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

FSIS NOTICE	22-09	4/1/09

FOLLOW-UP SAMPLING OF CERTAIN RAW GROUND BEEF PRODUCTS AFTER AN FSIS VERIFICATION SAMPLE TESTS POSITIVE FOR *E. coli* O157:H7

I. PURPOSE

This notice reissues FSIS Notice 17-07. The Food Safety and Inspection Service (FSIS) performs routine follow-up sampling at the slaughter establishments that produced and supplied the carcasses ("the originating supplying slaughter establishment") that provided the beef manufacturing trimmings or other raw ground beef or beef patty components used in the production of raw ground beef products that tested positive for *Escherichia coli (E. coli)* O157:H7 by FSIS. This sampling is a follow-up to the FSIS verification sampling at establishments that grind beef or at retail stores. This notice:

- applies to all sample requests labeled "MT-52" in block 14 of FSIS Form 10,210-3, Sample Request Form;

- instructs District Offices (DO) on how to initiate follow-up sampling at the originating supplying slaughter establishments that produce beef manufacturing trimmings and other raw ground beef or raw beef patty components; and

- instructs inspection program personnel on how to sample under the new sampling program for beef manufacturing trimmings and other raw ground beef or raw beef patty components.

II. BACKGROUND

A. As part of its more risk-based sampling program for *E. coli* O157:H7, FSIS traces positive samples of raw ground beef back to the establishment that slaughtered the animal. This follow-up sampling, in conjunction with routine sampling of beef manufacturing trimmings addressed in a separate FSIS Notice, is the first step towards developing a more risk-based sampling program for *E. coli* O157:H7 in raw beef. In Attachment 1 of FSIS Directive 10,010.1, Revision 1, "Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components," FSIS

indicated that its *E. coli* O157:H7 testing program would become more risk-based.

NOTE: The term “beef manufacturing trimmings” includes sub-primal cuts such as boneless chuck or parts of boneless chuck that are intended for further processing into ground beef and other non-intact raw beef product.

III. FOLLOW-UP SAMPLING FOR *E. coli* O157:H7

A. Inspection program personnel at the originating supplying slaughter establishments are to collect a follow-up sample of beef manufacturing trimmings or raw ground beef or raw beef patty components at that originating supplying slaughter establishment. This follow-up sampling occurs each time that FSIS verification samples from establishments or retail stores confirm positive for *E. coli* O157:H7 in raw ground beef products that incorporate source materials from that originating supplying slaughter establishment.

B. In accordance with FSIS Directive 10,010.1, Revision 1, and its accompanying questions and answers, inspection program personnel typically collect one raw ground beef product follow-up sample at the grinding establishment after a positive *E. coli* O157:H7 FSIS verification sample. However, FSIS will now also direct sample requests to the Inspectors-in-Charge (IIC) at the originating supplying slaughter establishments that produced the beef manufacturing trimmings or other raw ground beef or raw beef patty components used in the positive ground beef product sample.

C. If the grinding establishment used beef manufacturing trimmings or other ground beef or beef patty components from one or more suppliers, it is possible that some of the supplier establishments are not originating supplying slaughter establishments. FSIS will work stepwise through the information collected at each establishment to identify the originating supplying slaughter establishments that supplied product. FSIS will only collect follow-up samples from originating supplying slaughter establishments.

D. If a supplier establishment bones or fabricates beef primal or sub-primal cuts or processes Advance Meat Recovery (AMR) Product and Low Temperature Rendered Beef (LTR) Product (9 CFR 319.15(e)) but does not slaughter the animals from which the cuts or products came (i.e., this supplying establishment is NOT an originating supplying slaughter establishment), the DO will not generate a follow-up sample request for that establishment.

E. If any of the originating supplying slaughter establishments commingles beef manufacturing trimmings or other ground beef or beef patty components processed at other establishments, inspection program personnel are to forward the supplier information to the District Office. The DO will generate a request to sample beef manufacturing trimmings or other ground beef or beef patty components for each of the originating supplying slaughter establishments that FSIS identifies.

