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

FSIS DIRECTIVE	10,010.3	1/21/15

TRACEBACK METHODOLOGY FOR *ESCHERICHIA COLI* (*E. COLI*) O157:H7 IN RAW GROUND BEEF PRODUCTS AND BENCH TRIM

I. PURPOSE

This directive instructs Enforcement, Investigations, and Analysis Officers (EIAOs) and other inspection program personnel (IPP) on the steps that they are to take for traceback investigations when FSIS or another Federal or State agency finds that ground beef or bench trim have tested presumptive-positive for *E. coli* O157:H7. Additionally, this directive provides information on how IPP are to determine whether an establishment has experienced a high-event period (HEP), and information on when EIAOs or other IPP are to contact the Office of Field Operations (OFO) Recall Management and Technical Analysis Staff (RMTAS) to request a recall from suppliers.

KEY POINTS:

- *Instructs EIAOs and other IPP on how to conduct product traceback from the grinder or bench trim establishment*
- *Instructs EIAOs and other IPP on what an HEP is, and on the steps that they are to take to verify that an establishment's action in response to an HEP is appropriate*
- *Instructs District Office (DO) personnel and OFO RMTAS personnel on actions that they are to take during a product traceback*
- *Provides information on requesting that a sole source originating supplier slaughter establishment recall product when FSIS laboratories or another Federal or State agency identifies that establishment as having sent product into commerce from a lot that tested positive in a sample collected at the grinder or bench trim (receiving) establishment*

NOTE: For the purpose of this directive, the term "EIAO" includes Public Health Veterinarians trained in EIAO methodology.

II. BACKGROUND

The Agency announced in a Federal Register notice (79 FR 47417), dated August 13, 2014, that it was implementing new procedures for when FSIS or another Federal or State agency finds raw ground beef presumptive-positive for *E. coli* O157:H7. This methodology will improve FSIS' ability to determine whether the establishments that produced the source materials for contaminated product have produced other product that may not be microbiologically independent from the contaminated product. The Agency also announced that it will request a recall if an establishment was the sole supplier of beef trim source

materials for ground product that FSIS or another Federal or State agency finds positive for *E. coli* O157:H7, evidence suggests that contamination most likely occurred at the supplier establishment, and a portion of the product from the originating source lot was sent to other establishments. Finally, it announced the availability of a compliance guideline concerning establishment sampling and testing for Shiga toxin-producing *E. coli* (STEC) organisms or virulence markers and a compliance guideline on *E. coli* O157:H7 sampled and tested labeling claims. In the first compliance guideline, FSIS provides guidance on HEP.

III. DO RESPONSIBILITIES

A. The DO is to assign an EIAO or other IPP to conduct a product traceback investigation at the grinder or at the bench trim establishment and at any suppliers that provided source materials for that product as needed following the receipt of a Biological Information Transfer and E-mail System (BITES) notification of a presumptive-positive test result or notification by another State or Federal agency of such a result.

B. IPP are to follow the applicable procedures concerning the Administrative Enforcement Reporting (AER) System as described in FSIS Directive 5100.3, *Administrative Enforcement Reporting (AER) System,* and FSIS Directive 8010.3*, Procedures for Evidence Collection, Safeguarding and Disposal.*

C. The District Manager (DM) or designee is to assign an EIAO or other IPP to trace product to an originating slaughter establishment as needed for the traceback investigation. If the DO in an assisting district receives notification through System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) that an establishment in its district has produced positive product, or that slaughter establishments in its district supplied product found positive at a grinder, it is to dispatch an EIAO or other IPP to conduct a traceback investigation within 1 business day of the STEPS notification if necessary.

D. The DM or designee in the District in which originated the product that was the subject of the positive test result at the grinder or bench trim establishment, is to review and evaluate the product traceback information to determine whether adulterated product entered commerce, or whether additional enforcement action is warranted.

E. When a supplier establishment is located in a foreign country, the DO has to notify RMTAS to notify the foreign government. The DO is to inform RMTAS whether the foreign establishment is a sole-source supplier or a multiple-source supplier and is to provide foreign supplier information collected during the product traceback.

