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

FSIS DIRECTIVE

10,010.2
Revision 1

7/1/20

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

CHAPTER I – GENERAL

I. PURPOSE

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). FSIS is reissuing this directive to reflect current policy regarding the importation and movement of product through Federal establishments bearing instructional statements concerning STEC, in Chapter IV Sections V and VI. These instructions were previously included in FSIS notices. FSIS is also updating the directive to provide additional information on reassessment requirements when establishments have produced product found positive for STEC.

KEY POINTS:

- *IPP verify HACCP regulatory requirements in establishments that produce raw beef products by performing the HACCP verification task and the Hazard Analysis Verification (HAV) task*
- *FSIS verification activities for raw beef products include raw veal products*
- *IPP at import establishments are to follow the instructions in Chapter IV Section V when verifying instructional statements*

II. CANCELLATIONS

FSIS Directive 10,010.2 *Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products*, 08/20/15

Notice 19-19, *Label Verification of Imported Raw Beef Products Labeled "For Cooking Only" or "For Full Lethality Treatment"*, 06/19/19

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)) when it is contaminated with an adulterant, including *E. coli* O157:H7 and these six non-O157 STEC when the Shiga toxin (*stx*) and Intimin (*eae*) genes are present: O26, O45, O103, O111, O121, and O145.

B. STEC contamination is a food safety hazard that is reasonably likely to occur 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 this hazard 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 occurring through preventive measures in its Sanitation Standard Operating Procedures (Sanitation SOPs), through other prerequisite programs, or a combination of these mechanisms.

C. IPP are to be aware that establishments producing raw beef product need to effectively address the hazard. At this time, there are few controls specific to non-O157 STEC that are not also effective against *E. coli* O157:H7. However, 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.

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 HAV Tasks and HACCP Verification Tasks.

II. PERFORMING THE HAV TASK

IPP are to use the questions in Table 1 when performing Raw Intact and Raw Non-Intact HAV Tasks in addition to the instructions in FSIS Directive 5000.6 Performance of the HAV Task.

TABLE 1: QUESTIONS TO CONSIDER WHEN PERFORMING THE 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 *Sampling Verification for Shiga Toxin-producing Escherichia Coli in Raw Beef Products*).	• Has the establishment described all 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 Hazards and Controls Guide available on FSIS's website and Chapter IV, Section IV of this directive. Become familiar with any	• Has the establishment addressed all possible contamination from STEC in its hazard analysis? • If the establishment has determined that STEC is RLTO in the product, has the establishment implemented at least one CCP designed to control O157 and non-O157 STEC?	417.2(a)(1), 417.5(a)(1) 417.2(a)(1) 417.2(c)(2)

	prerequisite programs the establishment uses as preventive measures to support a hazard analysis decision that STEC is not reasonably likely to occur (NRLTO) for the specific product type.	• Has the establishment identified non-O157 STEC in its hazard analysis as NRLTO because its preventive measures for *E. coli* O157:H7 are adequate for non-O157 STEC? If so, has the establishment received 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, did IPP contact the District Office (D.O.) so the D.O. can take enforcement action? • Does the establishment use an instructional or disclaimer statement as a control or CCP to address STEC? (See Chapter IV).	417.2(a)(1), 417.5(a)(1) 417.5(a)(1) 417.5(a)(1)
Step 3	For each hazard that the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. *If no hazards are reasonably likely to occur, skip to step 4.*	• 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 ensure that it includes the monitoring procedures and frequencies that it uses to monitor the CCPs? • 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? *Critical parameters are those parameters (e.g., carcass or product coverage, temperature, concentration, contact time) of an intervention that must be met for the intervention to operate effectively as intended. **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 another prerequisite program. • If the establishment performs STEC testing, does the establishment have support for its sampling and testing procedures and the frequency for the procedures?	417.2(c)(2)) 417.5(a)(2) 417.2(c)(4) 417.2(c)(2), 417.5(a)(2), 417.2(c)(4) 417.5(a)(2)

