UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

JAN 29 2008

REPLY TO
ATTN OF: 24601-4-KC

TO: Charles F. Conner
Deputy Secretary

FROM: Phyllis K. Fong /s/
Inspector General

SUBJECT: Food Safety and Inspection Service Sampling and Testing for *E. coli*

In your memorandum, dated October 5, 2007, you requested that the Office of Inspector General (OIG) determine whether improvements can be made to the Food Safety and Inspection Service's (FSIS) sampling and testing procedures for *Escherichia coli* O157:H7 (*E. coli*) and identify any relative costs and benefits associated with these improvements.[1]

This memorandum provides our observations and suggestions that the Department may want to consider to strengthen its *E. coli* sampling and testing program. We also reported concerns relating to FSIS' processes for assessing and controlling food safety risks in our Audit Report No. 24601-07-Hy, "Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments," issued in December 2007. FSIS has developed action plans to address the recommendations we made in that report.

We examined the actions FSIS already has in process to improve its *E. coli* sampling and testing program. We also solicited feedback from various stakeholders, including representatives from other USDA agencies, other U.S. Government entities with similar sampling and testing programs, meat industry representatives, colleges and universities that perform *E. coli* research, and the quick-service restaurant industry. These stakeholders provided testimonial input on *E. coli* sampling and testing methodologies.

In October 2007, FSIS announced a number of actions to improve its *E. coli* sampling and testing program based on the significant increase in *E. coli* positive test results, related illnesses, and recalls of potentially contaminated raw ground beef product during the year. Microbial testing is one of several activities FSIS uses to verify that meat processing establishments have designed their food safety systems to prevent food safety hazards, such as *E. coli*, from being a hazard in product entering

[1] You also asked us to provide recommendations to improve FSIS' processes for handling recalls and to determine whether FSIS is taking full advantage of its current statutory authorities to address recall situations. We are currently conducting an indepth review of FSIS' recall processes and expect to report those results to you by April 2008.

commerce. FSIS' *E. coli* testing program is not designed to provide a statistically valid assessment of the food safety system of an individual establishment, but rather to monitor the effectiveness of the *E. coli* O157:H7 pathogen reduction program on a national level. The number of samples that can be tested for *E. coli* is limited by the capacity of FSIS' testing laboratories. Currently, FSIS tests about 5 percent of the total raw ground beef produced annually, or about 11,600 ground beef samples and 3,000 trim and other ground beef component [2] samples from federally-inspected establishments. FSIS officials estimate that it costs $90 for an initial screening test and an additional $400 to confirm an *E. coli* positive test result. They also estimate an additional cost of about $16 for the inspector to collect each sample.

The actions proposed by FSIS will improve its *E. coli* sampling and testing program and provide necessary information to monitor the occurrence of the pathogen in product produced for commerce. However, we believe that strengthening the adequacy, timeliness, and effectiveness of other aspects of FSIS' Hazard Analysis and Critical Control Point (HACCP) verification activities would provide stronger assurance that establishments are properly identifying and controlling their food safety hazard risks. FSIS has also recently proposed actions to strengthen some of these other verification activities.

The following paragraphs provide our observations, input from stakeholders, and additional information FSIS may want to consider in strengthening its *E. coli* pathogen reduction program.

Key Methods for Controlling *E. coli* Contamination

- Interventions - Stakeholders interviewed agreed that *E. coli* is difficult to detect through sampling because it is present only sporadically at very low levels. Therefore, most concluded that validated interventions[3] are the key to controlling *E. coli* and ensuring a safe product. FSIS, as well as the industry experts, other Federal agencies, and academics we interviewed, stated that *E. coli* is primarily spread on the carcass during the hide removal process. This process is performed at slaughter establishments, the primary suppliers of beef to processors and grinders. After hide removal, validated interventions need to be employed and tested to effectively control contamination. Research performed by the Agricultural Research Service found that *E. coli* was present on about 76 percent of all animal hides coming into the sampled establishment. Measurements taken immediately after the hide removal indicated *E. coli* prevalence on carcasses of about 14.7 percent. However, after the application of validated interventions, the amount of *E. coli* was reduced to an undetectable amount.