F. If the originating supplying slaughter establishment does not fabricate any beef manufacturing trimmings or other raw ground beef or raw beef patty components, inspection program personnel are to contact the Policy Development Division (PDD) via outline using the address “E. coli-testing” on how to proceed. The PDD will coordinate

with Headquarters (Office of Policy and Program Development), Office of Field Operations (OFO), and Office of Public Health Science (OPHS)) on sampling or other follow-up instructions.

G. If the grinding establishment also slaughters and produces its own beef manufacturing trimmings or other raw ground beef or beef patty component, inspection program personnel will collect a sample of beef manufacturing trimmings or other raw ground beef or beef patty components from the current production of its slaughter operation.

NOTE: A positive result from Agricultural Marketing Service (AMS) microbial testing is treated the same as a positive result from FSIS verification sampling. AMS will notify FSIS/OFO headquarters via e-mail whenever AMS raw ground beef samples test positive for *E. coli* O157:H7 under the AMS commodity purchase program. OFO will then contact the appropriate DO who will determine the originating supplying slaughter establishments as described in this notice.

IV. INITIATING FOLLOW-UP SAMPLE REQUEST FORMS BY DISTRICT OFFICES

A. As set out in FSIS Directive 10,010.1, Revision 1, when an FSIS verification sample from an establishment tests positive for *E. coli* O157:H7, the IIC forwards the supplier information to the designated District Office (DO) contact. The DO with jurisdiction over the grinding establishment enters the data into the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) and identifies all establishments associated with the production of the raw beef products that tested positive for *E. coli* O157:H7.

B. The DO:

1. Enters into STEPS all supplier information it received from the IIC at the establishment that received the original positive on its ground beef.

2. Determines whether any of the supplying establishments were originating supplying slaughter establishments and indicates the information under the remarks section in STEPS. With respect to supplying establishments that are not originating supplying slaughter establishments, the DO is to inform the IIC to collect supplier information on the product that went into the lot represented by the positive sample and forward the information to the DO. (To determine this, the IICs may need to examine establishment records and provide the information to the DO.)

NOTE: If the DO enters one or more establishments into STEPS that are not under its jurisdiction, STEPS will automatically notify the appropriate DO. The DO that receives the notification will repeat the step above (step 2) for establishments under its jurisdiction and add any additional information into STEPS.

3. Directs the IICs at **all** establishments that supplied product represented by the positive sample, including the originating supplying slaughter establishments, that

were identified in STEPS to perform an 02 procedure according to FSIS Directive 10,010.1, Revision 1.

4. Generates a sample request only for originating supplying slaughter establishments that are identified. The DO designee is not to generate a follow-up sample request for establishments that only bone or fabricate beef primal or sub-primal cuts but does not slaughter.

NOTE: If the supplier is a foreign establishment, the DO is to forward the supplier information (e.g. shipping marks, foreign establishment number, and country) via e-mail to the Office of International Affairs (OIA), Import-Export Programs Staff, as directed in FSIS Directive 10,010.1, Revision 1. OIA will notify the inspection program officials of the exporting countries and request them to collect and test follow-up samples at the originating slaughter establishment.

C. The DO with jurisdiction over the originating supplying slaughter establishments contacts the IIC at those slaughter establishments to ensure that inspection program personnel perform a HACCP 02 procedure according to Part III of FSIS Directive 10,010.1, Revision 1. At that time, the DO will inform the IIC which type of beef component that the establishment supplied to the grinder so that inspection program personnel can sample that component from the establishment's current production for follow-up testing when the IIC receives a sample request form for project code MT-52. If the originating supplying slaughter establishments produced more than one type of component that the grinding establishment used, the DO will generate a sample request form for each type of component.

D. If FSIS verification samples from a retail store test positive for *E. coli* O157:H7, the Office of Program Evaluation, Enforcement and Review (OPEER) Regional Manager or designee is to enter data regarding the identity of the originating supplying slaughter establishments into the STEPS database. OPEER investigators will determine through the firm's records and product labels the originating supplying slaughter establishment as directed by FSIS Directive 10,010.1, Revision 1 (9 CFR 320.1). The DO that has the originating supplying slaughter establishments in its district is to notify the IIC at the originating supplying slaughter establishments (as described above) and e-mail Headquarters to generate a sample request form for these establishments (as discussed below).

