



FSIS Notice 66-07

MULTIPLE FOLLOW-UP SAMPLING AFTER POSITIVE *E. coli* O157:H7 RESULTS



New Follow-Up Sampling

- This notice includes new instructions for multiple follow-up sampling of raw ground beef or raw ground beef or 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.



New Follow-Up Sampling

- 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.



Sampling Procedures

- After a positive result, 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.



Sampling Procedures

- 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.
- For all other establishments, inspectors are to submit 16 samples.



Sampling Procedures

Multiple follow-up sample forms codes:

- MT44 Raw ground beef product samples
- MT53 Beef manufacturing trimmings, or other raw ground beef or raw beef patty components
- MT52 Multiple follow-up sampling of suppliers



Sampling Procedures

Sampling Frequency:

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



Sampling Procedures

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.



Sampling Procedures

- Sampling procedures are the same as those in Directive 10,010.1 (for ground product) and FSIS Notices 17-07 and 18-07 (for raw ground beef and patty components).



Request Supplies

Electronically request at:

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



Request Supplies

- Include follow-up sampling project code (MT44 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.



Submitting Samples

- Inspectors 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 request.



Routine Samples

- If inspectors receive a routine sample request form while collecting follow-up samples, they should:
- continue to collect follow-up samples;
- 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; and
- not collect a follow-up sample and a routine sample from the same lot.



Multiple Follow-Up Samples at Suppliers

- 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 STEPS.
- PAD and DAIG will determine whether an originating slaughter establishment was the only supplier.



Multiple Follow-Up Samples at Suppliers

- 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.



Multiple Follow-Up Sampling at Suppliers

PAD Responsibilities

- If PAD, in consultation with DAIG
 - determines that an originating slaughter establishment was the only supplier or
 - any of the originating slaughter establishments were suppliers identified in STEPS within approximately 4 months of the current raw ground product positive result...



Multiple Follow-Up Sampling at Suppliers

PAD Responsibilities

- PAD will request 16 MT52 follow-up sample forms for the originating slaughter establishments identified.
- PAD will cc the DO with jurisdiction over the originating slaughter establishments.



Multiple Follow-Up Sampling at Suppliers

DO Responsibilities

- The DO, with jurisdiction over the originating slaughter establishment, will inform the IIC at that establishment the type of beef component supplied to the grinder. Inspection program personnel can then collect multiple follow-up samples of that component from the establishment's current production.



Multiple Follow-Up Sampling at Suppliers

DO Responsibilities

Note: If the information is in STEPS, the DO would not need to make this determination. OPPED is assessing this situation.



Multiple Follow-Up Sampling

If the DO determines (or is notified by PAD) 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 (NOTE: If PAD has this information about all source material used, the DO will not need to request the follow-up sampling forms); and



Multiple Follow-Up Sampling

2. schedule an FSA at the establishment within 30 days of determining or being notified 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).



Multiple Follow-Up Sampling at Suppliers

3. 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).



Multiple Follow-Up Sampling at Suppliers

4. 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.



Verification and Enforcement

- Procedures for writing NRs and verifying corrective actions following a positive follow-up sampling result are the same as those in FSIS Notice 62-07.
- The follow-up sampling results will provide objective data that an EIAO will use in formulating an Agency position when conducting an FSA.



Verification and Enforcement

- 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 Assessment Division, OPPD.



Verification and Enforcement

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



How to Contact PDD

- Preferred Method: AskFSIS
 - Interactive web-based information system
 - Access link on FSIS home page
 - 24-hour knowledge-base search option
 - Submit written questions if answer not found
- Alternate Methods: Phone
800-233-3935 / 402-344-5000