- Establishment Hazard Risk Analysis and Critical Control Points to Mitigate Those Risks – OIG has consistently reported concerns with FSIS' assessments of establishments' risk control effectiveness (i.e., the adequacy and effectiveness of establishment HACCP plans).[4] Under HACCP, establishments are required to assess their food safety systems and determine

[2] Other components include such things as heart meat, head meat, cheek meat, and weasand (throat) meat.

[3] Validated interventions include actions such as hot water and acid washes, steam vacuuming, and steam pasteurization.

[4] Our recent Audit Report No. 24601-07-Hy, "Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments," again discusses concerns relating to FSIS' assessments of establishment risk control effectiveness.

if *E. coli* is, or is not, a hazard "reasonably likely to occur." Appropriate controls should be established to mitigate the hazard if an assessment is made that a hazard is "reasonably likely to occur." Recent FSIS investigations into some 2007 recalls disclosed that the establishments identified *E. coli* as a hazard "not reasonably likely to occur" in their HACCP plans. However, in these investigations, FSIS found that the processing establishments relied on faulty decisions and poor controls in making that determination. Consequently, these establishments employed insufficient controls or interventions to address the apparent likelihood of contamination. These establishments also identified *E. coli* as a hazard "not reasonably likely to occur" in beef from suppliers. FSIS found that the establishments relied on supplier certifications, were not consistently testing incoming inventory from suppliers, and/or were not verifying that suppliers tested their product using a consistent sampling design. These findings raise questions about FSIS' prior assessments and verifications of the adequacy of those establishments' HACCP plans and control processes. They specifically raise a concern that clearer criteria may be needed in evaluating the assumptions in establishment HACCP plans and the control processes in place based on those assumptions.

- Establishment Testing Programs - According to FSIS officials, when *E. coli* is found by FSIS' testing program, it is generally found by happenstance. These officials also stated that while the rate at which individual establishments are currently sampled (at most once a month) does not allow for a statistically valid determination of the effectiveness of the food safety system of an individual establishment in a given year, they believe their testing program has stimulated industry action to reduce the presence of *E. coli* in raw ground beef. Since the initiation of FSIS' testing program in 1994, many grinders and suppliers of raw ground beef components have instituted programs to routinely test their ground beef products or raw materials used in ground beef products for *E. coli*. OIG believes that establishment testing programs can provide valuable information to FSIS as to whether adequate food safety controls are in place, but only if consistently and timely monitored by FSIS.

- Mandatory Reassessment for *E. coli* Control - On October 12, 2007, FSIS issued Notice 65-07 directing its inspection personnel to meet with establishment personnel to inform them that, in light of the recent high *E. coli* prevalence season, establishments are obligated to reassess their hazard analysis and HACCP plans. FSIS asked its inspectors to document whether the establishment considers *E. coli* a hazard likely to occur, applies validated interventions, and tests source material prior to grinding by completing a checklist titled "Raw Beef Food Safety System," attached to the Notice. From the information obtained in the checklists, FSIS should be able to determine the number of establishments that are employing validated interventions and whether the controls in place at establishments support the determination of whether *E. coli* is, or is not, a hazard "reasonably likely to occur."

  FSIS believes that the checklist will provide information to help it more effectively allocate inspection resources and schedule sampling. It will also allow FSIS to determine the proportion of ground beef, trim, and other components tested by the processing establishments. FSIS officials stated that this information will be used to determine the frequency of FSIS testing as part of its proposed targeted *E. coli* sampling and testing

program.[5] FSIS also plans to use checklist data to adjust programs or policies as needed. FSIS personnel were scheduled to complete collection of the checklist data by the end of November 2007. However, as of January 24, 2008, FSIS was still following up to determine why inspection personnel had not completed the checklists for about 70 of about 2,100 establishments. FSIS expects to receive the checklists by the end of January. According to an FSIS official, the Data Analysis and Integration Group, which is part of FSIS' Office of Food Defense and Emergency Response program area, is primarily responsible for pulling the data together and developing a plan for analyzing the data.