		NOTE: 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 and analysis) and frequency, as appropriate for their intended purpose. • Does the establishment use an instructional or disclaimer statement to address STEC? (See Chapter IV of this directive).	417.5(a)(1)
Step 4	For each hazard, the establishment considers NRLTO, determine what evidence the establishment uses to support the decision.	• If the establishment determines that STEC is NRLTO in its product, does it prevent STEC through a prerequisite program or its Sanitation SOP? Proceed to step 5. • Does the establishment determine that STEC is NRLTO in its product based on data concerning customary consumer preparation practices, in conjunction with its purchase specifications and its own preventive measures employed during further processing that are incorporated as part of a prerequisite program? For example, certain cuts of meat contain a large amount of connective tissue, so consumers need to cook the product for a specific time to make the product palatable (e.g., a brisket for use in corned beef). Other cuts of meat (e.g., "Philly" style cheese steaks) are thin and are cooked thoroughly quickly. Proceed to step 6.	417.5(a)(1) 417.5(a)(1)
Step 5	Review prerequisite programs and other supporting programs, including written programs, records, and employee activities. Verify the implementation of prerequisite programs.	• Does the establishment use prerequisite programs to support hazard analysis decision-making? • Do the establishment's antimicrobial intervention measures on raw materials incorporate the critical operating parameters (e.g., product or carcass coverage) identified in the establishment's scientific support? **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. • If the establishment has incorporated its antimicrobial intervention preventive measures or other STEC preventive procedures in a prerequisite program, does the establishment	417.5(a)(1) 417.5(a)(1) 417.5(a)(1)

		implement the antimicrobial intervention or other STEC preventive measures according to its supporting documentation? • If the establishment has determined that its prerequisite programs for *E. coli* 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? • Do the prerequisite programs support the establishment's hazard analysis decision-making on an ongoing basis?	417.5(a)(1) 417.5(a)(1) 417.5(a)(1)
Step 6	Review other supporting documentation.	• Does the establishment use data concerning customary consumer preparation practice 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?	417.5(a)(1) 417.5(a)(1)
Step 7	Review establishment validation documents, including scientific supporting documents and validation data.	• 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?	417.4(a)(1)
Step 8	Verify reassessment requirements. Check the most recent signature and date for each HACCP plan.	• If an establishment that identifies non-O157 STEC in its hazard analysis as NRLTO because its preventive measures for *E. coli* O157:H7 are adequate for non-O157 STEC, but then 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 the information in Table 2 when performing Raw Intact and Raw Non-Intact HACCP Verification Tasks.

TABLE 2: INFORMATION TO CONSIDER WHEN 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.	• IPP are to review the list of products, to ensure all product types are selected over time.	None
Step 2	Verify the monitoring requirements.	• If the establishment has included its antimicrobial intervention control measures as a CCP, IPP are to verify that the establishment implements the procedure as written. • If the establishment has determined that its CCPs for *E. coli* O157:H7 adequately control non-O157 STEC, IPP are to verify the establishment implements its procedures according to its support.	417.2(c)(4) 417.5(a)(2)
Step 3	Verify the verification requirements.	• If the establishment performs STEC testing, IPP are to: --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 collects in addition to *E. coli* 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.	• 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.	• IPP are to verify that the establishment: --Has included corrective actions as part of its HACCP plan and --Takes corrective action in response to positive STEC 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.	• IPP are to verify that product which bears an instructional or disclaimer statement 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.	• 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 found positive for STEC from FSIS or establishment testing receive 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). IPP are to be aware that use of the instructional statement "For Cooking Only" statement is not sufficient control; and

    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., for cooking), IPP at the receiving establishment are to verify that it adequately addresses the pathogen in the product. Specifically, IPP are to verify that the receiving 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 STEC- positive product 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 uses in its request, and obtain permission from the D.O.;

    c. IPP are to verify that the establishment follows the procedures agreed upon with the D.O.; and

    d. 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 D.O. through supervisory channels.

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. Control is typically lost once the cold storage facility takes ownership of the product (see Section VI). 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 the adequacy of 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 in its hazard analysis, 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 the establishment:

        1. Performs reassessment to determine whether the newly-identified deviation or other unforeseen hazard should be incorporated into the HACCP plan, per 9 CFR 417.3(b)(4);

2. Documents the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment, per 9 CFR 417.4(a)(3)(ii); and

3. Provides all supporting documentation, including support for the decisions made during reassessment, per 9 CFR 417.5(a)(1).

c. IPP are to question whether the design or implementation of the establishment's unique food safety system is sufficient to control STEC when non-O157 STEC contamination is identified in the production process even though the *E. coli* O157:H7 results and other processing CCP records may indicate process control was maintained.

d. In response to one or more non-O157 STEC positives, IPP are to verify whether any additional establishment testing conducted includes non-O157 STEC as part of the validation, verification and reassessment requirements of 9 CFR 417.4 and supporting documentation requirements of 9 CFR 417.5(a)(1), until the establishment is able to demonstrate control over STEC in their unique HACCP system, or the HACCP system may be deemed inadequate (9 CFR 417.6).

