IKE Scenario 05-07: Application of Common Source Rule to *E. coli* O157:H7 Samples

Purpose: This IKE is issued in support of FSIS Directive 10.010.1, Rev.1 and the accompanying guidance materials as they relate to product implicated by a positive *E. coli* O157:H7 laboratory result. This is one thought process that can be used to assist inspection personnel in determining if the establishment has appropriately held all product that may be affected by a positive sample result.

Situation: You are an inspector at a grinding facility. During weekly meetings and in the course of your inspection activities, you have become familiar with the establishment's production practices for raw ground beef. The establishment generally blends several combos of trim when grinding, but for one customer, it uses beef cheek and head meat in formulating the product. The establishment purchases the head and cheek meat in sixty pound boxes, usually one pallet at a time. It typically takes up to two weeks to use all the boxes of product from the pallet. You note that they started using a new pallet of beef cheek and head meat today. In addition, you are aware that it is the establishment's current production practice to carry over partial lots of raw ground beef components, specifically the beef cheek and head meat, to subsequent production days. Thus, the establishment defines the production lot as all product produced over the course of two weeks.

You receive a sample kit to test the establishment's raw ground beef. In accordance with Directive 10,010.1, Section II, B. 3, you provide the establishment with notification that you will be collecting a sample from the establishment's defined production lot (i.e., randomly selected from product produced throughout the entire production period) in order to ensure that the establishment has the opportunity to hold all product that may be implicated by the sample. Further, you recognize that there is potential for any *E. coli* O157:H7 that may be present to grow and be detectable if the handling procedures over the two-week period of using the source materials are not optimal for preventing growth. Thus, you contemplate not pulling the sample of finished product until the end of the full production period. The plant manager thanks you for the notification and indicates that after the FSIS sample is collected, he will conduct a special clean up. Also, he informs you that he will be holding all finished product that was produced prior to the cleaning procedure (i.e. "clean-up to clean-up") contained in the FSIS-sampled production lot.

Because there is routine carry over of partial lots of raw ground beef components, including beef cheek and head meat, to subsequent production days, a positive test result could affect more than one day's production. In addition, because the same source material is used for up to two weeks, a positive sample could result in a recall of all the product produced during that two week time period if any of the finished product is put into commerce. FSIS would consider that all the ground beef that was produced using the same source head meat and cheek meat would be the product represented by the sample, in the absence of any data to support that the likely presence of *E. coli* O157:H7 is different from use of one of the 60-pound boxes to any other box.

Discussion: You are familiar with FSIS Directive 10,010.1 and the accompanying guidance, especially as they relate to product implicated by a positive result.
You recognize that "clean-up to clean-up" cannot be used as the sole method of distinguishing one portion of production of raw ground beef from another when common source material is used across multiple "clean-up to clean-up" periods. You ask the

establishment if it is familiar with the Question and Answer document, issued by FSIS as a supplement to FSIS Directive 10, 010.1, Rev.1, which states that:

The establishment would need to have a basis other than the clean-up to determine that the ground product produced after the clean-up from the same source materials as the product found positive or presumptive positive is not implicated by the test results.
(See Part I., A., 2. at
http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/Directives_Q&A.pdf,
PDF Only)

You share the information from the directive with the plant manager. The plant manager then identifies that he may pursue, in the future, changes in the grinding operation in order to limit the size of production lots (e.g., he may consider developing a sampling and testing plan sufficiently rigorous to ensure that one or more 60 pound box of source product is independent of others).

Resolution: In this situation affecting the production lot designated for sampling by you, plant management elects to hold all the finished ground product produced from this pallet of beef head and cheek meat and will freeze it pending the receipt of the FSIS sample result. You consider that the plant has an effective means by which the plant will demonstrate that it will hold all finished ground beef product implicated by the FSIS sample. You determine that you will randomly select finished ground beef product at the completion of the production lot in a manner that is representative of all product produced over the course of the two weeks. You then collect the sample and submit it for analysis.