



## The Role of an N-60 Sampling Program in Ground Beef Safety

### Introduction:

All microbial sampling programs have limitations. That is why food safety experts continue to say unequivocally that testing alone cannot guarantee that food is safe. Prevention of *Escherichia coli* (*E. coli*) O157:H7 in beef products requires the development and implementation of a complete food safety system that includes multiple hurdles to prevent harmful pathogens in the final product. Once implemented, these food safety systems can be verified and continually improved using microbiological testing.

### What N-60 Is

The term “N-60” is a term used by the beef industry to describe a sampling program for raw beef components that are used to make ground beef. The components may be various cuts of beef or, more commonly, “beef trimmings.” Beef trimmings are the portions of a beef carcass that are removed as the carcass is cut into steaks and roasts.

Statisticians use the letter “n” to indicate the number of samples taken from a production unit or “lot.” Hence, the term N-60 describes a sampling plan where 60 individual samples are randomly drawn from a lot. The samples are removed from the exterior surface of beef cuts or trimmings that will be used for the making of ground beef.

A company that manufactures beef trimmings may define a “lot” in many ways. A lot is a quantity of product produced from similar manufacturing conditions, product types or time periods. Each lot is identified with a unique identification number that defines the product that is sampled and tested.<sup>1</sup>

A “lot” of beef trimmings is typically 10,000 pounds or less depending on the number of units in the lot. Beef trimmings are normally collected and transported in large bins that hold approximately 2,000 pounds of trim. The bins or “combos” can be sampled as individual units, grouped in a five combo lot or other lot sizes that fit a company’s manufacturing process. Beef trimmings may also be packaged in 60 pound boxes that may be grouped in various lot sizes.

The 60 samples are commonly combined into a 375 gram unit for analytical testing in a microbiological laboratory. Many different analytical methods can be utilized by meat companies for testing ground beef, but the laboratory method must be validated to provide accurate results and be equivalent to the analytical methods used by the USDA Food Safety and Inspection Service (FSIS).<sup>2</sup>

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<sup>1</sup> Microorganisms in Foods 2. Sampling for microbiological analysis: Principles and specific applications. 2nd Ed. International Commission on Microbiological Specifications for Foods. 2nd ed. (1986). Toronto: University of Toronto Press. ISBN: 0802056938. Downloaded: November 17, 2009

<sup>2</sup> FSIS Directive 10,010.1 Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products, Revision 2, July 31, 2009. Downloaded: December 4, 2009

The test method must not produce false positives when the sample is negative and not produce false negatives when the sample is positive in accordance with FSIS requirements. The method must also be sensitive and reliable.

### What N-60 Can Do

Industry-wide, N-60 sampling programs have improved beef safety based on historical testing results for *E. coli* O157:H7. Beef slaughter plants use N-60 testing results to provide feedback that is used to monitor and maintain sanitary slaughter procedures and to verify the effectiveness of microbial interventions. High rates of positive test results indicate that the process needs to be reviewed and that corrective actions may be required to address the finding. All lots that test positive for *E. coli* O157:H7 are diverted from use in raw ground beef.

A comprehensive N-60 testing program is a tool to drive meaningful food safety improvements. Test results from beef trimmings are analyzed daily and over weeks, months and years indicate what works, what does not work, and what needs to be done next to improve the process. Significant food safety progress has occurred as a result of robust N-60 trim testing programs. FSIS ground beef testing data show a 45 percent reduction in percent positive tests for *E. coli* O157:H7 since 2000. Data for 2009 show a 0.32 percent positive rate.

Since *E. coli* O157:H7 testing began in the mid-1990s, the sensitivity of the analytical testing procedures has increased. *E. coli* O157:H7 is found at lower and lower levels of detection. Robust N-60 trim testing programs have detected substantial amounts of *E. coli* O157:H7-positive beef trimmings that subsequently have been diverted from use in raw ground beef. Equally important are the improvements being made in the slaughter and production processes as a result of the information provided by a comprehensive N-60 trim testing program.

Sampling and testing schemes in the beef slaughter plant must be designed with a “test-to-find” approach, and when found at higher rates than might be expected, appropriate actions must be taken on other potentially affected products. It is not what you find; it is what you do when it is found.

In a broad food safety context, N-60 trim sampling must be robust, the analytical test method must be accurate and sensitive, and actions must be taken on associated product in response to multiple findings of positives during a production period. This is a ‘systems’ approach issue, not a sampling scheme issue.

### What N-60 Cannot Do

A false perception exists that N-60 testing makes raw ground beef totally safe. It does not; just as any sampling scheme short of 100 percent testing cannot make food safe. N-60 testing cannot guarantee with 100 percent certainty that beef trimmings are free from *E. coli* O157:H7 contamination.

Rather, N-60 testing programs are a valuable process feedback verification tool. When done correctly – and only when done correctly – does an N-60 program achieve this outcome. As stated above, a total food safety systems approach must be used that includes effective sampling procedures, accurate laboratory analysis and appropriate response to positive findings. Individual test results do not -- and cannot -- guarantee that a product is ‘free’ of *E. coli* O157:H7.

For example, FSIS sampling data show a rate of slightly more than 1 percent positive for *E. coli* O157:H7 in beef trimmings. If the prevalence rate is 1 percent and 60 sample units (n=60) are tested, there is a 45 percent probability that the sample will test positive and the lot will be rejected. But if the prevalence rate is 5 percent, as may be the case with a more highly contaminated lot, and 60 sample units are tested, there is a 95% probability that the sample will be found positive and the lot will be rejected.

In fact, it is statistically impractical to implement a sampling program to detect and reject contaminated product with a very low prevalence of contamination. For example, if the prevalence rate of *E. coli* O157:H7 in beef trimmings is 0.1 percent, the number of samples required to detect the pathogen would be 2995 units with a 95 percent confidence level.

Furthermore, the probability of finding *E. coli* O157:H7 in a lot does not increase when the lot is re-sampled. Testing a single lot of beef trim over and over again does not guarantee that raw product is “free” of *E. coli* O157:H7 unless all of the product is tested. Under that scenario, no beef product would remain to enter the marketplace.

### Conclusion:

All microbial sampling programs have limitations. That is why food safety experts continue to support the development and implementation of a complete food safety system that includes multiple hurdles to prevent harmful pathogens in the final product. These multiple hurdles include not only, microbial intervention treatments, but also methods to measure their effectiveness. The N-60 Sampling Program is one such metric used by the meat industry and FSIS to monitor, verify and continually improve the safety of raw ground beef.