E. The DO will e-mail headquarters to generate a sample request form by sending an e-mail message to the outlook address:

Sampling Forms - Headquarters

The e-mail request is to contain the following:

1. "Request for MT-52 Follow-up Samples" in the subject line of the e-mail;

2. the establishment number for each originating supplying slaughter establishment identified as contributing product to the confirmed positive raw ground beef product sample;

3. the number of sample requests forms needed for each originating supplying slaughter establishment; and

4. the form number of the positive ground beef product sample listed in the STEPS data base.

V. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES FOR COLLECTING SAMPLES OF BEEF COMPONENTS FOR USE IN RAW GROUND BEEF PRODUCTS

These instructions address sampling for beef manufacturing trimmings and other ground beef or beef patty components. In the case that the originating supplying slaughter establishment does not bone or fabricate primal or sub-primal cuts, inspection program personnel are to contact the PDD for further instructions on how to proceed. The PDD will coordinate with Headquarters (OPPD, OFO, and OPHS) on sampling or other follow-up instructions.

NOTE: These instructions replace the "Procedures for Sampling Raw Ground Beef Components and Raw Beef Patty Components" in Attachment 2 of FSIS Directive 10,010.1, Revision 1.

A. The sampling collection procedure outlined below is the same as the method shown in the Trim and Sub-primal Sample Collection Training CD that FSIS issued to inspection program personnel at beef manufacturing trimmings suppliers participating in the nationwide raw ground beef component microbiological baseline. Inspection program personnel who previously completed this training are not required to retake the training. The training CD will be sent along with the sample collection materials when inspection personnel are directed to collect samples under the new sample program. If inspection program personnel need the training CD and do not receive the CD in the sample collection materials, they are to:

- e-mail the Continuing Education and Distance Learning mailbox in Outlook to request the Trim Sample Collection Training CD at CEDL@fsis.usda.gov ; and

- complete the training as soon as practical before collecting samples.

NOTE: The Agency will allocate up to one hour of official time (code 01 time) to inspection program personnel to complete the requisite training.

B. Upon receipt of a sample request form, inspection program personnel are to sample beef manufacturing trimmings or other raw ground beef components or raw beef patty components and document the sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code O5B02. Inspection program personnel are to randomly select samples of beef manufacturing trimmings, or raw beef components, or raw beef patty components from an establishment's ***current production***.

C. Inspection program personnel are to sample only beef manufacturing trimmings and other ground beef or beef manufacturing components from carcasses slaughtered at the originating supplying slaughter establishment. If this establishment commingles beef manufacturing trimmings or other raw ground beef or raw beef patty components with beef product from other establishments, inspection program personnel are to collect the sample before the establishment commingles the product.

NOTE: Inspection program personnel at an originating supplying establishment are not to collect follow-up samples of commingled beef manufacturing trimmings or other raw ground beef or beef patty components produced at a different establishment. Inspection program personnel at those locations will collect the supplier samples.

D. Inspection program personnel are to collect samples of beef manufacturing trimmings or raw ground beef components or beef patty components that the establishment intends for use in raw ground beef or other raw ground beef products. Trimmings that the establishment intends for use for further processing into ready-to-eat products are not to be sampled. In cases where the establishment records and HACCP documents are unclear about the intended use of the product, FSIS inspection program personnel are to consider the product intended for use in ground beef and other non-intact raw beef products.

1. Inspection program personnel are to collect the type of beef manufacturing trimmings or ground beef or beef patty components supplied to the sampled lot of ground beef product that FSIS tested positive for *E. coli* O157:H7 if possible. As described in Section IV. B., the DO office will inform IIC which beef component to sample.

2. If the establishment is not currently producing the type of component requested, inspection program personnel are to collect a sample of another component that is available. Inspection program personnel are to sample beef manufacturing trimmings if the establishment is producing them. If the establishment is also not producing beef manufacturing trimmings, then inspection program personnel are to collect a sample of another type of raw ground beef or beef patty component (e.g., head meat, heart meat, product from advanced meat recovery (AMR) systems) that the establishment intends to use in the production of raw ground beef products.

