Risk-based Sampling for *Escherichia coli* O157:H7 in Ground Beef and Beef Trim

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February 2008

FSIS

Executive Summary

Until January 2003, the Food Safety and Inspection Service (FSIS) tested for the presence of *Escherichia coli* O157:H7 in raw ground beef and beef trim using an approach in which all beef-producing establishments were sampled at approximately the same frequency. Because all eligible establishments had an equal probability of being selected for verification sampling, FSIS resources were allocated uniformly among establishments that may differ greatly in terms of their microbiological controls for *E. coli* O157:H7 in ground beef and trim, and the resulting public health impact of these products.

As part of its effort to provide improved public health assurance of the safety of ground beef, FSIS developed an *E. coli* O157:H7 risk-based verification sampling program. This algorithm was independently peer reviewed in accordance with the Office of Management and Budget guidelines for peer review. The risk-based *E. coli* O157:H7 sampling program provides more comprehensive verification of domestic ground beef servings and allocates more samples to establishments with a higher risk of causing *E. coli* O157:H7 illness.

The risk-based sampling algorithm allocates samples in a random draw where the probability of each establishment being sampled is weighted by FSIS microbiological test results for *E. coli* O157:H7 and production volume. As FSIS collects and analyzes data on establishment *E. coli* O157:H7 interventions and testing programs these will also be used to weight sampling probability. In the simplest terms, the greater an establishment's potential for causing *E. coli* O157:H7 illness, the higher the probability it will be sampled.

OBJECTIVES

The risk-based sampling algorithm is designed to accomplish three primary objectives:

- To increase the proportion of FSIS samples taken at establishments that are more likely to produce product contaminated with *E. coli* O157:H7.

- To allocate FSIS resources more efficiently by verifying a greater portion of the U.S. trim and ground beef supply with the same number of samples as the current program.

- To verify *all* eligible establishments at a reasonable frequency regardless of an establishment's production volume, interventions, or predicted public health risk associated with their product.

PRINCIPLES

The risk-based algorithm uses data from FSIS sampling programs for *E. coli* O157:H7 in ground beef and beef trim and from FSIS surveys. The algorithm works on the following principles:

- Every establishment eligible for *E. coli* O157:H7 testing of raw beef is placed in a sampling frame each month – one frame for producers of raw ground beef products and one for suppliers of beef trim.

- Each establishment in the sampling frame is assigned a portion of the probability "space" from 0 to 1. The higher an establishment's potential to cause *E. coli* O157:H7 illness, the larger the space.

- A random number generator selects numbers between 0 and 1. If the number is within an establishment's space, the establishment is selected for sampling. The larger an establishment's probability space, the greater the chance it will be selected.

- The algorithm selection of an establishment ("draw") is random. In each draw, each establishment has a chance of being sampled; but the probability of being selected is dictated by the potential public health risk.

OUTCOMES

- The monthly probability of selection for *E. coli* O157:H7 sampling in the current program for ground beef producers is the same for every establishment and was estimated at approximately 60% (resulting in an average of about 7 samples per establishment per year). Using the risk-based algorithm to assign samples, 1,443 of the smallest establishments (by production volume) will be sampled slightly less than they are currently, while 92 of the largest producers will be sampled at a slightly higher frequency than they are currently.

- The frequency of sampling will change further as establishment practices become included in the algorithm to account for testing programs and interventions. For example, establishments with interventions and testing programs known to control *E. coli* O157:H7 will be sampled significantly less, while establishments that lack these practices and have little or no testing will show a relative increase in the number of positive samples. In addition, the risk-based sampling program significantly increases the frequency of sampling for establishments that have tested positive for O157:H7 in the past 4 months.

FUTURE DIRECTION

By summer of 2008, FSIS plans to incorporate establishment practices into the *E. coli* O157:H7 sampling algorithm, including those interventions that reduce *E. coli* O157:H7 contamination and testing programs that effectively detect *E. coli* O157:H7. Accounting for establishment practices such as these will allow FSIS to further target high-risk establishments and provide incentives for establishments to implement the best available practices during the production of ground beef and trim.

CONCLUSIONS

Compared to FSIS' prior *E. coli* O157:H7 verification sampling program, the risk-based sampling algorithm described in this report (and initiated in January 2008) offers an improved verification testing program for *E. coli* O157:H7 in ground beef and trim. Importantly, because the risk-based sampling algorithm accounts for production volume but does not make it a primary driver, the sampling program will verify the safety of more of the beef supply than an unweighted random program, while still verifying small producers at a reasonable frequency. This is because the algorithm strikes a balance between sampling more of the total beef supply and targeting the sampling of product with the most potential for causing *E. coli* O157:H7 illness. Use of the algorithm to allocate samples for *E. coli* O157:H7 should therefore provide a greater benefit to public health through more efficient allocation of FSIS resources.