B. Determining and documenting noncompliance:

1. IPP are to document a noncompliance record (NR) for the confirmed positive result from FSIS testing, as described below and as instructed in FSIS Directive 5000.1.

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.

i. 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 (citing 9 CFR 301.2 and 9 CFR 9 CFR 417.4(a)) because the establishment's HACCP system did not identify the adulterated product being produced.

ii. IPP are to issue an 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.

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 both found the product positive for either *E. coli* O157:H7 or non-O157 STEC. FSIS testing and establishment testing do not have to identify the exact same adulterant STEC serogroup as long as both testing results have identified the sample as STEC positive.

3. 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 DO. If the results are confirmed positive for STEC, the DO is to take appropriate administrative action and contact the Recall Management and Technical Analysis Division (RMTAD) and Office of Investigation, Enforcement and Audit, Compliance and Investigation Division (CID), Regional Director (RD). As appropriate, FSIS will request a recall or detain the product. The CID RD, in consultation with Headquarters, will consider whether additional enforcement actions or sanctions are necessary.

4. 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 (Step 5 in Table 2).

5. 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. Associate noncompliance (e.g., previous FSIS STEC positive 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).

6. 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 an 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. 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, IPP are to verify that the establishment addresses the product as if it had tested positive. The establishment cannot use negative results from a second screening test for STEC 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), 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 muscle). 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. IPP are to be aware that STEC positives occur on an infrequent basis, (i.e., typically less than 1%). When an establishment conducts frequent testing and never finds a positive, IPP are to notify their Supervisor and D.O. as this may indicate problems with the validity of the sampling and testing methodology. When an establishment conducts frequent testing and frequently finds STEC positives, including numerous positives within a day or week, IPP are to notify their supervisor and D.O. as the results may indicate the establishment is not maintaining process control. In these situations, the D.O.

may schedule an Enforcement, Investigations and Analysis Officer (EIAO) to review the establishment's STEC control and verification measures.

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

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.

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

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.

1. 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 ready-to-eat (RTE) products that will receive a full lethality treatment."

    a. Cooking is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate STEC.

    b. Full lethality treatment may be cooking or another process that eliminates STEC, such as fermentation or salt curing.

B. 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."

C. Product bearing instructional or disclaimer statements are not to be offered for export, sent to state-inspected establishments or sent to retail exempt firms, including hotels, restaurants, or institutions (HRI).

D. 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. If IPP observe the use of the above statements, they are to notify the D.O. through their supervisory chain-of-command.

III. PRODUCTS BEARING 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, and that these statements require prior approval by the Office of Policy and Program Development (OPPD), Labeling and Program Delivery Staff (LPDS). As a condition of label approval, 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 prior approval from LPDS. If IPP find that the establishment does not have prior 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 sufficient 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. VERIFICATION ACTIVITES AT ESTABLISHMENTS THAT APPLY INSTRUCTIONAL OR DISCLAIMER STATEMENTS

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 is not using an 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 be shipped to official establishments that cook it or that provide other full lethality treatments. IPP are to verify that the shipping establishment has controls in place to ensure that the product goes to establishments that cook it. The product may be further processed at other official establishments prior to being received at official cooking establishments if control is maintained by the original shipping establishment (see Section VI of this chapter). 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., or 2., or that the establishment's use of disclaimer statements does not meet the criteria in Section IV. A. 1., 2., or 3. 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 maintain evidence that the product was sent 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 AT IMPORT ESTABLISHMENTS FOR PRODUCTS BEARING INSTRUCTIONAL OR DISCLAIMER STATEMENTS

A. This section provides instructions to IPP for conducting verification of imported raw beef products bearing the "For Cooking Only" or "For Full Lethality Treatment" instructional statement claims. This is applicable only to import reinspection of raw beef products certified to go to a Federal establishment that applies cooking or a full lethality treatment to eliminate STEC.

