

Guidance for Small and Very Small Establishments on Sampling Beef Products for *Escherichia coli* O157:H7

The purpose of this guidance is to help small and very small establishments develop sampling plans for monitoring the effectiveness of process controls that are designed to prevent *Escherichia coli* (*E. coli*) O157:H7 contaminated product from leaving the establishment. If you would like additional information about any aspect of this guidance, consult the larger document that is attached.

A sampling plan used to verify process controls should address the following:

1. products to be tested
2. size of the lot (amount of product from which samples are taken)
3. size of portions that are selected from the product
4. number of portions that comprise a composite sample that is tested in the laboratory
5. number of samples to be collected per lot (typically 1)
6. use of an acceptable aseptic procedure for collecting samples
7. the amount of product that would actually be tested in the laboratory
8. testing methods used
9. actions to take when samples are positive
10. the frequency of sampling

FSIS recommends that establishments should perform the following activities associated with conducting verification testing for *E. coli* O157:H7:

- a. Establishments maintain and examine records of results over time.
- b. Grinding establishments conduct testing to verify that their controls (e.g. purchase specifications) before and during the grinding process are effective.
- c. Establishments should test product from each supplier separately to limit the products to be recalled if a positive result is found
- d. Establishments should ensure that rework (i.e., carryover beef materials from previous production) if used, is specially accounted for when defining lots
- e. For positive results, establishments need to investigate to find the reason or source of the positive and to take corrective action to prevent repeat occurrences, in accordance with 9 CFR 417.3.

If a positive finding of *E. coli* O157:H7 for a sample from a lot is found, the entire product in the lot is implicated and must be disposed of. Methods for doing so are outlined in FSIS Directive 10,010.1 “Microbiological Testing Program and Other Verification Activities for *Escherichia Coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components.”

Two examples of sampling plans are given below:

Example 1:

Product to be tested: Trim product

Lot size: combo bins produced and available for a day's production, consisting of up-to 2,000 pounds each, not exceeding 5 combo bins.

Sample size: a composite sample consisting of 60 pieces of product sliced from the surface of the meat. The number of samples per combo bin is determined by dividing 60 by the number of combo bins: if there are 5 combo bins, then 12 randomly selected slices from each combo bin are taken; if there are 4 combo bins, 15 slices are taken from each; and so forth.

Portion size: Each portion consists of a slice from the surface of the meat of about the same dimensions (e.g., 2 inches by 4 inches), with 1/8 inch thickness.

Test sample size: At least 325 grams (to reflect the FSIS method; the beef industry method typically uses at least 375 grams), composited from the 60 slices or portions. This sampling plan is called N60 because there were 60 portions collected from a lot.

Example 2:

Product to be tested: finished ground beef product

Size of the lot: product ground from a supplier's trim product.

Samples and portions to be collected and material tested:

The establishment determines that the supplier's trim product can be processed in 2 hours. Subsamples of ground product portions of about 65-75 grams are taken every 24 minutes of grinding. The five consecutive portions (representing 2 h of production) are combined into 1 composite sample to be tested (at least 325 grams to reflect the FSIS method; the beef industry method typically uses at least 375 grams per composite sample).

FSIS recognizes that extensive, high frequency, sampling might be cost prohibitive for small and very small establishments. FSIS believes, however, that testing is necessary for product produced by these establishments. Consequently, the Agency offers the following *minimum* sampling frequencies as guidelines for small and very small establishments for testing finished ground product. It is important to note that FSIS recommends that establishments producing finished ground beef product should be requiring their suppliers to be testing, rigorously, the source trim beef and other source material, such as fat, used that is ground to produce the finished ground product. The minimum frequencies recommended below assume that all source trim product has been tested. If this is not the case, then sampling frequencies for finished ground beef product should be much higher than those given below. FSIS recommends that any product that is released should have been subjected to sampling at least once.

These recommendations may be changed as more information becomes available to FSIS.

1. More than 250,000 pounds produced daily—sample more than once per month (>12 times annually);
2. More than 50,000 pounds but less than or equal 250,000 pounds daily—sample at least once every month (12 times annually);

Draft for Stakeholder Comment
August 12, 2008

3. More than 1,000 pounds but less than or equal 50,000 pounds daily—sample at least once every 2nd month (6 times annually);
4. Less than or equal 1,000 pounds daily—sample at least once every 3rd month (4 times annually)

FSIS recommends that the sampling rates be increased during warmer months, from April through October, because studies have shown that shedding of *E. coli* O157:H7 by cattle is greater during these months. Consequently, the likelihood of detecting this pathogen on raw beef is expected to be greater. Hence, FSIS recommends that the sampling frequency for these months be increased (e.g., by a factor of 2).

NOTES:

Establishments can seek guidance from University Extension Service specialists within the state that the establishment is located on how to design sampling plans using this guidance document, how to sample, and how to test beef samples for *E. coli* O157:H7.

For sampling purposes, lots should be defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called (mutually) independent lots. Product from different carcasses can be considered as independent lots provided the meat from the carcasses from each lot was handled so as to not cross-contaminate one another. This includes having assurances that the carcasses were not co-mingled. Defining lots by supplier would be acceptable if the product from one supplier could not have cross-contaminated the product from the other. For example, following the grinding of product from one supplier, the lines and equipment were sanitized before the product from the next supplier was processed.

If parts of carcasses are in more than one lot, and one of the lots test positive, then the other lots might be implicated as well. FSIS requires scientific evidence be provided, which could include further testing of the other implicated lots for the presence of *E. coli* O157:H7, before the other product can be released.