**VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS**
**FOOD SAFETY CONSUMER PROTECTION DIVISION**
**Meat Inspection Service**
**MONTPELIER, VT**
**Chuck Ross, Secretary**

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| # MIS DIRECTIVE<br>**Adopted from FSIS Directive 10010.2** | 10010.2 | 10/1/15 |

## 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 VAAFM 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 these instructions are being incorporated in this new directive, the Agency has not made fundamental changes to the approach IPP use when performing STEC verification activities other than VAAFM 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 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 VAAFM samples to cooking when the establishment receives a positive VAAFM sample result unless the establishment also tested the product and found it positive for STEC.

## III. BACKGROUND

A. VAAFM 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)) and 6V.S.A Chapter 204, 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 III – IPP RESPONSIBILITIES RELATED TO POSITIVE STEC SAMPLE RESULTS

### I. IPP RESPONSIBILITIES WHEN AN ESTABLISHMENT RECEIVES A POSITIVE STEC SAMPLE RESULT FROM VAAFM, 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 VAAFM 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 VAAFM control (e.g., under VAAFM seal); 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 uses in its request, and obtain permission from the Meat inspection office; and

c. IPP are to verify that the establishment follows the procedures agreed upon with the Meat inspection office.

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 VAAFM control (e.g., under VAAFM seal);

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 VAAFM 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 VAAFM 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 VAAFM result (Step 7 in Table 2):

1. IPP are to document a noncompliance record (NR) for the confirmed positive result from VAAFM testing, as described below. IPP are to take the following into consideration when issuing NRs:

    a. If VAAFM 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 VAAFM 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. VAAFM 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 VAAFM 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 VAAFM 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 meat inspection office. If the results are confirmed positive for adulterant STEC, the office is to take appropriate administrative action and contact recall management team. As appropriate, VAAFM will request a recall or detain the product, and in consultation with Compliance and Enforcement and the Division Director, 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 VAAFM 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 VAAFM 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 VT Directive 5000.1. In situations where the establishment has not properly moved the product, IPP also are to notify the office 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 meat inspection office. In addition, if establishment records show multiple positives for STEC in its own testing, evidencing a potential systemic problem, IPP are to notify the meat inspection office. The Office 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 VAAFM 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."

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 Staff approves the use of instructional labeling statements, they specify 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. 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 VT 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 Program Chief 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 VT 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 VT 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 office through supervisory channels of the conditions observed in association with the use of instructional or disclaimer statements.

## VI. Questions

Questions can be referred to the meat inspection office at 802-828-2426.

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