We believe it is critical for FSIS to timely complete its analysis of the data gathered through its checklist, as well as use this data in the development of its planned targeted sampling and testing program. We suggest that FSIS establish reasonable timeframes and milestones to complete these actions. Our Audit Report No. 24601-07-Hy, "Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments," has already made a number of recommendations to improve FSIS' food safety assessments. We would encourage FSIS to closely monitor its planned corrective actions and timeframes for completing them. In regards to FSIS' oversight of establishment testing programs, FSIS' proposed actions for addressing the recent high prevalence of the *E. coli* pathogen do not acknowledge or specify how this data can be used by FSIS to better control systemic hazard risks. In October 2007, FSIS issued FSIS Notice 66-07 instructing inspection program personnel to collect multiple followup samples of raw beef products in response to an FSIS positive *E. coli* test result. FSIS might want to consider developing some criteria in its planned targeted testing program to perform targeted sampling if the testing programs conducted by establishments show consistent positive *E. coli* test results.

Industry Best Practices

In 2007, recalls by Topps and United Food Group disclosed that even large-scale producers need additional education and encouragement to ensure that best practices for controlling *E. coli* are implemented and are effective. FSIS is gathering best practices through its checklist to identify a set of best practice measures that, while not required, FSIS will consider essential for controlling *E. coli*. Currently, FSIS does not have a formal campaign for educating industry on best practices and encouraging implementation of these practices. However, FSIS has announced an information and education campaign as part of its recent action items for addressing the high prevalence of *E. coli* during 2007.

The American Meat Institute, which represents a significant portion of the industry, provides guidance and recommends best practices through a series of documents available through the Beef Industry Food Safety Council (BIFSCo) Website. Among other best practices, the BIFSCo documents state that validated interventions, together with an *E. coli* testing program, are critical. Major members of the food service industry have already adopted these best practices. For example, one food service industry member (1) requires at least two critical control points (CCPs) for controlling food safety hazards at each supplier location, one of which is an *E. coli* related intervention; (2) requires its suppliers to conduct product sampling every half-hour; (3) requires two different audits and/or reviews at suppliers each year, one independent and one internal; and

[5] In October 2007, FSIS announced that it planned to begin routine targeted *E.coli* sampling at slaughter and grinding facilities in January 2008.

(4) maintains an extensive inventory system that labels, records, and processes each product received by time, date, type of product, and supplier to ensure that all product could, if needed, be timely traced back to the original source.

FSIS needs to fully utilize the data from the checklist to develop or enhance its current list of best practices. FSIS should also formalize its campaign for educating industry on best practices and encourage their implementation.

Improving Quality and Efficiency of Sampling and Testing for *E. coli*

Although FSIS has made improvements to its *E. coli* sampling and testing program over the last decade, it does not have a formal, continuous program to identify ways to improve its sampling and testing methods. Since FSIS began its *E. coli* sampling and testing program in 1994, FSIS initiated actions to improve the sensitivity of tests to detect *E. coli* at lower levels. Specifically, FSIS has (1) increased the amount analyzed from a 25 gram sample to a 325 gram sample to provide increased detection sensitivity (October 1997), (2) introduced a new selection and detection method to further increase test sensitivity (September 1999), and (3) introduced a new screening method to reduce the number of screen positives that do not confirm positive (October 2005). In February 2008, FSIS plans to begin using a newly developed sample preparation process for *E. coli* testing—a new enrichment broth will be incubated at 42 degrees Celsius to increase test sensitivity.

Because *E. coli* is difficult to detect and is sporadically present at very low levels, FSIS' sampling and testing methodologies should be continuously assessed for new testing methods, as well as ways to improve the efficiency of its sampling and testing procedures.