E. Inspection program personnel are to notify the establishment before sampling and provide enough time for the establishment to hold all product represented by the sample. Inspection program personnel are to meet with establishment management and discuss times and situations that may affect the lead time for notification. Inspection program personnel are also to inform the establishment that, if the sample tests positive for *E. coli* O157:H7, the beef manufacturing trimmings or beef components represented by that sample are adulterated and would be subject to a recall if in commerce.

F. Inspection program personnel are to inform the establishment that it is responsible for supporting its basis for defining the product represented by the sample (i.e., the sampled lot). (See Attachment 1 for factors that establishments may find useful to define the product represented by the sample).

G. Inspection program personnel are to collect samples from one specific production lot. They are to ship the sample to the laboratory ***after*** the establishment completes its pre-shipment review.

H. When collecting samples, inspection program personnel are to:

1. sanitize the caddy, knife, hook, or tongs before collecting the samples by using the establishment's sanitizing solution according to label instructions. If an establishment uses hot water only, then inspection program personnel are to also use hot water to sanitize sampling equipment; and

2. use gloves and handle all sanitized surfaces so that they do not become contaminated;

I. **Beef Manufacturing Trimmings.** To sample beef manufacturing trimmings, select samples using the N60 method of sample collection (as described below) and collect 60 individual pieces from raw beef manufacturing trimmings;

1. if a specific production lot is composed of more than 5 containers of raw ground beef components, randomly select 5 containers for sampling;

2. if the specific production lot is composed of 5 or less containers, use the chart below for sampling:

Number of Sample Pieces to Collect Per Container	
# of containers in each specific production	*# of sample pieces to select from **each** container*
5	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

3. aseptically collect the appropriate number of pieces of beef manufacturing trimmings based on the number of containers that represent one specific production period. Use the sanitized hook or tong to lift a piece of meat off the top of the container. The total number of pieces collected is 60 pieces for each sample;

4. cut off a slice that is approximately a 4 inch length by 2 inch width and 1/8 inch thick from each of the 60 pieces. Cut off as much of the beef manufacturing trimmings' outer surface as possible. The priority is to collect samples from pieces of product taken from the original surface of the beef carcass. Samples are to be very thin slices (approximately 1/8 inch thick);

5. collect and bag the sample slices. Weigh the sample to ensure approximately 2 pounds of product are collected in the whirlpak sample bag; and

6. check the product temperature of the top pieces of meat from randomly selected containers of beef components (do not take the temperature of the actual sample slices). Record the temperature on the sample request form in block 21. If the sample pieces came from more than one container, record the temperature of the warmest container in block 21 of the sample request form. If the product is warmer than 40° F, place the bag containing the sample in a cooler to chill before shipping;

J. **Advance Meat Recovery (AMR) Product and Low Temperature Rendered Beef (LTR) Products.** To sample AMR or LTR products, randomly select a sample consisting of 2 pounds of product from a specific production lot.

K. **Other Raw Beef Components.** To sample other raw beef components, randomly collect one piece, or enough pieces, of the beef components to equal 2 pounds. If the component is very large, cut slices in the manner as described in Section I. 4. of this part.

L. Fill out the sample request form. Check the box that best describes the beef component sampled. Ensure that the product temperature in block 21 and the requested information in Block 28 of the sample request form are complete.

M. Secure sample during preparation, storing, packaging, and submission for testing (see FSIS Directive 7355.1, Revision 2);

N. Pack the sample with ice packs. Mail the sample via FedEx overnight shipping.

O. Check LEARN in accordance with FSIS Directive 10,200.1 to obtain test results; and

P. Provide LEARN results to establishment management even if the establishment receives e-mail notifications. The Biological Information Transfer and e-mail System (BITES) messages will report positive test results to the DO.

