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

# FSIS NOTICE	62-07	9/28/07

INSTRUCTIONS FOR VERIFICATION SAMPLING PROGRAMS FOR *E. coli* O157:H7 IN RAW BEEF PRODUCTS

I. PURPOSE

This notice responds to questions that have arisen concerning FSIS Notices 17-07 and 18-07 and provides new guidance to inspection program personnel on collecting samples of beef manufacturing trimmings and other raw ground beef and patty components for *Escherichia coli* (*E. coli*) O157:H7 testing. In addition, this notice provides new instructions for submitting samples to the laboratory for *E. coli* O157:H7 testing.

FSIS intends to fully implement risk-based verification sampling and testing for *E. coli* O157:H7 in raw beef products. The Agency will be issuing to inspection program personnel the instructions necessary to fully implement this risk-based sampling and testing. Meanwhile, this FSIS Notice, which directs inspection program personnel to submit samples to the laboratory without waiting for the establishment to complete pre-shipment review, is a component of risk-based verification testing that the Agency is now implementing.

II. BACKGROUND

Currently, under Directive 10,010.1 and FSIS Notices 17-07 and 18-07, inspection program personnel are not to send samples to the laboratory until the establishment has completed pre-shipment review for the sampled lot. Current policy allows inspection program personnel to collect raw beef samples from an establishment before the establishment has completed pre-shipment review. However, if the establishment collects a sample from the same production lot that was sampled by inspection program personnel, and the establishment finds its sample positive for *E. coli* O157:H7, the establishment likely will not complete pre-shipment review for the product until there has been proper disposition of the product. Similarly, if the establishment decides to cook the product after inspection program personnel have collected the sample, it would not complete pre-shipment review of the sampled product until after cooking. In both of these situations, the inspection program personnel have not submitted the sample to

the laboratory, because the product that would enter commerce is not the raw product. Consequently, under the current policy, inspection program personnel spend work time collecting samples that FSIS laboratories do not analyze, and for which FSIS does not obtain *E. coli* O157:H7 test results.

However, with this notice, inspection program personnel are not to wait until the establishment completes pre-shipment review before submitting raw beef samples to the laboratory for *E. coli* O157:H7 testing. Rather, inspection program personnel are to submit the raw beef sample to the laboratory after the establishment has completed all interventions, except for any intervention that is based on microbiological test results. Thus, inspection program personnel, in many cases, will be collecting and submitting FSIS samples to the laboratory before the establishment completes pre-shipment review.

This new policy will better ensure that inspection program personnel's work time is productive and provides better public health protection. In addition, this new policy will provide FSIS greater access to and awareness of *E. coli* O157:H7 in raw beef products.

III. NEW PROCEDURES FOR COLLECTING AND SUBMITTING SAMPLES

NOTE: Sections III - VI apply to the following sampling programs:

- Routine sampling of beef manufacturing trimmings;
- Routine sampling of raw ground beef;
- Follow-up sampling of raw ground beef; and
- Follow-up sampling of trimmings and other raw ground beef and patty components.

A. Inspection program personnel are to collect the sample after the establishment has completed production of a lot (as defined by the establishment) and applied all interventions except any 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.

B. Consistent with current instructions, inspection program personnel are to sample product that is intended for use in raw ground beef or other raw non-intact beef products. When pulling samples, inspection program personnel should determine which product to sample based upon information available at the time that they notify the establishment of the sample request. For information on determining the intended use of sampled product, see Notice 18-07, Section III., B; Notice 17-07, Section V.; and FSIS Directive 10,010.1, Revision 1, Section IV., B., 3.

IV. FSIS AND ESTABLISHMENT TEST RESULTS

A. 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).

B. 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.

C. If the establishment held the product or maintained control of the product (e.g., the establishment moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS and the establishment found the product positive for *E. coli* O157:H7, FSIS inspection program personnel are not to issue an NR. Inspection program personnel are to verify that the establishment performs the appropriate corrective actions.

Preparing Email Message for Positive Results

D. 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 1 to this notice if FSIS or the establishment find the product to be positive.

E. 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 1 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 1 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.

F. If the establishment decides to change the intended use of the product and to cook all the product represented by the sample after FSIS has collected the sample, inspection program personnel are to proceed with submitting the sample to the FSIS laboratory for analysis. Generally, if the FSIS sample tests positive for *E. coli* O157:H7, inspection program personnel are to issue a noncompliance record (NR), unless the establishment based their decision on their own positive sample result. However, in the usual case that the establishment has a written program to divert all product that FSIS samples to cooking, inspection program personnel are not to issue an NR.