IV. OFO-RMTAS-IMPORTS HEADQUARTERS RESPONSIBILITIES

A. OFO RMTAS-Imports Headquarters staff is to notify the Central Competent Authority (CCA) of the involved exporting country as soon as the DO contacts OFO RMTAS in order to identify whether the foreign establishment has any other production lots associated with the presumptive-positive production lot on route to or in the United States. OFO RMTAS-Imports Headquarters is to request that the foreign establishment conduct a traceback investigation at the foreign producing establishments and identify all source materials and potential suppliers of beef components used as source materials in the production of the sampled lot of ground beef or bench trim.

B. OFO RMTAS-Imports Headquarters is to review documentation received from the foreign country.

C. OFO RMTAS-Imports Headquarters is to issue an alert to import inspection personnel to refuse entry for the same lot of product with the same production codes that the foreign country presents for FSIS import reinspection after the confirmed positive result.

V. EIAO OR OTHER IPP RESPONSIBILITIES FOR CONDUCTING PRODUCT TRACEBACK

A. EIAO or other IPP product traceback investigations are to identify all source materials and potential suppliers of beef components used as source materials in the production of the sampled lot of ground beef or bench trim. The EIAO is to consider the slaughter process, sanitary dressing, and fabrication process employed at the original source slaughter establishment.

B. The EIAO or other IPP are to examine the results of any sampling conducted by either the grinding or bench trim establishment at which the positive was found or by the slaughter establishment that produced the source materials.

C. EIAOs or other IPP are to:

1. Review the supplier and source material information collected by the IPP at the time of the sample collection (see Attachment 1), including information documenting whether any source material that has been co-mingled with other product or potentially contaminated product is available for sampling, as well as the volume (e.g., weight) of the product;

2. Document evidence as described in FSIS Directive 5100.3 and FSIS Directive 8010.3 and prepare a written analysis that provides a summary of the findings and any recommendations for further action when:

    a. Product may be in commerce, and the DM may need to contact the RMTAS;

    b. An enforcement action is warranted; or

    c. A food safety assessment (FSA) is needed.

3. Provide the Case Specialist the final analysis with the summary of the findings for the Case Specialist to create a Case File in AER categorized as “Other.”

4. Stop the investigation if the “presumptive-positive” test result confirms as “negative” during the course of the investigation;

5. Contact the DO immediately whenever traceback findings indicate that adulterated product entered commerce, or that additional administrative action is warranted; and

6. Use the questions in Attachment 2 as a guide when conducting a traceback investigation.

D. As part of their traceback investigation, EIAOs or other IPP are to review slaughter establishment test results to determine whether the establishment has experienced a HEP. If establishments have developed their own HEP definition based on their unique operations, IPP are to verify that establishments have support for their definition of HEP. For purposes of FSIS traceback activities, FSIS will identify HEP occurrences based on the establishment’s HEP criteria, provided the establishment’s criteria are appropriately supported. If the establishment has not developed its own HEP criteria, or its criteria are not supported, IPP are to determine whether the establishment experienced a HEP based upon the following criteria:

1. For a local HEP: 3 or more STEC (or virulence markers) positive results out of 10 consecutive samples from production lots containing same source materials; that is, the trim was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift); and

2. For a systemic HEP: 7 or more STEC (or virulence markers) positive results out of 30 consecutive samples from production lots containing same source materials.

3. Table 1 in Attachment 3 for HEP criteria if an establishment tests more than 60 samples per day or local HEP for 10 consecutive samples.

Based on the results of their traceback activities, IPP are to make recommendations on whether regulatory and enforcement actions are warranted. The DM is then to determine whether adulterated product entered commerce. If it has, the DM is to decide whether to contact the FSIS RMTAS, and whether an enforcement action is appropriate.

VI. RECALLS FROM SOLE SOURCE SUPPLIERS

If IPP become aware that contaminated product has entered commerce and meets the following criteria, they are to contact the DO. The DO is to contact RMTAS to convene the recall committee to determine whether a recall is warranted.