NOTE: These instructional statements can only be applied to raw beef testing negative for STEC or that is untested. Raw, non-intact beef and raw beef intended for non-intact use presented for importation and determined to be either positive or presumptive positive for STEC at the time it is offered for importation is adulterated and is not permitted entry into the United States (U.S.) (9 CFR 327).

B. IPP are to verify instructional statement label claims in accordance with *Qualifiers, Claims, Grade or Declaration Concerns* (Section VI, G) in FSIS Directive 9900.5, *Label Verification of Imported Meat, Poultry, and Egg Products*.

C. IPP are to verify instructional statement label claims for each lot presented, in accordance with FSIS Directive 9900.1, *Imported Product Shipment Presentation*.

D. Raw beef products bearing the "For Cooking Only" or "For Full Lethality Treatment" instructional statement claims can only be further processed in official establishments and cannot be exported, sent to State-inspected establishments, or enter commerce. These products can be shipped through ID Warehouses or official establishments, pending delivery to the official establishment which applies cooking or full lethality treatment to eliminate STEC.

NOTE: All instructional statement label claims must be evaluated by LPDS prior to use. The instructional statement claim is not a control for STEC and is not a control for movement of product.

E. IPP are to verify the instructional statement claims through review of supporting documentation provided by the importer and the intended destination as described in D. below. If IPP have concerns regarding label claims, IPP are to retain the lot, use the Lot Tracking function in the Public Health Information System (PHIS) to select "Place the lot on hold" and contact their Frontline Supervisor (FLS).

F. To verify that the lot is intended to be cooked or receive a full lethality treatment by an official establishment, IPP are to:

1. Review contracts, bills of lading, letters of guarantee, agreements or other supporting documentation from the importer of record indicating how the lot will be handled to ensure the lot will be cooked or receive full lethality treatment; and

2. Review the import inspection application (Form 9540-1) to determine the destination establishment name and number (the consignee) and verify the establishment conducts RTE processing in PHIS by reviewing the establishment's PHIS profile.

G. In addition to the Label Verification Type of Inspection (TOI) result (Pass/Fail), IPP are to record the "For Cooking Only Claim" or "For Full Lethality Treatment Claim" in the remarks to track imported lots bearing these claims.

H. IPP are not to sample raw beef products labeled "For Cooking Only" or "For Full Lethality Treatment". In accordance with FSIS Directive 9900.6 *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products* (Section VI, C), IPP are to request through PHIS not to perform a laboratory sample TOI assigned by PHIS, and are to select "Instructional Claim: Cook/Lethality at Federal Est." as the reason.

VI. VERIFICATION ACTIVITIES AT PRODUCING AND INTERMEDIARY ESTABLISHMENTS FOR PRODUCTS BEARING INSTRUCTIONAL OR DISCLAIMER STATEMENTS

A. VERIFICATION ACTIVITIES AT PRODUCING ESTABLISHMENTS

1. When conducting a HACCP verification task, IPP at an establishment that applies instructional statements are to follow the instructions in Chapter IV. They are to verify the producing establishment maintains and implements sanitation procedures to prevent cross-contamination. They are to also ensure records adequately demonstrate the product was sent to an official establishment for a full lethality process.

2. When IPP identify noncompliance, 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).

3. IPP are to be aware that product for export or HRI, or product sent to a state-inspected establishment or to a retail firm may not bear an instructional statement.

B. VERIFICATION ACTIVITIES AT INTERMEDIARY ESTABLISHMENTS

1. IPP are to be aware that products labeled with instructional statements may be produced and labeled at one establishment and undergo further processing (e.g., repackaging, grinding) at an intermediate, non-cooking official establishment prior to being sent to another official establishment for cooking or other full lethality treatment.

2. Intermediary establishments that receive product labeled with an instructional statement and further process the product may reapply (i.e., "carry forward") the instructional statement without label approval. IPP at intermediary establishments that carry forward labeling of product with an instructional statement are to:

   a. Follow the instructions in Chapter IV to verify the establishment is appropriately using the instructional statement. The HACCP system for establishments that carry forward the instructional statement do not need to include a validated intervention for STEC as the product is intended for cooking or other full lethality treatment;

   b. Verify the establishment's hazard analysis (9 CFR 417.2) and decision-making documents (9 CFR 417.5) meet the criteria in Chapter IV when performing the HACCP verification task;

c. Verify the establishment tracks and facilitates communication between the supplying establishments and receiving establishments to ensure records are available showing each lot of product was sent to an establishment for cooking or other full lethality treatment; and

d. IPP are to document 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) when they find that the intermediate establishment has not met the criteria above.

