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

# FSIS NOTICE	66-07	10/12/07

MULTIPLE FOLLOW-UP SAMPLING AFTER FSIS POSITIVE *Escherichia coli (E. coli)* O157:H7 RESULTS

I. PURPOSE

This notice provides inspection program personnel with new instructions for multiple follow-up samples of raw ground beef, raw ground beef trimmings, and other raw ground beef and raw beef patty components in response to an FSIS positive *E. coli* O157:H7 result or another Federal or State entity's positive *E. coli* O157:H7 result.

FSIS is implementing multiple follow-up samples in response to a positive *E. coli* O157:H7 result because analysis of *E. coli* O157:H7 sample data from 2000 through 2005 shows that plants are more likely to have a second positive sample if they have had a positive sample within the preceding 120 days.

II. BACKGROUND

Under FSIS Notice 64-07, District Office (DO) is to schedule a Food Safety Assessment (FSA) at an establishment within 30 days after being notified that FSIS or another Federal or State entity has found raw beef product positive for *E. coli* O157:H7. The Enforcement Investigations and Analysis Office (EIAO) is to conduct the FSA when scheduled.

FSIS Directive 10,010.1 instructs inspection program personnel, under certain circumstances, to collect a follow-up sample for *E. coli* O157:H7 testing as soon after the establishment has taken its corrective action as possible. In this notice, FSIS is clarifying that inspection program personnel should routinely collect the follow-up samples as soon as possible following the positive result, without waiting for the establishment to complete corrective actions. The follow-up sampling results will provide objective data that an EIAO will use in formulating an Agency position when conducting an FSA.

III. FOLLOW-UP SAMPLING PROCEDURES

A. If FSIS or another Federal or State entity finds raw ground beef product, beef manufacturing trimmings, or follow-up samples of trimmings or other ground beef or raw beef patty components, to be positive for *E. coli* O157:H7, inspection program personnel will receive 16 follow-up sample forms to sample product from the establishment that produced the positive product. Forms will be automatically generated. At low volume establishments (establishments that produce less than 1,000 pounds per day of product in question), inspectors are only to submit 8 samples and are to return the unused sample forms (see F below). Multiple follow-up sample forms for raw ground beef product samples will have the MT04 sampling project code in block 14 of FSIS Form 10,210-3, Requested Sample Programs. Multiple follow-up sample forms for beef manufacturing trimmings or other raw ground beef or raw beef patty components will have the MT53 sampling project code in block 14 of the form. As is explained in Section IV of this notice, inspection program personnel may also receive multiple follow-up sample forms with the MT52 sampling project code in block 14 of the form.

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. 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.

B. Inspection program personnel are to begin collecting samples from lots produced after the positive product as soon as possible following receipt of the multiple follow-up sample forms, even if the establishment is still completing corrective actions required under 9 CFR 417.3. Although inspection program personnel are not to wait for the establishment to complete corrective actions, they are to collect follow-up samples when the establishment has resumed normal production.

C. Inspection program personnel are to collect 8 samples for low volume establishments (establishments that produce less than 1,000 pounds per day of product in question), or 16 for all other establishments, at the following daily and weekly frequencies:

1. a maximum of 2 follow-up samples per shift per day from different lots (or up to 4 samples per day at a 2-shift establishment), unless the establishment cannot continue to operate under that sampling frequency (e.g., because the establishment cannot fill orders and hold all sampled product), or the inspection program personnel's workload cannot accommodate that sampling frequency; and

2. a minimum of 3 follow-up samples per week, unless the establishment produces the product in question less than three times per week, the establishment cannot continue to operate under that sampling frequency, or the inspection program employee's workload cannot accommodate that sampling frequency.

NOTE: To sample beef manufacturing trimmings, inspection program personnel are to collect samples using the N60 method of sample collection and are to collect 60 individual pieces from raw beef manufacturing trimmings following the instructions in FSIS Notices 17-07 and 18-07.

D. If inspection program personnel need sampling supplies for follow-up sampling, 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 any one of the following e-mail addresses:

SamplingSupplies–EasternLab@fsis.usda.gov
SamplingSupplies–MidwesternLab@fsis.usda.gov
SamplingSupplies–WesternLab@fsis.usda.gov

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

- follow-up sampling project code (MT04 for multiple follow-up ground beef product samples; MT53 or MT52 for multiple follow-up beef manufacturing trimming and other raw ground beef or raw patty component samples);

- identify the exact supplies needed and request several boxes;

- establishment address (not a P.O. Box); and

- establishment phone number.

E. Inspection program personnel may submit one or more individually identified samples per box. If necessary, they are to include additional cooling packages in the box to keep the sample or samples cool during transportation. To submit multiple samples, inspection program personnel may request larger boxes from any of the laboratories by sending an e-mail message to one of the e-mail addresses for sampling supplies above.

F. Inspection program personnel should return any unused forms to the laboratory. Unused forms can be returned in the box with the last follow-up sample.