1. FSIS or other Federal or State agencies find raw ground beef positive for *E. coli* O157:H7 at a grinding establishment;

2. FSIS determines that *E. coli* O157:H7 cross-contamination is unlikely to have occurred at the grinding establishment where the sample was taken (based on FSIS's assessment of the grinding establishment's handling practices);

3. FSIS determines that the grinding establishment did not combine material from multiple source lots to create the lot of product that tested positive;

4. After conducting traceback to identify the slaughter and trim fabrication supplier that provided the sole source material, FSIS determines that the supplier or downstream users split the implicated lot before sending it to the establishment where the positive sample was taken; and

5. Some portion of the split lot sent to the grinder was sent into commerce for further processing into product that does not receive a full lethality to eliminate *E. coli* O157:H7 in a federally inspected establishment.

VII. QUESTIONS

Refer questions regarding this directive to the Risk and Innovations Management Staff through askFSIS or by telephone at 1-800-233-3935 (press 5). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,010.3**
Question Field: Enter question with as much detail as possible.
Product Field: Select General Inspection 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

Supplier and Source Material Information for the Sampled Lot Collected by IPP at the Time of Ground Beef or Bench Trim Sample Collection

A. Supplier information used in the production of the sampled lot if the establishment produces the source materials in-house:

1. Confirmation exists that it was produced in-house (establishment name and number);

2. Lot numbers or slaughter dates;

3. Production dates including slaughter production days if available;

4. Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat) or any information that clearly identifies the source material used;

5. Information on the label of the source product; and

NOTE: IPP can keep the actual label from empty packages.

6. Approximate amount of the beef component produced in each lot (in lbs).

B. Supplier information from each supplier used in the production of the sampled lot if the establishment uses the source materials from a domestic outside source:

1. Establishment name and number;

2. Establishment phone number;

3. Establishment point of contact:

    a. Name;

    b. Title;

    c. E-Mail address; and

    d. Fax number:

4. Supplier lot numbers or slaughter dates;

5. Production dates;

6. Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat or any information that clearly identifies the source material used). Collect information from the label of the product; and

NOTE: IPP can keep the actual label from empty packages.

7. Approximate amount of the beef component produced in each lot (in lbs).

C. Supplier information from each supplier used in the production of the sampled lot if the establishment uses the source materials from a foreign outside source:

1. Foreign establishment name;

2. Country of origin;

3. Foreign establishment number;

4. U.S. Import establishment number (stamped on shipping cartons or on FSIS Form 9540-1);

5. Import establishment and importer of record (if available) point of contact, collect the following information:

    a. Name;

    b. Title;

    c. E-mail address; and

    d. Fax number:

6. Inspection certificate number (contained on the inspection certificate and FSIS form 9540-1; for Canada, it is on the cartons and is the same as the “shipping mark”);

7. Production date or any other information, such as barcodes or production codes that identifies the product’s date of production;

8. Shipping marks (see NOTE);

9. Date the imported product entered the country (obtained from shipping documents, if available);

10. Name or description of supplied source material used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or check meat or any information that clearly identifies the source material used).

NOTE: Shipping marks are unique alphanumeric characters applied to the shipping cartons in the foreign country. They are important for tracing the product. The mark links product with the foreign inspection certificate.

Traceback Questions

II. Traceback at Ground Beef Positive (MT43) and Bench Trim (MT55) Establishments Where FSIS or other Federal or State Entity Found the Positive Sample Result

General Questions

G1. Provide the FSIS sample form number or any identifying information for the positive.

G2. What is the production date of the positive sample?

G3. Indicate whether all raw beef products implicated by the positive test result (includes ground product and source materials) are under establishment control or if they have been shipped.