VII. VERIFICATION ACTIVITIES AT IDENTIFICATION WAREHOUSES FOR PRODUCTS BEARING INSTRUCTIONAL OR DISCLAIMER STATEMENTS

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

1. Contact the DO immediately through their 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).

VIII. VERIFICATION ACTIVITIES AT COOKING AND FULL LETHALITY TREATMENT ESTABLISHMENTS

A. When performing a HACCP verification task to verify that the HACCP requirements are met for 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 as well, 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. Retained 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.

IX. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development 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.

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 CCP, Sanitation SOP, or another 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 product is treated – is necessary for the intervention to operate effectively as intended.

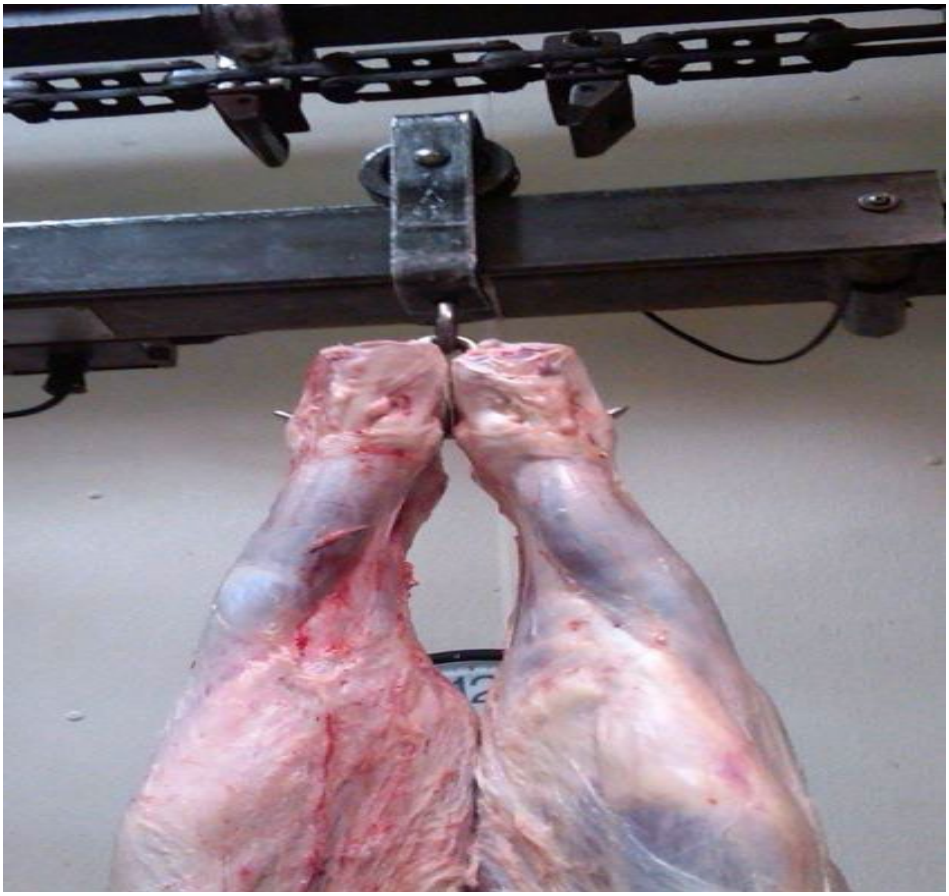


Figure 1. Example of a veal carcass with both hind limbs suspended from a single hook. This practice prevented the antimicrobial treatment from achieving full carcass coverage, a critical operating parameter.

