated – is necessary for the intervention to operate effectively and as intended.

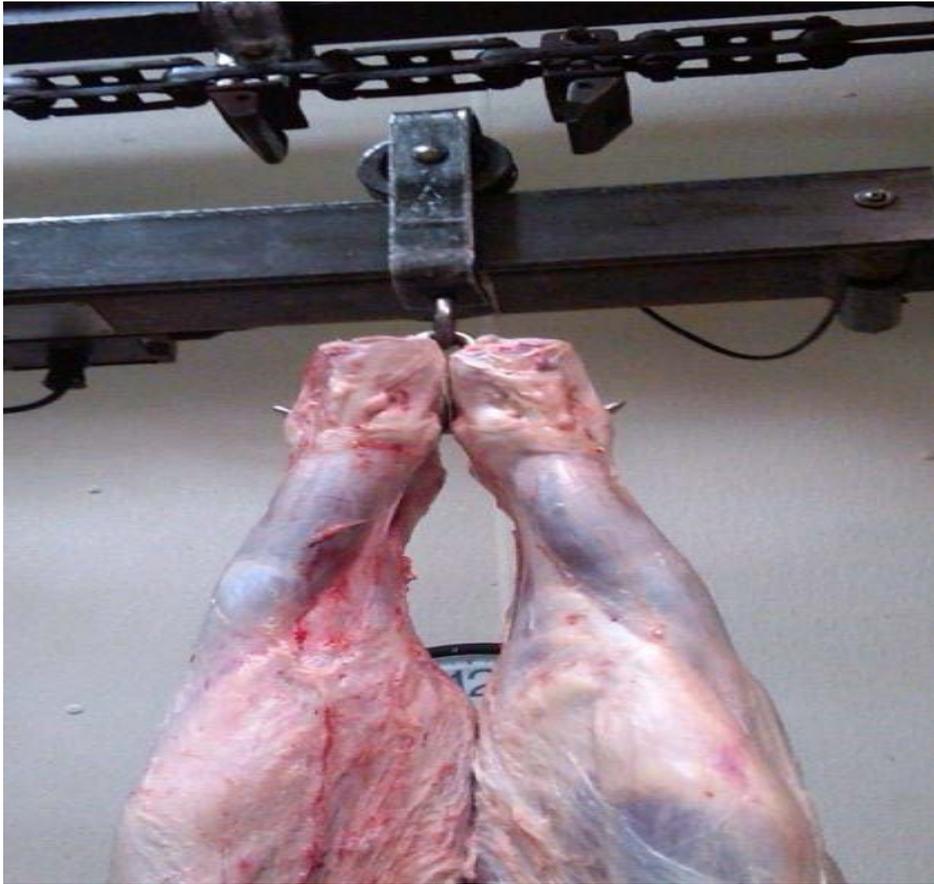


Figure 2. Example of a veal carcass with both hind limbs suspended from a single hook. This practice prevented the antimicrobial treatment from achieving full carcass coverage, a critical operating parameter.