NOTE: Traceback at Bench Trim (MT55) Establishments go to "Purchased Source materials (Supplier information)" Section

Source Materials Slaughtered On-Site

S1. Were any of the source materials used to produce the positive product from the establishment's own slaughter operation (i.e., in-house source materials)?
- — Yes some of the source materials were produced in-house
- — Yes, all of the source materials were produced in-house (i.e., establishment is a **sole-source supplier**)
- — No, none of the source materials were produced in-house (i.e., the source materials were from purchased product only) (skip in-house source materials, Sanitary Dressing, and HEP).

Was the slaughter establishment the sole supplier for the bench trim or the ground beef that tested presumptive positive?

S2. Did the supplier co-mingle primal or subprimal cuts and then send some of the same lot used to produce the bench trim that FSIS found positive to additional establishments?

S3. Did the establishment ship any of the lot(s) of in-house source materials used to produce the positive to another establishment or into commerce?

S3a. Explain where product is shipped and if it is implicated.

III. Sanitary Dressing (Supplying slaughter establishments only)

The following questions ask about the supplying slaughter establishment's sanitary dressing procedures for the production period in question

SD1. Did the establishment successfully execute its sanitary dressing procedures as written during the production period in question?
- — Yes

— No
— The establishment does not have a written sanitary dressing program
— Other (Specify)

SD2. From your observations of the establishment's sanitary dressing procedures, did you identify any concerns?
— Yes
— No
— No, did not observe slaughter process

SD3. Explain your concerns.

SD4. During the production period in question, is there any evidence (establishment records or NRs during zero tolerance, sanitary dressing, SPS (incidental contamination), SSOP, HACCP tasks, etc.) that cross-contamination occurred for the production period in question?
— Yes (specify)
— No

SD5. Is there any evidence of other systematic failures in the establishment's sanitary dressing and process controls during the time period in question?

SD6. If the establishment experienced systematic failures in its sanitary dressing and process controls, describe the conditions. List the evidence that supports this conclusion. Include in your discussion the results of the establishment's sanitary dressing and process control procedures (see FSIS Directive 6410.1) that are included in its HACCP plan, Sanitation SOP, GMP, or other prerequisite programs for the production day in question.

SD7. Summarize your findings of the establishment's implementation of its sanitary dressing procedures based on your records review and observations. Explain if the establishment did not maintain adequate separation during dressing.

Microbiological Independence

M1. How does the establishment define the sampled lot of ground beef products?

M1a. Are the same source materials used in product across multiple days' production?

M1b. Are the same source materials used in other production periods or lots at the establishment?

M1c. Does the establishment have adequate support for its sampled lot definition?

M3. Does the establishment apply interventions to any of the source materials used in ground beef production during the production period in question?

— No, the establishment does not apply any interventions
— Yes, the establishment applies interventions to some source materials
— Yes, the establishment applies interventions to all source materials
— Other

M3b. Describe what interventions are applied during the production period in question.

M3c. Is there any basis for concern about whether the intervention is validated, or whether it was properly implemented for the production period in question?

M7. Describe other information pertinent to any sanitation failures that the establishment or FSIS documented during the slaughter production period in question that is not already included in your previous answers

M8. Does the establishment notify their purchasers of product of its intended use?

IV. Establishment Sampling for In-house Source Materials (Slaughter establishments only)

General Questions

2) Provide the following information regarding the establishment's generic *E. coli* or other indicator organism testing programs.

   a. What are the results of the establishment's generic *E. coli* testing or other indicator organism testing program for the production period in question?

   b. Do the results for the production period in question indicate a loss of control? Explain and support your answer.

3) Does the establishment conduct its own testing for *Salmonella* spp.? If so, does its testing results for the production period in question indicate a loss of control? Explain and support your answer.

4) Is there any evidence that the establishment experienced ongoing loss of process control according to establishment or FSIS test results for the production period in question?

5) If the establishment experienced temporary or ongoing loss of process control, describe the extent of the loss of control for the production period in question. List the evidence that supports this conclusion.