G. During the period that inspection program personnel are conducting follow-up sampling for *E. coli* O157:H7, they may receive a routine sample request form for product to be tested for *E. coli* O157:H7. In this situation, inspection program personnel are to continue to collect follow-up samples and are to make follow-up sampling the priority, rather than routine sampling. Inspection program personnel are to collect the sample for routine testing within the allotted 30 days if they are able to do so based on their workload and the establishment's production practices. Inspection program personnel should not collect a follow-up sample and a routine sample from the same lot.

IV. Follow-up Sampling at Suppliers

A. On a monthly basis, the Policy Analysis Division (PAD) (OPPED), in consultation with the Data Analysis and Integration Group (DAIG) (Office of Food Defense and Emergency Response) will review data from the Systems Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS). If FSIS finds raw ground beef product positive for *E. coli* O157:H7, PAD and DAIG will determine whether an originating slaughter establishment was the only supplier. If multiple originating slaughter establishments supplied source materials for the ground product, PAD and DAIG will determine whether those originating slaughter establishments are identified in STEPS as suppliers of source materials for product that FSIS found positive within approximately 4 months (or 120 days) prior to the date of the current raw ground product positive result.

B. If PAD, in consultation with DAIG, determines that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had been identified in STEPS within approximately 4 months (or 120 days) of the current raw ground product positive result, PAD will request 16 MT52 follow-up sample forms for the originating slaughter establishments identified.

C. PAD will request multiple MT52 follow-up sample forms by sending an e-mail message to the following address:

SamplingForms-Headquarters@fsis.usda.gov

The e-mail request is to contain the following:

1. “Request for Multiple MT52 Follow-up Samples” in the subject line of the e-mail;

2. the establishment number for each originating supplying slaughter establishment;

3. the number of sample requests forms needed for each originating supplying slaughter establishment (16) ;

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

PAD will cc the DO with jurisdiction over the originating slaughter establishments.

D. The DOs with jurisdiction over the originating slaughter establishments are to inform the inspector in charge at each originating slaughter establishments concerning which type of beef component the originating slaughter establishment supplied to the grinder, so that inspection program personnel can collect multiple follow-up samples of that component from the establishment’s current production.

E. The DO and inspection program personnel are to follow the procedures in FSIS Notice 17-07 for follow-up sampling. However, inspection program personnel are to collect multiple follow-up samples (16 or 8, depending on the size of the establishment) following Section III of this notice.

F. If the DO determines that an originating slaughter establishment has been identified in STEPS more than once within approximately 4 months (or 120 days), the DO should—

1. request 16 follow-up MT52 sample forms for that supplier for each applicable positive raw ground beef product sample; and

2. schedule an FSA at the establishment within 30 days of determining that the establishment meets the criteria as an originating slaughter establishment that has been identified in STEPS more than once within approximately 4 months (or 120 days).

G. Inspection program personnel are to continue to collect the multiple follow-up samples at the originating slaughter establishment, following instructions in this notice and in FSIS Notice 17-07 unless the DO makes a determination to initiate an enforcement action that would stop production.

V. *E. coli* O157:H7 Positive Follow-Up Sample Results

A. If the establishment held the product sampled (or maintained control of the product) pending its own test results, and FSIS and the establishment both found the product positive for *E. coli* O157:H7, FSIS inspection program personnel are not to issue a noncompliance record (NR). Inspection program personnel are to verify that the establishment performs the appropriate corrective actions and follow instructions in FSIS Notice 62-07.

B. If an FSIS follow-up sample is positive for *E. coli* O157:H7, and the establishment did not find the product positive, 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) as set out in FSIS Directive 5000.1, Revision 2, Amendment 1;

2. determine whether the establishment held or shipped the affected product. If the establishment no longer has control of the product, inspection program personnel are to contact the Recall Management Staff through the DO; and

NOTE: District personnel often make this determination at the presumptive positive stage.

3. as soon as possible after the establishment has implemented its corrective action, perform a HACCP 02 procedure for the specific production lot that tested positive for *E. coli* O157:H7 and verify that the establishment has implemented corrective action that meets the applicable requirements in 9 CFR 417.3.

C. 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.

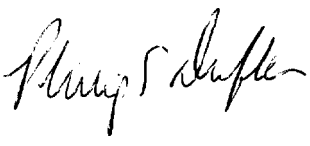
D. If inspection program personnel find noncompliance with the requirements in C, they are to document it in accordance with FSIS Directive 5000.1, Revision 1. In situations where the establishment has not properly moved the product, inspection program personnel also should notify their DO through supervisory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

VI. Role of the DO and EIAO

A. The EIAO is to consider all follow-up sampling data available during the FSA. In addition, if, during the FSA, the EIAO thinks additional sampling may be useful, he or she should contact the DO. If DO personnel determine that the sampling is appropriate, they should contact the Risk Management Division, OPPED, at (202) 205-0210. RMD will consult other offices within FSIS, including the Office of Public Health Science.

B. The DO is to consider the results of follow-up sampling and take the appropriate enforcement actions (e.g., NOIE, withhold or suspend inspection, reinstate a suspension), if warranted.

Refer any questions to the Policy Development Division at 1-800-233-3935



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