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

FSIS NOTICE	18-07	3/1/07

ROUTINE SAMPLING OF BEEF MANUFACTURING TRIMMINGS INTENDED FOR USE IN RAW GROUND BEEF

I. PURPOSE

On March 19, 2007, inspection program personnel will begin routine verification sampling of beef manufacturing trimmings intended for use in raw ground beef or beef patty products at the slaughter establishments that produced those trimmings. This notice:

- applies to all sample requests labeled "MT-50" in block 14 of FSIS Form 10,210-3, Sample Request Forms; and

- instructs inspection program personnel on how to sample under the new sampling program for beef manufacturing trimmings.

II. BACKGROUND

This routine sampling of beef manufacturing trimmings, in conjunction with follow-up sampling addressed in a separate notice, is the first step towards developing a more risk-based sampling program for *E. coli* O157:H7 in raw ground beef and raw beef patty components. 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 the *E. coli* O157:H7 testing program would become more risk-based. FSIS is also developing a risk-based sampling program for other types of raw ground beef and beef patty components.

NOTE: The term "beef manufacturing trimmings" includes trimmings from sub-primal cuts such as boneless chuck or other parts of boneless beef that are frequently used as components of raw ground beef. Inspection program personnel are not to sample other beef components such as head meat, cheek meat, weasand meat, organ meat, and advanced meat recovery (AMR) product at this time under the routine MT-50 sample code.

DISTRIBUTION: Inspection Offices; T/A Inspectors; TSC; Import Offices	NOTICE EXPIRES: 4/1/08	OPI: OPPED

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES FOR COLLECTING SAMPLES OF BEEF MANUFACTURING TRIMMINGS INTENDED FOR USE IN RAW GROUND BEEF PRODUCTS

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. Inspection program personnel are only to collect samples, when directed, of beef manufacturing trimmings that the establishment intends for use in raw ground beef or other raw ground beef products. Trimmings that the establishment intends for use in 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, FSIS will consider the product intended for use in raw ground beef products and other non-intact raw beef products. Product sent to cooking is not to be sampled.

C. Upon receipt of a sample request form, inspection program personnel are to sample beef manufacturing trimmings 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 from the establishment's current production.

D. Inspection program personnel are to sample only beef manufacturing trimmings produced from carcasses slaughtered at the establishment. If the establishment commingles beef manufacturing trimmings with beef product processed at other establishments, inspection program personnel are to collect the sample before the establishment commingles the product.

NOTE: Inspection program personnel are not to collect samples of commingled beef manufacturing trimmings produced at a different establishment.

E. Inspection program personnel are to notify the establishment before sampling and provide enough time for the establishment to hold the entire sampled lot. 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 to inform the establishment that if a sample of beef manufacturing trimmings tests positive for *E. coli* O157:H7, the product represented by that sample is 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 use to define the product represented by the sample.)

G. Inspection program personnel are to collect samples from one specific production lot. They are to mail the sample 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 the establishment uses hot water only, then inspection program personnel are to also use hot water to sanitize sampling equipment;

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

3. select samples by using the N60 method of sample collection (as described below) and collect 60 individual pieces from raw beef manufacturing trimmings:

a. if a specific production is composed of greater than 5 containers of beef manufacturing trimmings, randomly select 5 containers for sampling; and

b. if the specific production 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

4. 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 are to be 60 for each sample;

5. 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);

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

7. check the product temperature of the top pieces of meat from randomly selected containers of beef manufacturing trimmings (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^{o} F, place the bag containing the sample in a cooler to chill before shipping;

8. fill out the sample request form. Ensure that the product temperature in block 21 and the requested information in Block 28 of the sample request form are complete;

9. secure samples during preparation, storing, packaging, and submission for testing (see FSIS Directive 7355.1, Revision 2);

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

11. 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 District Office (DO).

IV. ENFORCEMENT ACTIONS AT ESTABLISHMENTS THAT SUPPLY BEEF MANUFACTURING TRIMMINGS 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, preferably at the presumptive positive stage, 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, including sampling of subsequent production lots.

NOTE: The agency recognizes that it is probable that, despite the ongoing processing interventions for controlling E. coli O157:H7, some samples of beef manufacturing trimmings 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. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

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

A. 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.

B. 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.

VI. 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:

SamplingSupplies–EasternLab@fsis.usda.gov

SamplingSupplies–MidwesternLab@fsis.usda.gov

SamplingSupplies–WesternLab@fsis.usda.gov

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

- sampling project code (MT-50);
- identify the exact supplies needed;
- establishment address (not a P.O. Box); and
- establishment phone number.

Refer questions to the Technical Service Center at 1-800-233-3935.

Assistant Administrator
Office of Policy, Program, and Employee 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.