

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

FSIS NOTICE

85-08

11/20/08

NOTE: This notice reissues the content of FSIS Notice 80-08, but makes clear that 2 piece chucks and other primal/sub-primal parts intended for use in making raw ground beef are not subject to sampling under this notice as noted in FSIS Notice 63-08. Such products are sampled under the routine sampling program for beef manufacturing trimmings. This notice cancels 80-08.

ROUTINE SAMPLING AND TESTING OF RAW GROUND BEEF COMPONENTS OTHER THAN TRIM AND IMPORTED RAW GROUND BEEF COMPONENTS FOR *ESCHERICHIA COLI (E. COLI) O157:H7*

I. PURPOSE

The purpose of this Notice is to inform inspection program personnel that they are to begin routine sampling of raw ground beef components (including raw beef patty components) other than beef manufacturing trimmings for *E. coli* O157:H7 when they receive a sample request form (FSIS Form 10,210-3) with the MT54 project code. FSIS inspection program personnel are to collect samples of this product from slaughter establishments. When the automated import information system (AIIIS) requests a sample of beef manufacturing trimmings or other specified raw ground beef component for *E. coli* O157:H7 testing, import inspection program personnel are to sample the product identified in AIIIS, using the MT51 code on the sampling request form. This product is adulterated if positive for *E. coli* O157:H7.

This Notice is being issued as part of FSIS' more risk-based sampling program for *E. coli* O157:H7. FSIS inspection program personnel already conduct routine sampling of beef manufacturing trimmings under FSIS Notice 18-07. (**NOTE:** On March 27, 2008, FSIS extended the expiration dates for FSIS Notice 18-07 until April 1, 2009).

II. DEFINITION

Raw Ground Beef Components (including raw beef patty components) other than beef manufacturing trimming means raw esophagus (weasand) meat, head meat, cheek meat, beef from advanced meat recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 12/1/09

OPI: OPPD

This notice does not address irradiated beef or gaseous ammoniated low temperature rendered beef produced under a HACCP plan with a validated intervention controlled by a Critical Control Point (CCP) because such products are treated to destroy *E. coli* O157:H7. FSIS sampling of ammoniated product is addressed in FSIS Notice 77-08

III. HOW TO DECIDE WHAT RAW GROUND BEEF COMPONENT TO SAMPLE FOR *E. COLI* O157:H7

A. Inspection program personnel are only to collect samples of raw ground beef components other than beef manufacturing trimmings that are intended for use in raw ground beef or other raw non-intact beef products. To determine the intended use of the product, inspection program personnel should refer to FSIS Notices 18-07, Section III., B; Notice 17-07, Section V.; and FSIS Directive 10,010.1, Revision 1, Section IV., B., 3. (**NOTE:** On March 27, 2008, FSIS extended the expiration dates for FSIS Notice 17-07 until April 1, 2009).

B. Inspection program personnel are to sample only raw ground beef components produced from carcasses slaughtered at the establishment. If the establishment commingles such product with beef product processed at other establishments, inspection program personnel are to collect the sample before the establishment commingles the product.

C. When inspection program personnel receive a sampling request form (FSIS Form 10,210-3) with the MT54 sampling project code in block 14, they are to choose among the products that are available to sample by following the priority list below. For example, if the establishment produces product from AMR systems (#1 on the priority list below) on the day of collection, inspection program personnel are to take a sample of it; if not, they are to collect low temperature rendered LFTB (#2 on the priority list) if it is available, and move down the list until there is an available product.

The priority list is:

1. Product from AMR (Advanced Meat Recovery) Systems
2. Low Temperature Rendered LFTB (lean finely textured beef)
3. Partially Defatted Beef Fatty Tissue
4. Partially Defatted Chopped Beef
5. Weasand Meat
6. Head Meat
7. Cheek Meat
8. Heart Meat

D. When inspection program personnel receive subsequent sample request forms with the project code MT54 in block 14, they should also continue down through the list in the same manner, choosing the next item on the priority list that is produced by the establishment that day. They are to select a different component than previously collected, when possible.

NOTE: The priority list was developed from the National Advisory Committee on

Microbiological Criteria for Food (NACMCF) Response to USDA/FSIS Request for Guidance on Baseline Study Design and Evaluations for Raw Ground Beef Components found at http://www.fsis.usda.gov/OPHS/NACMCF/2003/gb_base.pdf. In the future, FSIS may establish additional project codes to capture more detailed information concerning this sampling.

IV. ESTABLISHMENT NOTIFICATION AND SAMPLE COLLECTION

A. Before collecting samples, inspection program personnel are to notify the management of the official establishment that they will be collecting a sample and are to provide enough time for the establishment to hold the sampled lot, should they choose to (see FSIS Directive 10,010.1, Part II., B., 3.; FSIS Notice 17-07, V., E.; FSIS Notice 18-07, III., E.).

