

Plant-generated Sampling

Some plants may have their own sampling programs for *E. coli* O157:H7. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes produce safe, wholesome unadulterated product. These sampling programs may or may not be included in the plants' SSOP or HACCP plans. Even though these programs may not be included as part of the SSOP or HACCP system, plants are still required to share records and analyses results with you.

Based on the regulatory requirements of 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of such testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, ***on at least a weekly basis***, inspection program personnel must review the results of any testing and of any monitoring activities the plant performed that may have an impact on the hazard analysis. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite programs, contact the Technical Service Center or raise the concern through supervisory channels. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test results reveal about food safety and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

Note: *You can collect a sample, with supervisory approval, anytime you suspect noncompliance or have reason to believe that a sample is warranted.*

The plant is not obligated to notify FSIS when it receives a positive sample, but it must take corrective actions that meet the requirements of §417.3 each time a positive result is obtained. The plant must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

Example 2

A plant has its own testing program for *E. coli* O157:H7 for its raw hamburger patties. The plant has not included it as a verification activity in its HACCP plan. In the last test, the result was positive. The plant always holds product pending results. The plant does not need to inform you of its positive result. But, the plant must implement corrective actions that meet the requirements of 9 CFR 417.3. You must verify that the plant took the necessary corrective actions to meet these requirements. You should become aware of the positive from your regular review (at least weekly) of the plant's sampling results or from reviewing

corrective action records or observing corrective actions the plant takes.

Example 3

A plant has its own testing program for *E. coli* O157:H7 in its beef trim. The testing is part of the verification of the overall HACCP plan. The plant analyzes the samples while the product is in transit, but still under the plant's control. When the result is received, the plant completes the pre-shipment review. The product is **not** in commerce, but in transit. The last test result was positive. The plant must implement corrective actions that meet the requirements of 9 CFR 417.3. Again, you must verify that the plant meets **all** four requirements described in 417.3.

Whether the plant brings the product back to the establishment for disposition, or it diverts it for further processing at another official establishment or to a landfill or renderer, the plant must demonstrate control of the adulterated product until that product receives proper disposition. The establishment must provide documents evidencing proper disposition.

When you are aware that there was a positive result you must
Conduct an 01 or 02 procedure to verify the plant's corrective actions (§417.3(a) or (b)), and
Issue an NR **only** if the plant fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

Note: *The HACCP 02 procedures cannot be completed until pre-shipment review, which includes disposition documentation.*

Some plants may opt to divert the product to another official establishment for cooking when they receive a **presumptive positive** in their testing program, or to a landfill or renderer. However, the plant is still obligated to meet **all** parts of 417.3. It is still required to have proper control of the product while it is in transit for disposition. It also must maintain documentation of appropriate disposition.

When product that is **presumptive positive or positive** for *E. coli* O157:H7 is transported to another official establishment for appropriate disposition, the plant sending the product must

- maintain records identifying the official establishment, renderer, or landfill operation that receives the presumptive positive or positive product,
Note: *If the product is analyzed while in transit, the plant must maintain records identifying the official establishment to which the product is being sent.*
- maintain control of product (company controls or FSIS controls),
- maintain records that indicate product received proper disposition, and
- completes pre-shipment only after it has all disposition records for that particular product.

If you are aware that presumptive positive or positive product is in transit, verify the controls. In addition, e-mail the DO information about the intended product disposition location (establishment number, or name and address of renderer or landfill).

If inspection personnel find noncompliance with the plant's handling of presumptive or confirmed positive product contact the District Office. The DO will investigate to determine if the plant sold or transported adulterated product.

Example 4

The establishment has a finished product sampling program as part of its verification of the HACCP plan for raw ground beef product. Its last sample was presumptive positive.

The plant diverted the product to cooking at its own in-plant cooking operation. It identified all affected product and cooked it separately from its other products. The company utilized a HACCP plan that had been designed specifically for product known to contain *E. coli* O157:H7 and which contains a CCP for lethality that was validated to eliminate *E. coli* O157:H7. Records demonstrating the positive product received proper disposition are available.

The plant identified the source of the presumptive positive *E. coli* O157:H7 contamination as coming from a new supplier. Plant management required the supplier to demonstrate that validated antimicrobial interventions are implemented in its process before purchasing any other products from that supplier.

The plant includes this certification as HACCP verification.