VI. ENFORCEMENT ACTIONS AT ESTABLISHMENTS THAT SUPPLY BEEF COMPONENTS INTENDED FOR USE IN RAW GROUND BEEF PRODUCTS

A. When FSIS verification samples test positive, as set out in FSIS Directive 5000.1, Revision 2, Amendment 1, inspection program personnel are to:

1. issue an NR under the appropriate 03 ISP code using the “verification” trend indicator (cite 9 CFR 301.2 and 417.4(a) in the pull down regulatory menu);

2. verify whether the establishment held or shipped the affected product. If the establishment has shipped the product, inspection program personnel are to contact the Recall Management Staff through the DO. Inspection program personnel are to be familiar with the establishment’s lot definition and the establishment’s rationale for determining sampled lots;

3. as soon as possible after the establishment has implemented its corrective action, perform a HACCP 02 procedure for the specific production that tested positive for *E. coli* O157:H7 and verify that the establishment implements corrective action that meets the requirements of:

a. 9 CFR 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan;

b. 9 CFR 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan or if it is addressed in prerequisite programs; or

c. 9 CFR 417.3(b) and 416.15(b) if *E. coli* O157:H7 is addressed in the Sanitation SOPs; and

4. the DO is to determine what, if any, additional follow-up actions need to be taken.

NOTE: The agency recognizes that it is probable that, despite the ongoing processing interventions for controlling *E. coli* O157:H7, some samples of raw beef manufacturing trimmings or other raw ground beef or beef patty components used in the production of raw ground beef products may test positive for *E. coli* O157:H7. These positives may be random events caused by common cause variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions. Verification testing must occur at a frequency to help establish the difference between common cause and assignable cause variation in the testing results associated with beef manufacturing trimmings or other raw ground beef or beef patty components used in the production of raw ground beef products. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

VII. VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT TRANSPORT POSITIVE PRODUCT TO ANOTHER SITE FOR DISPOSITION

If the establishment transports positive product to another site for appropriate disposition, inspection program personnel are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

1. maintained records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;

2. maintained control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);

3. maintained control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

4. maintained 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; and

5. completed pre-shipment review for the presumptive positive or positive product only after it has received the records described above for that particular product.

If inspection program personnel find noncompliance with these requirements, they should document them in accordance with FSIS Directive 5000.1, Revision 1, Amendment 1. In situations where the establishment has not properly moved the product, inspection program personnel also should notify their DO through supervisory channels.

VIII. REQUESTING SAMPLING SUPPLIES

A. If inspection program personnel need sampling supplies, they should request them via e-mail at least 72 hours before sampling is to begin. E-mail the laboratory identified in block 9 of the sample request form (FSIS Form 10,210-3) by using one of the following e-mail addresses in outlook:

Sampling Supplies - Eastern Lab

Sampling Supplies - Midwestern Lab

Sampling Supplies - Western Lab

B. Include the following information in the supply request e-mail:

- sampling project code (MT-52);
- identify the exact supplies needed;
- establishment address (not a P.O. Box); and
- establishment phone number.

Refer questions regarding this notice to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

The following factors may help the establishment in supporting the basis for defining the product represented by the sample:

- Any scientific, statistically-based sampling programs for *E. coli* O157:H7 that the establishment uses to distinguish between segments of production.

- Sanitation Standard Operating Procedures (Sanitation SOPs) and any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production. The controls that establishments use should adequately distinguish segments of production for lot identification purposes. Basic operational sanitation is generally not sufficient to distinguish between production lots.

- Some additional production factors to consider are:

    - sanitary dressing procedures;
    - product contact surfaces on equipment such as machinery and employee hand tools;
    - employee hygiene;
    - processing interventions that limit or control *E. coli* O157:H7 contamination; or
    - beef manufacturing trimmings and raw beef components or rework carried over from one production period to another.

Generally, FSIS recommends that establishments develop and implement statistical in-plant sampling plans scientifically designed to define production lots or sublots independent of other production lots or sublots. The establishment should design sampling and testing procedures to achieve a high degree of confidence of detecting contamination.

In the absence of a scientifically defensible testing plan to define production lots or sublots of beef manufacturing trimmings or other raw ground beef components, the Agency will consider all available data to discern the amount of product represented by the sample. FSIS may default to defining the product represented by the sample as all raw beef components derived from animals slaughtered on a particular production day. Therefore, product represented by a given sample may include raw product produced on more than one day.

FSIS has outlined additional information on lot determination in Question and Answer documents on the FSIS web page with FSIS Directive 10,010.1, Revision 1.