B. Inspection program personnel are to inform establishment management that it is responsible for supporting its basis for defining what product is represented by the sample (i.e., the sampled lot). The establishment's definition for the sampled lot components other than trim may be different from its definition for the sampled lot for beef manufacturing trimmings or ground beef products. If establishments co-mingle any head meat, heart, or cheek or weasand meat from an individual carcass with other product, then the co-mingled product should be considered as part of a single production lot. See Attachment 1 for factors that establishments may find useful to define the product represented by the sample, including any scientific, statistically-based sampling programs for *E. coli* O157:H7 that the establishment uses to distinguish between segments of production.

C. To provide establishments enough time to hold the production lot, inspection program personnel need to be knowledgeable concerning the establishment's production practices. Inspection program personnel need to be familiar enough with the process to realize that, in some cases, notifying the establishment one day before collecting the sample may not be adequate time to allow the establishment to hold all product represented by the sample. If the establishment requests more than a couple days notice before FSIS collects the sample, inspection program personnel are to consider the request based on establishment product and process flow.

D. Inspection program personnel are to collect the sample after the establishment has completed the production lot (as defined by the establishment) and applied all interventions, except for a microbiological testing intervention. If the establishment intends to test the product for *E. coli* O157:H7 before completing pre-shipment review, inspection program personnel are not to wait for the establishment to receive the test results. Rather, inspection program personnel are to collect the sample and prepare it for shipment to the laboratory on the first available Federal Express pick-up.

E. When collecting samples, inspection program personnel are to follow the applicable instructions in FSIS Notice 17-07, V. For heart meat, inspection program personnel are to follow the procedures in FSIS Notice 17-07, V., K. For comminuted components, AMR, and low-temperature rendered products, inspection program personnel are to follow the procedures in FSIS Notice 17-07, V., J.

V. FSIS AND ESTABLISHMENT TEST RESULTS

A. Consistent with FSIS Notice 77-08, inspection program personnel are to make themselves aware of the establishment's sampling and testing programs for *E. coli* O157:H7. Specifically, when the establishment completes preshipment review for the production lot that FSIS sampled, inspection program personnel are to make sure that they know whether the establishment tested that particular lot for *E. coli* O157:H7 so they can answer the questions in Attachment 2 to this notice if FSIS or the establishment find the product to be positive.

B. Inspection program personnel are to check LEARN in accordance with FSIS Directive 10,200.1 to obtain test results and 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 FSIS positive test results to the District Office (DO).

C. If FSIS finds the product positive and the establishment tested the product, inspection program personnel are to check establishment *E. coli* O157:H7 test results to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7.

D. If FSIS finds its sample positive, or the establishment finds the same production lot that FSIS sampled positive for *E. coli* O157:H7, inspection program personnel are to respond to questions in Attachment 2 to this notice in an e-mail message to O157H7EstablishmentPractices@fsis.usda.gov. This e-mail address will appear in the FSIS Outlook Global Address List as O157H7 Establishment Practices.

1. For the subject line in the email message, inspection program personnel are to type, "Establishment testing follow-up."

2. In the text body of the message, inspection personnel are to refer to the chart in Attachment 2 to this notice. They are to type the question number of each question that applies to the product that FSIS or the establishment found positive for *E. coli* O157:H7 followed by the response to each applicable question. If a particular question does not apply, they need not type the question number or the response.

E. If FSIS finds product positive for *E. coli* O157:H7, inspection program personnel should follow the instructions in FSIS Notice 77-08, IV. for issuing noncompliance records, verifying appropriate disposition of *E. coli* O157:H7 positive product, and verifying corrective actions.

VI. ALTERNATIVE LOT DEFINITIONS

A. Consistent with FSIS Notice 77-08, VI., inspection program personnel may permit an establishment that samples raw ground beef components under its own testing program to reduce its lot size to one combo bin or other unit (e.g., box) on the day that FSIS conducts sampling if the establishment:

1. Has an intervention for *E. coli* O157:H7 at a CCP in the HACCP plan that covers the product or has an intervention for *E. coli* O157:H7 at a CCP for that product's

source materials (the slaughter establishment would also produce the source materials); and

2. Samples and tests **every** production lot for *E. coli* O157:H7 and generally collects its samples of raw ground beef components other than beef manufacturing trimmings across multiple combo bins or other sample units;

B. If an establishment meets the criteria in section VI., A. of this Notice and reduces its lot size to a single combo bin or sample unit when FSIS samples the product, inspection program personnel are to collect samples from that the single combo bin or sample unit following applicable instructions in this notice. If the establishment does not meet the criteria, inspection program personnel are still to collect the sample, consistent with applicable instructions in this notice

