

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

FSIS NOTICE

63-06

9/27/06

VERIFICATION PROCEDURES INVOLVING *E. COLI* O157:H7

I. PURPOSE

The high prevalence season for *E. coli* O157:H7 lasts until the end of September. There has been a recent increase in the rate at which the Food Safety and Inspection Service (FSIS) is finding this pathogen in its verification sampling of raw ground beef. This trend is of concern to FSIS. For calendar year (CY) 2005, the percentage of positive samples for *E. coli* O157:H7 in ground beef was approximately 0.17%. Thus far for CY 2006, the rate of positive samples is approximately 0.19%. FSIS has established a rate of 0.20% as the standard for the success of its program for this fiscal year. Because of the upward trend in its verification sampling, and because this summer has been extremely hot in some areas, which tends to exacerbate problems with this pathogen, FSIS is issuing this notice to remind inspection program personnel of the verification activities they are to perform regarding *E. coli* O157:H7.

II. VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT TEST RAW BEEF PRODUCTS FOR *E. COLI* O157:H7

FSIS encourages establishments that handle beef products to design statistically-based sampling plans to purposefully find this pathogen and then identify steps to reduce the likelihood of its presence. FSIS Directive 5000.2 provides instructions to inspection program personnel to review records of the establishment's testing and other establishment monitoring programs. Because of the concern for the increase in the findings of *E. coli* O157:H7 in FSIS verification samples, inspection program personnel are to conduct the following records review.

NOTE: Because the establishment may store records off-site, inspection program personnel are to ask for them in advance of the review:

- for each establishment that tests raw beef products for *E. coli* O157:H7 as part of its food safety system, review 60 days of records prior to April 1, 2006, to determine the percent of positives before the high prevalence season.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; TRA; TSC; Import
Offices

NOTICE EXPIRES: 10/1/07

OPI: OPPED

- review all *E. coli* O157:H7 microbiological testing records from April 1, 2006 (the start of the high prevalence season) through the current date;
- determine whether, since April 1, 2006, the records reveal an increased percent of positive *E. coli* O157:H7 findings in the verification sampling that the establishment performs;
- verify that the corrective action requirements were met by the establishment when it identified increases in positive *E. coli* O157:H7 findings. If decreases in positive findings are noted, assess whether the establishment has stopped looking for the pathogen or has modified its procedures whereby the likelihood of finding the pathogen is reduced. By assessing the information generated by the system, inspection program personnel are verifying that the total food safety system is functioning as intended and are verifying that the establishment is reacting appropriately to the information. If steps have been taken to decrease the likelihood of identifying positive product, report this to the District Office through supervisory channels; and
- contact the next level of supervision when this current review of the records shows that there is an increased percentage of positive results continuing to occur even though corrective actions are taken and, therefore, concerns exist about the overall effectiveness of the establishment's corrective actions or the design of the microbiological testing program.

III. VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT TEST RAW BEEF PRODUCTS FOR *E. COLI* O157:H7 AND TRANSPORT THE PRODUCT TO ANOTHER SITE FOR DISPOSITION

If an establishment has found raw beef product *E. coli* O157:H7 presumptive positive or positive, and the establishment intends to move, or has moved, that 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. maintains 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. maintains 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 preshipment review for the presumptive positive or positive product only after it has received the records described in paragraph III. 4. for that particular product.

If inspection program personnel find noncompliance with these requirements, they should document them 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 the District Office through supervisory channels.

The inspector should also perform all other verification activities listed in FSIS Directive 10,010.1, Revision 1, Part VII. B.

IV. VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT RECEIVE *E. COLI* O157:H7 PRESUMPTIVE POSITIVE OR POSITIVE RAW BEEF PRODUCTS

When performing a HACCP 01 or 02 procedure at an establishment that receives *E. coli* O157:H7 presumptive positive or positive raw beef products, inspection program personnel are to verify that:

1. the establishment documents the receipt of the product, as required under 9 CFR 417.5, by directly observing establishment practices or by reviewing the establishment's HACCP records;
2. the establishment maintains control of the product, by observing the establishment's control of the product during the production process or by reviewing the establishment's HACCP records; and
3. *E. coli* O157:H7 is addressed in the establishment's hazard analysis and HACCP plan, so the presumptive positive or positive product will receive a lethality treatment adequate to destroy the pathogen, by observing the establishment's production process or by reviewing the establishment's HACCP records.

These verification activities are listed in FSIS Directive 10,010.1, Revision 1, Part VIII.

Inspection program personnel should also perform all other verification activities listed in FSIS Directive 10,010.1, Revision 1, Part IX., C. and D.



Assistant Administrator
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