6) If the establishment has an STEC Sampling Program provide the following information:

   a. Did the establishment perform sampling as described in the establishment's sampling program during the production period in question?

   b. What does the establishment sample as part of its STEC Sampling Program?
      - Samples carcasses during slaughter
      - Samples carcasses during fabrication
      - Samples beef manufacturing trimmings
      - Samples primal and subprimals during fabrication
      - Samples finished product ground beef (applies to grinder establishments only)
      - Samples other raw ground beef components (e.g. head meat, cheek meat, etc.)

   c. How does the establishment define production segments to allow identification of affected source materials?

   d. Do the establishment's sampling results provide a clear definition between production segments to allow identification of affected source material?

7) Provide the following information regarding the establishment's test results:

a. Did the establishment receive any positive test results for the production period in question?

b. What HACCP noncompliance did the establishment receive, if any, for the production period in question?

8) Provide the following information for the FSIS ground beef sample or for any establishment positive test results, if applicable.

Did the establishment produce other raw beef products from the source materials produced on the same production lines or food contact surfaces as the source materials for the production period in question? Explain and support your answer.

HEP1. For the production period in question, are any of the products or source materials produced during the high prevalence season (i.e., April through October)?
__Yes
__ No

HEP2. Has the establishment defined what constitutes a HEP (a period of time in which the number of STEC organisms (e.g., *E. coli* O157:H7 positives) or associated virulence markers exceeds its predetermined criteria that indicates that there has been a loss of process control)?
— No, the establishment does not have a HEP program
Yes, the establishment has a written HEP program

HEP3. Describe how the establishment defines HEP, the criteria used, and how it is supported.

HEP4. Does the establishment support the criteria it developed?
— Yes, the criteria are as stringent or more stringent than the FSIS criteria
— Yes, however the criteria are less stringent
— No, the criteria are not supported

HEP5. During the time period in question, did the establishment experience a HEP as defined by FSIS or the establishment?
— Yes, a local HEP (3 or more/10), as defined by FSIS
— Yes, a systemic HEP, as FSIS defines it (7 or more/30)
— Yes, the establishment experienced an HEP according to its own definition
— No

HEP5. Which of the following actions did the establishment take during the HEP? *Check all that apply.*
— Diverted all trimmings produced during the HEP to cooking regardless of test result
— Applied an intervention to primals/subprimals produced during the HEP
— Tested subprimals/primals produced during the HEP for *E. coli* O157:H7 or other STEC
— Diverted subprimals/primals produced during the HEP to cooking
— Reduced its lot size (e.g., from 5-combo lots to one-combo lots) to increase its confidence that it is not producing adulterated products
— Tested food-contact surfaces for *E. coli* O157:H7 or other STEC
— Other ____(mandatory specify)
— The establishment took no action

Purchased Source materials (Supplier information)

P1. Did the establishment purchase any of the source materials it used in the production of the ground beef product or bench trim product that tested positive?
- Yes
- No

P2. What type of establishment did the establishment purchase its source material product from?
- Sister slaughter establishment
- Slaughter establishment
- Foreign establishment
- Non-slaughter establishment

NOTE: A sister slaughter establishment is a slaughter establishment that ships all of its carcasses, carcass halves, or quarters to a single sister processing establishment within its corporate structure.

P3. Are any of the suppliers identified during the traceback as an originating slaughter establishment (that is not a sister establishment)?
- — Yes
- — No, the suppliers are not slaughter establishments
- — Cannot determine
- —

Pa. Provide the establishment number of the known originating slaughter establishments.

P9. Did the establishment receive its source materials from a broker?
- — Yes
- — No
- —

P9a. Provide contact information for each broker.

NOTE: Traceback will not be performed at brokers.

Microbiological Independence

M1. How does the establishment define the sampled lot of ground beef products or bench trim?

M1a. Are the same source materials used in product across multiple days' production?

M1b. Are the same source materials used in the other production periods or lots at the establishment?

M1c. Does the establishment have adequate support for its sampled lot definition?

M2. Does the establishment apply one or more interventions to any of the source materials used in ground beef or bench trim production during the production period in question?

- — No, the establishment does not apply any interventions
- — Yes, the establishment apply interventions to some source materials
- — Yes, the establishment applies interventions to all source materials
- — Other

M3. Describe what interventions are applied during the production period in question.