VII. ESTABLISHMENTS THAT PRODUCE AND GRIND RAW GROUND BEEF COMPONENTS

It is possible that establishments produce product that is subject to other routine verification sampling programs, (e.g., MT03, MT50). Therefore, inspection program personnel may receive multiple sample requests during the same 30-day sampling window. Inspection program personnel are to complete all sample requests by selecting samples from independent production lots, unless inspection program personnel are only able to collect one sample (e.g., because the establishment produces 1,000 pounds or less of product on a daily basis, or only on an intermittent basis). In this situation, inspection program personnel should prioritize by sampling the beef manufacturing trimmings under the MT50 sampling program, consistent with FSIS Notice 77-08, VIII. If this establishment also routinely uses other raw ground beef components, inspection program personnel should also attempt to collect the MT54 sample if multiple sample requests are received during the same sampling window multiple times.

VIII. REQUESTING SAMPLING SUPPLIES

Inspection program personnel are to follow the instructions in FSIS Notice 17-07, VIII. for requesting sample supplies.

X. FOLLOW-UP SAMPLING OF RAW GROUND BEEF COMPONENTS OTHER THAN TRIM

If any component is found positive for *E. coli* O157:H7, the inspector will receive 16 follow-up sampling forms (MT53). The forms will be automatically generated. The inspector is to collect and submit follow-up samples of the components found positive for *E. coli* O157:H7, following the instructions in FSIS Notice 79-08.

X. INSTRUCTIONS FOR COLLECTING IMPORT SAMPLES

When the automated import information system (AIIIS) requests a sample of beef

manufacturing trimmings or other specified raw ground beef component for *E. coli* O157:H7 testing, import inspection program personnel are to use the MT51 code on the sampling request form (FSIS Form 10,210-3) with project code MT51 block 14 and should follow the sample collection procedures as set out in FSIS Notice 18-07 for sampling of beef manufacturing trimmings or in FSIS Notice 17-07 for sampling of other raw ground beef components. In the future, FSIS may establish additional project codes to capture more detailed information concerning this sampling.

XI. ANALYSIS OF THE DATA

FSIS headquarters staff will analyze its *E. coli* O157:H7 sample results for raw ground beef components, including imported components. Headquarters staff will analyze the number of samples scheduled, the number of samples shipped, the number of samples analyzed, and the number of positive samples. The data will be analyzed to determine trends (e.g., geographical, seasonal and annual trends) in *E. coli* O157:H7 percent positive results and to inform future FSIS policies.

Direct question 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

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.

Questions to Answer when FSIS collects a sample and FSIS or Establishment finds Product Positive for <i>E. coli</i> O157:H7	
1. What is the establishment's name and number?	
2. What is the FSIS Sample number for the lot that FSIS or the establishment found positive for <i>E. coli</i> O157:H7?	
3. Did the establishment test product from the production lot that FSIS sampled?	
YES	
NO	
Establishment's Testing Results	
4. If the establishment tested the lot, what were the establishment's test results?	
Positive	Confirmed or Presumptive Positive (and not confirmed negative)
Negative	Negative
N/A	Did not sample {end response and send e-mail message}
Product Disposition	
5. For positive product, what was the disposition?	
Diverted (treated or destroyed)	
Released into commerce	
Establishment's Sampling Program regarding the FSIS sampled production lot	
6. Does the establishment only test product when FSIS samples product?	
YES	
NO	
Don't Know	
7. Does the establishment have a CCP that addresses the disposition of product that tests positive for <i>E. coli</i> O157:H7? (See Q&A #5 in Attachment 1 to Directive 10,010.1 for additional guidance on CCPs for disposition based on finished product <i>E. coli</i> O157:H7 testing.)	
YES	
NO	
Don't Know	
Hearts	

8. Did you observe the establishment collect one piece, or enough pieces, of the beef components to equal 2 pounds?	
Yes	
No	
9. Did the establishment analyze at least 325 grams of product for <i>E. coli</i> O157:H7?	
Product from AMR or low temperature rendered product	
10. Did the establishment analyze at least 325 grams of product for <i>E. coli</i> O157:H7?	
YES	
NO	
Don't Know	
11. If no, did the establishment test the source materials used to produce the comminuted product?	
YES	
NO	
Don't Know	
12. If the establishment tested the source materials, did you observe the establishment collect 60 slices of product (i.e., did the establishment follow an N60 procedure)?	
YES	
NO	
Don't Know	
13. If the establishment tested source materials, did the establishment analyze at least 325 grams of product for <i>E. coli</i> O157:H7?	
YES	
NO	
Don't Know	