G. If FSIS finds product positive for *E. coli* O157:H7, but the establishment does not, 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" noncompliance classification indicator (cite 9 CFR 301.2 and 417.4(a) on the NR); and

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 in accordance with Directive 8080.1.

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 applicable requirements in 9 CFR 417.3.

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

I. 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 that 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 it in accordance with FSIS Directive 5000.1. In situations where the establishment has not properly moved the product, inspection program personnel also should notify their DO through supervisory channels.

V. Notifying Establishments and Knowing Production Practices

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

B. To provide establishments enough time to hold the entire sampled lot, inspection program personnel are 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 prior to 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 prior to FSIS' collection of the sample, inspection program personnel are to consider the request based on establishment product and process flow.

VI. ALTERNATIVE LOT DEFINITIONS

A. Inspection program personnel may permit an establishment that samples beef manufacturing trimmings, other raw ground beef components, or raw beef products 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 requires an intervention for *E. coli* O157:H7 at a CCP for that product's source materials; and

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

B. If an establishment meets the criteria in section A 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 FSIS Notices 17-07, 18-07, or Directive 10,010.1. If the establishment does not meet the criteria, inspection program personnel are still to collect the sample, consistent with applicable instructions in FSIS Notices 17-07 or 18-07; or Directive 10,010.1.

VII. FOLLOW-UP SAMPLING (MT52) OF INTACT BEEF COMPONENTS THAT ARE <u>NOT</u> INTENDED FOR USE IN RAW GROUND BEEF PRODUCTS

NOTE: FSIS Notice 17-07 (issued on March 1, 2007) provides instructions to inspection program personnel on collecting a follow-up sample of beef manufacturing trimmings or raw ground beef or raw beef patty components at an originating supplying slaughter establishment in response to an FSIS *E. coli* O157:H7 positive result in raw ground beef products.

A. If intact product was used as a component in the raw ground beef product that FSIS finds positive for *E. coli* O157:H7, inspection program personnel are to select a carcass (rather than the component of the carcass) at the originating supplying slaughter establishment for follow-up sampling under the following conditions:

1. HACCP plan records and purchase specification records for product produced at the originating slaughter establishment show that the intact product supplied by the originating slaughter establishment was not intended for grinding or non-intact product, and that the establishment informed purchasers that the product was not intended for grinding; and

2. Intact product was derived from the carcass in a manner to minimize cross-contamination with other product and was packaged separately from other product without co-mingling with other beef prior to the product being packaged (e.g., boneless chucks were placed on a conveyor belt and were then off-loaded for packaging without being co-mingled with other product). Inspection program personnel can verify that the product was handled in this way through records review and direct observation.

B. If both conditions in paragraph A are met, inspection program personnel are to cut enough slices off of the surfaces of the carcass to equal 2 pounds (following instructions for sampling large components in FSIS Notice 17-07, Sections V., I., 4., and K). When possible, inspection program personnel are to cut slices from the surface of the same part of the carcass that was used in the positive FSIS raw ground beef product. Inspection program personnel are to take the slices from the carcass while the carcass is hanging in the cooler prior to fabrication. If it is not possible to do either of these things, contact the Policy Development Division (PDD) through askFSIS at http://askfsis.custhelp.com/. The PDD will cc the appropriate district personnel on their reply.

C. If the FSIS sample described in B is positive, only the sampled carcass is implicated because *E. coli* O157:H7 contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. The establishment may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (e.g., by cooking or irradiation). Because the head and cheek meat is removed from the skull during the slaughter process and processed separately from the rest of the carcass, FSIS will not consider head or cheek meat implicated by the positive FSIS result.

VIII. ESTABLISHMENTS THAT PRODUCE AND GRIND TRIM

A. It is possible that establishments produce product that is subject to both routine verification sampling programs, MT03 and MT50. Therefore, inspection program personnel may receive a sample request for both MT03 and MT50 samples during the same sampling window. If possible, inspection program personnel should complete both sample requests by selecting samples from two independent production lots. If 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), they are to sample beef manufacturing trimmings under the MT50

sampling program.

B. If a slaughter establishment produces trim for grinding but does not ship trim, the trim is subject to sampling and testing under the MT50 sampling program. Therefore, at such establishments, inspection program personnel should collect the trim sample following the applicable instructions in FSIS Notice 17-07 or 18-07.