M3a Is there any basis for concern about whether the intervention is validated or whether it was properly implemented during the period in question?

Does the establishment sample purchased source materials or bench trim?

Yes

No

a. Did the establishment perform sampling as described in the establishment's sampling program during the production period in question?

b. How does the establishment define production segments to allow identification of affected source materials?

c. Do the establishment's sampling results provide a clear definition between production segments to allow identification of affected source material?

f. Based on experience, expertise, and knowledge of industry practices, what additional information regarding the establishment's sampling program is relevant?

P2. Provide the following information regarding the establishment's test results.

g. Did the establishment receive any positive test results for the production period in question?

i. How did the establishment identify all product affected including addressing source materials from other production lots if implicated?

l. If the establishment received positive test results, did the test results indicate a systematic cause of breakdown of process controls for the time period in question?

M4a. Describe any concerns regarding the establishment's testing program

M6. Do the source materials used in the production of ground beef or bench trim that tested positive have a certificate of analysis associated with them?

M6a. Describe the purchase agreements for purchased product during the production period in question.

M7. Does the establishment require any of its suppliers to meet the following specifications as part of its purchase specifications? Purchase specifications are a set of requirements for incoming product established by buyer and agreed upon by the supplier before the product is purchased.

i. Validated intervention methods during slaughter
ii. Validated intervention methods during fabrication

iii. Testing of carcasses for STEC
iv. Testing of trim for STEC
v. Testing of primal and subprimals for STEC
vi. Testing of other raw ground beef components
vii. Others, please specify.

M8. Does the establishment have information or results from the supplying slaughter establishment on the source materials for the production period in question?

M8a. If yes, what were the results?

M9. Is there evidence of FSIS or establishment documented any sanitation failures during production period in question? If so, describe the failures.

b. If the establishment or FSIS documented an event which would distinguish between the production period in question and other production periods, describe the event. List the evidence that supports this conclusion.

c. If the establishment received any Sanitation Standard Operating Procedure (SSOP) noncompliance records (NRs) for the production period in question, describe any of the following if applicable:

    i. Insanitary conditions on product contact surfaces
    ii. Direct product contamination
    iii. Other, please list.

d. If the establishment received any SPS NRs for the production period in question, describe any of the following if applicable:
    i. Improper employee hygiene
    ii. Incidental contamination
    iii. Insanitary equipment, utensils, rooms or compartments
    iv. Food contact surfaces
    v. Pest control failures
    vi. Other, please list.

M10. Describe other information pertinent to any sanitation failures that the establishment or FSIS documented during the slaughter production period in question that is not already included in your previous answers

M11. Summarize the results of the HACCP plan, Sanitation SOP, GMP, or other prerequisite program on the source materials for the production period in question.

M12. Process Changes: Were there any changes in the process or procedures for the production periods in questions including but not limited to changes in monitoring procedures, process step, inventions or process and procedures? Specify.

M13. If there was any non-routine event that may have affected product during the production period in question, describe the event and the establishment's response.

M14. Describe other information pertinent to process changes that is not already included in your previous answers.

P5. Does the receiving establishment use primal and subprimal products as bench trim in their entirety to produce non-intact product?

M15. Has the establishment been notified of the supplier's establishment intended use of the product?

M16. Are the source materials being used consistent with the supplier's intended use?

Table 1: HEP Criteria when Establishment test more than 60 samples per Day or local HEP for 10 consecutive samples

Unacceptable # Positives	Number of Samples	Confidence	Observed Percentage of Positive
3	10	98.8%	30.0%
8	61	98.9%	13.1%
9	74	98.9%	12.2%
10	86	98.9%	11.6%
11	100	98.9%	11.0%
12	113	98.9%	10.6%
13	127	98.9%	10.2%
14	141	98.9%	9.9%
15	155	98.9%	9.7%
16	169	98.9%	9.5%
17	184	98.9%	9.2%
18	198	98.9%	9.1%
19	213	98.9%	8.9%
20	228	98.9%	8.8%