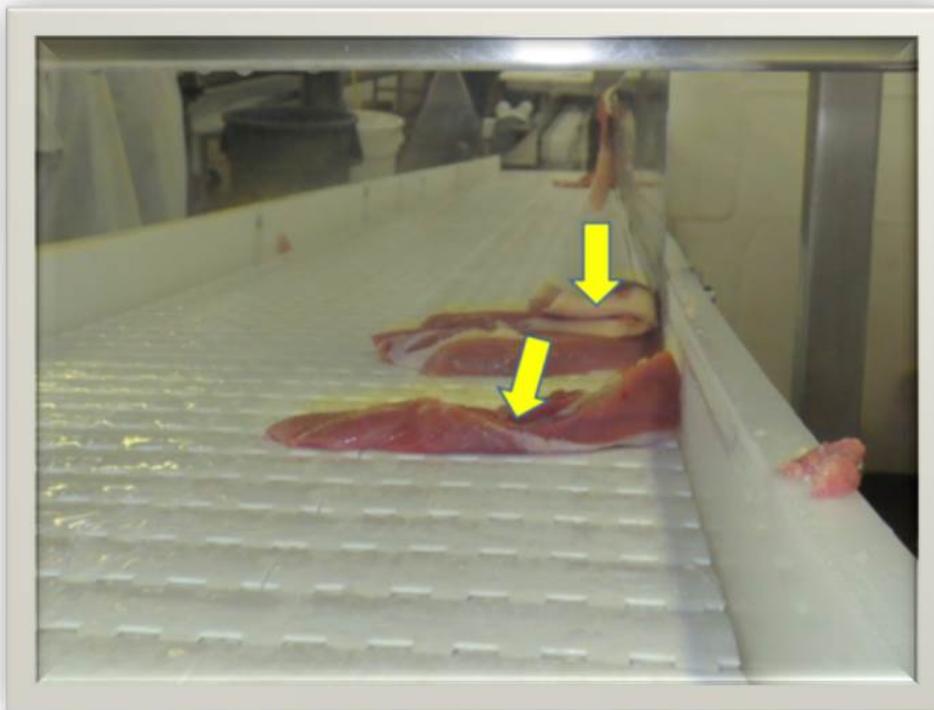


Figure 3. Product is folded as the antimicrobial treatment is applied, which prevents the antimicrobial

treatment from achieving full product coverage, a critical operating parameter.