IX. SAMPLING AMMONIATED LOW-TEMPERATURE RENDERED PRODUCTS FOR THE MT50 VERIFICATION SAMPLING PROGRAM

NOTE: Low-temperature rendered products (including partially defatted chopped beef, lean finely textured beef, and product known as boneless lean beef tissue (BLBT)) are produced from beef trimmings and can be used as a component in raw ground beef and beef patty products. This product can also undergo an additional step that involves injecting gaseous ammonia into the product to rapidly raise the pH. Scientific studies support that this step serves as an antimicrobial intervention that reduces *E. coli* O157:H7 in beef manufacturing trimmings to an undetectable level. If FSIS becomes aware of other interventions for *E. coli* O157:H7 that reduce the pathogen to an undetectable level and that may be used on raw beef product, FSIS will issue appropriate instructions to inspection program personnel.

A. If the establishment produces ammoniated low-temperature rendered product, inspection program personnel are <u>not</u> to sample this product or trimmings intended for use in ammoniated low-temperature rendered product under the routine sampling program for beef manufacturing trimmings (MT50) if the establishment:

1. has one or more CCP for production of ammoniated low-temperature rendered product in its raw ground HACCP plan; and

2. clearly segregates beef manufacturing trimmings destined for the ammoniated process from the beef manufacturing trimmings that will not undergo the ammoniated process because other beef manufacturing trimmings do not receive an intervention and may be subject to FSIS sampling and testing for *E. coli* O157:H7.

B. If the establishment produces beef manufacturing trimmings that are not ammoniated or intended to be used in ammoniated low-temperature-rendered product, the trimmings are subject the MT50 sampling verification program.

X. SAMPLING AMMONIATED LOW-TEMPERATURE-RENDERED PRODUCTS FOR THE MT52 VERIFICATION SAMPLING PROGRAM

A. Ammoniated low temperature rendered product ***<u>is</u>*** subject to the MT52 verification sampling program when it is used as a component in raw ground beef products that tested positive for *E. coli* O157:H7 when sampled by FSIS under MT03 or MT04.

B. Under FSIS Notice 17-07, FSIS samples beef manufacturing trimmings and other raw ground beef product components from originating supplying slaughter establishments that produce such products. However, the District Office (DO) is to direct inspection program personnel to collect a sample of ammoniated BLBT at the establishment that produced the ammoniated low-temperature-rendered product, even if that establishment is not an originating supplying slaughter establishment as described in Notice 17-07. Inspection program personnel are to sample the ammoniated low-temperature-rendered product in the manner as described in FSIS Notice 17-07, Section V., J.

C. If the establishment that produced the ammoniated BLBT is not an originating supplying slaughter establishment, the DO is NOT to request MT52 sampling for the slaughter establishments that produced the source materials used in the ammoniated BLBT.

D If the ammoniated low-temperature rendered product from X. B. tests positive under the MT52 verification sampling program, inspection program personnel are to collect supplier information from the establishment that produced the ammoniated low-temperature rendered product. The DO is to enter the supplying establishments into STEPS and generate MT52 sample requests for the slaughter establishments that produced the source materials used in the positive BLBT product.

Refer questions to the Policy Development Division (formerly the Technical Service Center) at 1-800-233-3935.

Assistant Administrator
Office of Policy, Program, and Employee Development

Questions to Answer when FSIS or Establishment find Product Positive for *E. coli* 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 *E. coli* 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 *E. coli* 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 *E. coli* O157:H7 testing.)	
YES	
NO	
Don't Know	

Beef manufacturing trimmings or other raw ground beef components (*other than* AMR or low temperature rendered product)	
8. Did you observe the establishment collect 60 slices of product (i.e., did the establishment follow an N60 procedure)?	
Yes	
No	
Raw ground beef product, any comminuted ground beef components, or AMR or low temperature rendered product	
9. Did the establishment analyze at least 325 grams of product for *E. coli* O157:H7?	
YES	
NO	
Don't Know	
10. If no, did the establishment test the source materials used to produce the ground product?	
YES	
NO	
Don't Know	
11. If the establishment tested the source materials, such as beef manufacturing trimmings, did you observe the establishment collect 60 slices of product (i.e., did the establishment follow an N60 procedure?	
YES	
NO	
Don't Know	
12. If the establishment tested source materials, such as coarse ground product, AMR or low temperature rendered product, did the establishment analyze at least 325 grams of product for *E. coli* O157:H7?	
YES	
NO	
Don't Know	