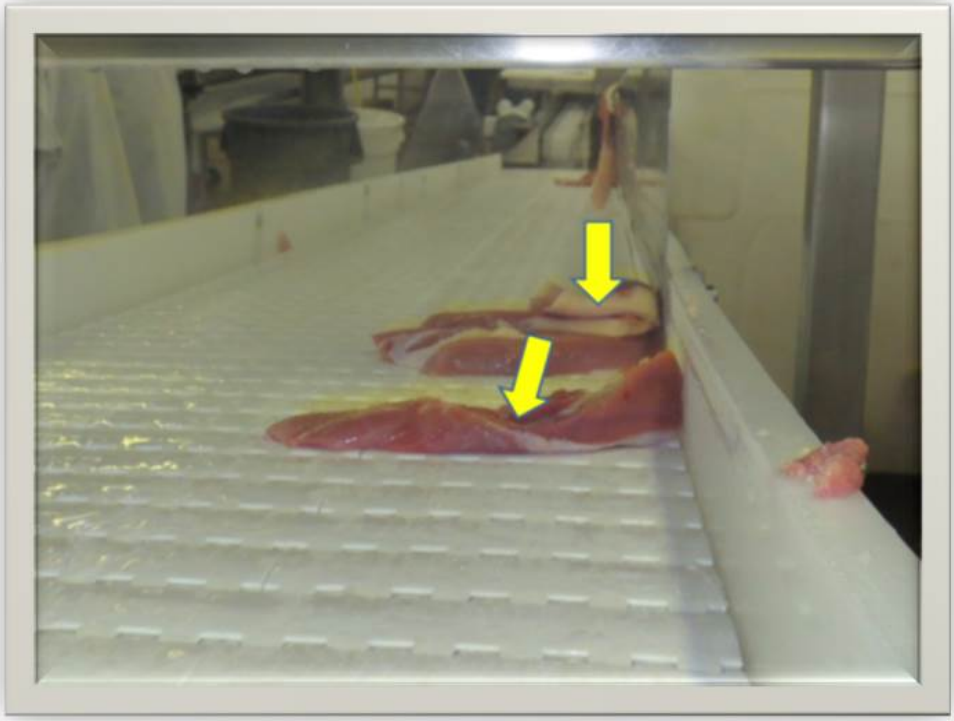


Figure 2. Product is folded as the antimicrobial treatment is applied, which prevents the antimicrobial