- Gathering a More Representative Sample - The experts we interviewed agreed that *E. coli* is not randomly distributed throughout the product. Regardless of the number of samples tested, the pathogen's existence cannot be detected in all cases nor can the prevalence be determined and projected to the total production in a particular lot or on a given day. According to FSIS and other experts, there is no scientific basis for any volume of sampling and testing other than 100 percent testing of all products all the time, which is unrealistic and cost prohibitive. There is also no feasible sampling plan that can ensure the complete absence of the pathogen; it cannot be guaranteed that the lot is completely free of the organism no matter how large the number of sample units.

  However, industry experts, academics, and other USDA agencies involved in food safety widely believe that multiple samples taken from the same product lot over a period of intervals throughout the day can provide a more "representative sample." This is the preferred method used by the Agricultural Marketing Service, large food service industry members, and other large establishments. This approach would be a challenge for FSIS to implement considering its available resources. FSIS' *E.coli* testing program at processing and grinding establishments is limited to the amount of time the inspector spends in each assigned establishment, which generally precludes sampling in intervals throughout the daily production cycle. Implementing this recommended procedure across all 1,400 federally-inspected establishments that produce raw ground beef would require a substantial increase in inspection personnel or the development of an alternative means for these collection

strategies or techniques. FSIS should still, however, pursue the feasibility of having this sampling methodology implemented by industry.

- Minimizing or Eliminating Discarded Samples - One limitation in FSIS' testing program is the proportion of samples collected that are discarded and never tested. Of the 22,472 ground beef and trim[6] samples collected,[7] 7 percent (1,547 out of 22,472) were discarded and not tested for *E. coli* by FSIS. Samples are discarded and not tested when, for example, they are mailed to the wrong laboratory or when incorrect or incomplete documentation accompanies the sample. FSIS recognizes the need to reduce the number of discards and plans to issue a new procedure emphasizing the proper methods for collecting and sending samples to laboratories for analysis. FSIS also acknowledges the importance of enhancing its monitoring of inspectors' performance in this critical task. We suggest that FSIS develop appropriate processes to minimize or eliminate discarded samples and establish controls to ensure that inspectors are complying with sampling requirements.

- Reducing Turnaround Time on Laboratory Results - FSIS acknowledges there is a time lag between collecting a sample and providing the testing results to inspectors and establishments. Industry representatives expressed concerns that the FSIS sampling and testing program has an economic impact on them. This impact relates to the costs of removing product from income generating distribution and holding product until testing results are known. Industry representatives stated that they usually receive results from their own *E. coli* screening tests in 1 day. In contrast, FSIS usually takes 48 hours, or 2 business days, to report screening test results and can take longer if a sample is taken on a Friday. Because establishments often hold product tested by FSIS until the results are received, industry representatives stated that product is often diverted to cooking or rendering to gain any salvage value in lieu of spoilage. The longer product must be held, the more costly FSIS testing is to the industry.[8]

  In addition to the industry economic factor, there is an increased risk that public health concerns will not be timely investigated and addressed, either through appropriate enforcement actions or recalls. FSIS should determine if more efficient sample collection and testing procedures can be implemented to minimize the time for reporting *E. coli* test results.

We have discussed these issues with FSIS officials. They advised us that they are committed to the timely implementation of their plans for updating establishment food safety assessments, analyzing establishments' reassessments of their interventions and *E. coli* controls, and using this data to develop its targeted sampling and testing program. We believe these actions, if timely and effectively implemented, will strengthen FSIS' HACCP verification activities and have a positive impact on identifying and mitigating food safety risks.

If you have any questions, or would like to discuss these issues, please do not hesitate to contact me at (202) 720-8001, or Robert Young, Assistant Inspector General for Audit, at (202) 720-6945.

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[6] The first trim sample was collected on April 13, 2007.
[7] Scheduled sample dates from January 1, 2006 – September 30, 2007.
[8] This review was not designed to confirm industry's assertions of the economic impact or its actions to mitigate costs.