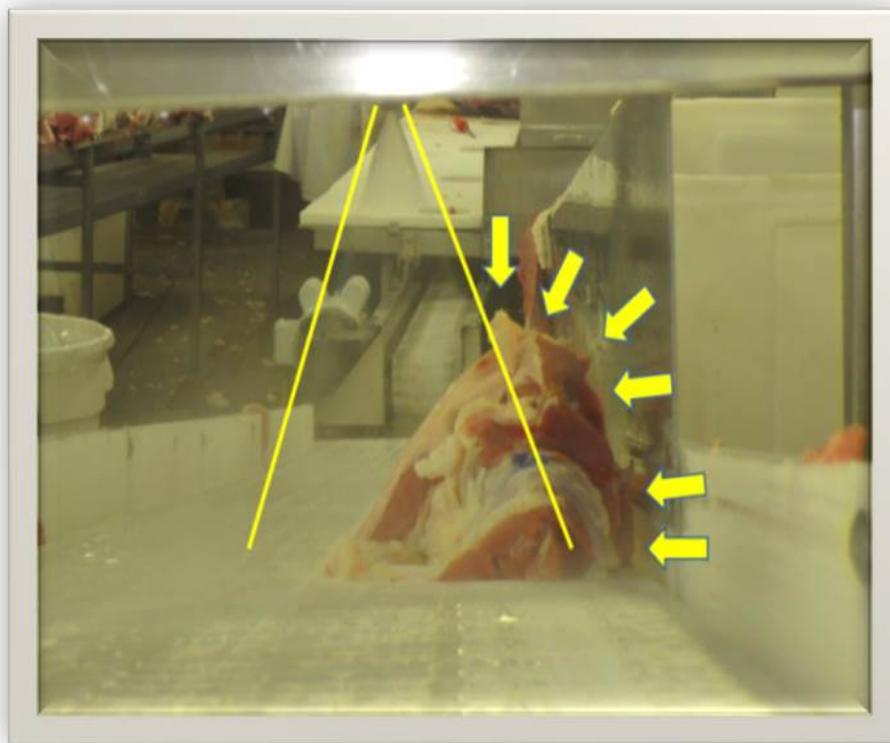
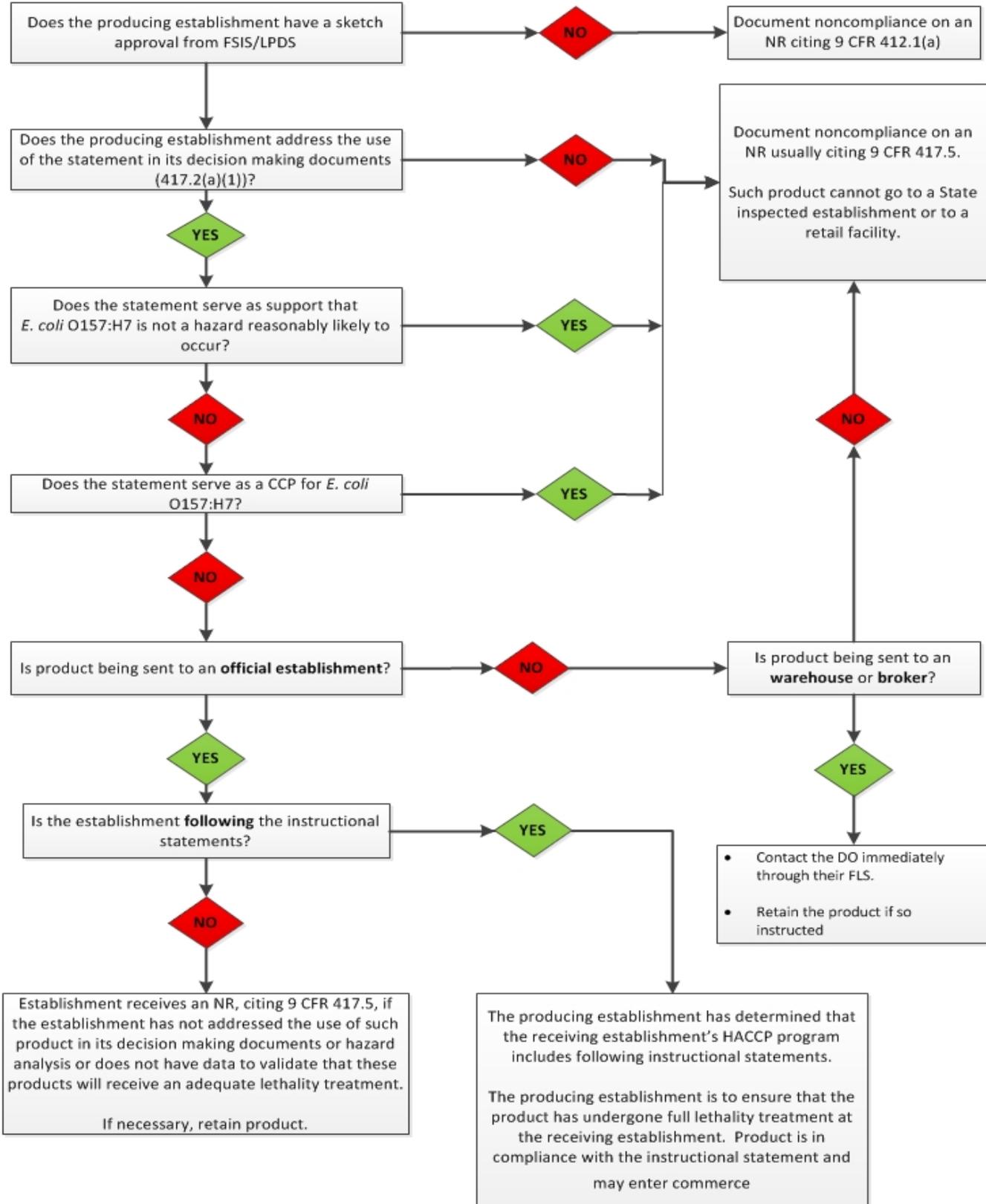


Figure 4. Product is stacked and folded and some of the product is outside the arc of the antimicrobial treatment. As a result, the antimicrobial treatment does not achieve full product coverage, which is a critical operating parameter.

Instructional Statement: Addresses how an establishment should prepare or handle product to ensure the pathogen is eliminated or reduced to acceptable levels.

Examples: "For Cooking Only", "For Full Lethality Treatment"



Disclaimer Statement: Addresses the types of verification activities the establishment did NOT perform

Example: "Product has not been tested for *E. coli* O157:H7"