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

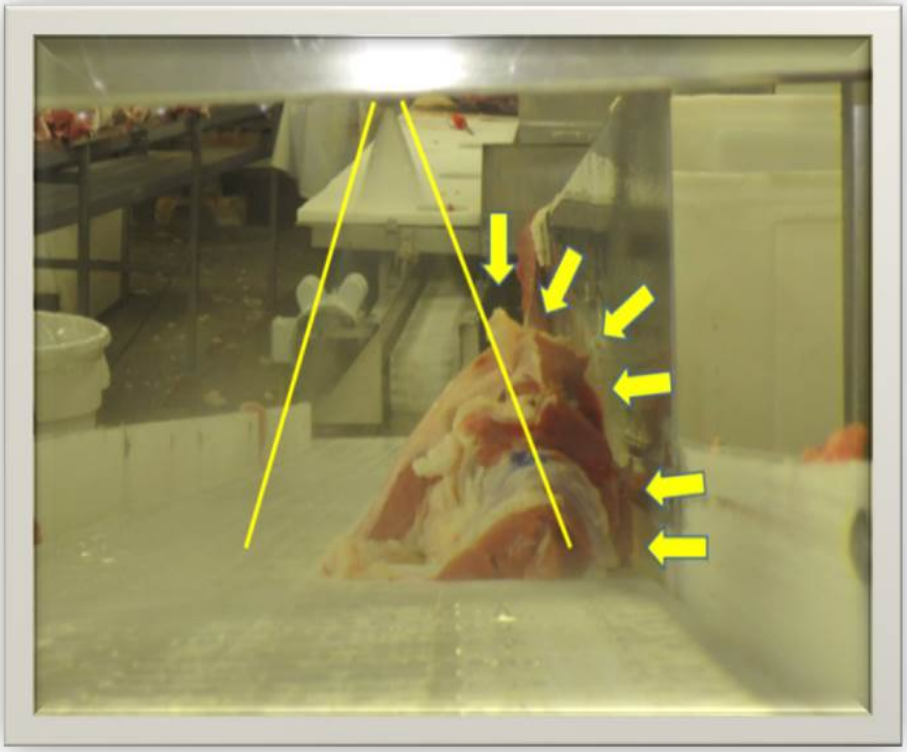


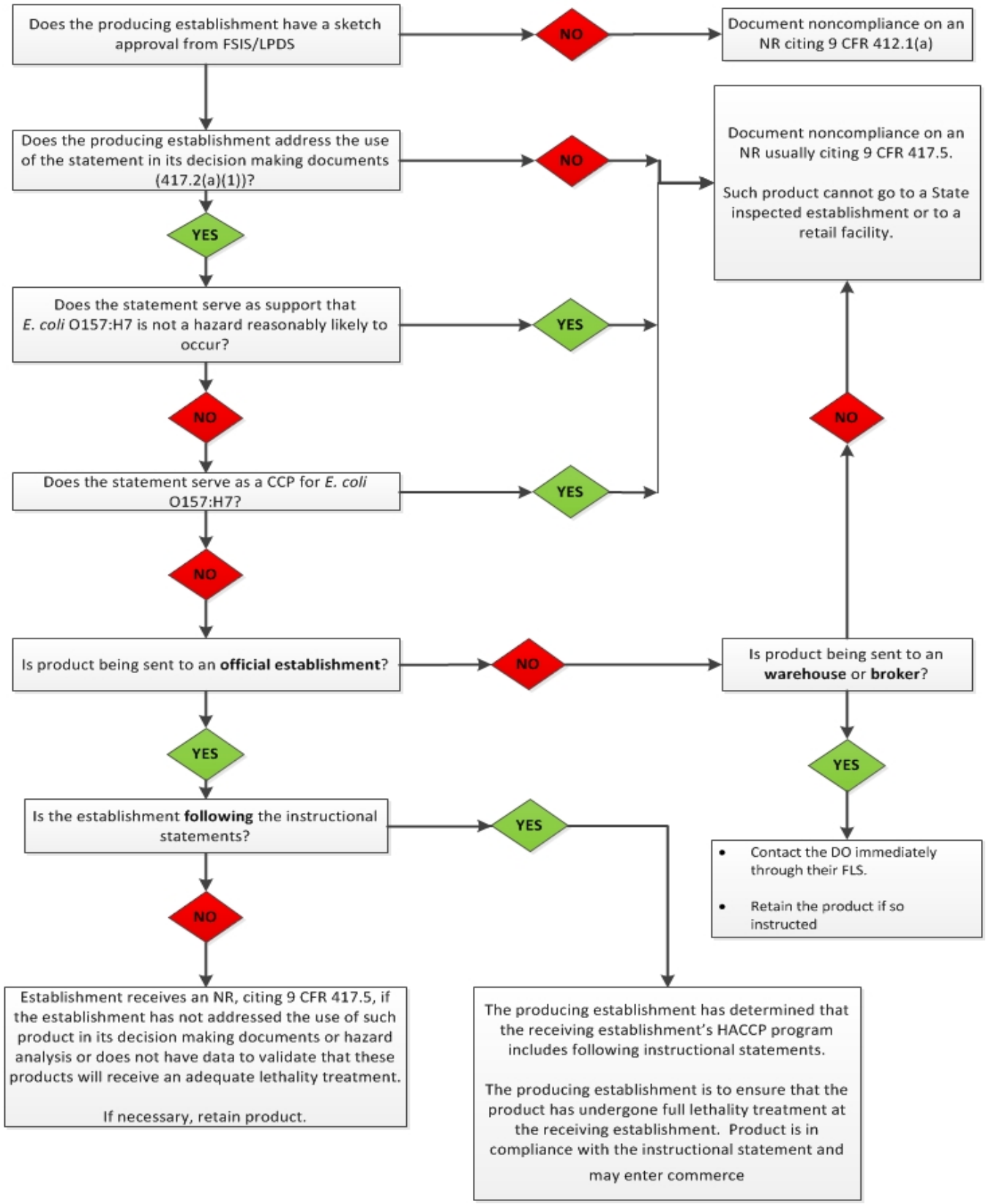
Figure 3. Product is stacked and folded and some of the product is outside the arc of the antimicrobial treatment. As a result, the antimicrobial treatment does not achieve full product coverage, which is a critical operating parameter.

Instructional Statements
(Product Not Adulterated = Enters Commerce)

Attachment 2

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 Statements
(Product Not Adulterated = Enters Commerce)

Attachment 3

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

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