

SUMMARY FINDINGS - *E. coli* O157:H7 REASSESSMENT :

1. Did the establishment reassess its HACCP plan(s) based on the relevant scientific data cited in the *Federal Register* notice? YES NO

2. Did the establishment change its HACCP plan(s) as a result of considering the new scientific data cited in the *Federal Register* notice? YES NO

3. If YES, how were the HACCP plan(s) modified? (Check all that apply)

- A. The hazard analysis was modified to recognize that *E. coli* O157:H7 is a hazard reasonably likely to occur.
- B. The HACCP plan was modified to include microbial intervention(s) as CCP's. (describe the interventions in your narrative report)
- C. The HACCP plan was modified to include a statistically valid microbiological sampling program for *E. coli* O157:H7 to verify the effectiveness of the intervention(s) (CCP's).
- D. The HACCP plan was modified to include a CCP requiring its suppliers certify that all lots of raw materials received are subjected to a validated intervention and have tested negative for *E. coli* O157:H7.
- E. Other (describe below in narrative)

4. If the HACCP plan(s) were not changed, what was the reason(s) the plan(s) were not changed? (Check only one item)

- A. The HACCP plan was not changed because prior to the *Federal Register* notice the establishment had already considered *E. coli* O157:H7 as a hazard reasonably likely to occur.
- B. The establishment concluded, even after considering the new scientific data cited in the *Federal Register*, *E. coli* O157:H7 is still not a hazard reasonably likely to occur in its process.
- C. Other (describe below in narrative)

5. Did grinding establishments incorporate controls into their Sanitation SOP's or other prerequisite programs? (Check all that apply)

- A. The SSOP was modified to include specific controls for *E. coli* O157:H7. (Please describe the controls in narrative below.)
- B. Other prerequisite programs were modified to include controls for *E. coli* O157:H7. (Please specify which program and how in narrative below.)
- C. The establishment either had in place or incorporated purchase specifications for suppliers to test all lots of raw materials under a prerequisite program, and shares records with inspection personnel.
- D. The establishment either had in place or incorporated temperature controls under a prerequisite program to ensure no growth of *E. coli* O157:H7, and shares records with inspection personnel.
- E. Other (describe below in narrative)

NARRATIVE:

The establishment performed a reassessment of their HACCP and SSOP programs prior to June 09, 2003 as a result of FSIS Notice 44-02. The modified their HACCP program

identifying *E. coli* O157:H7 as a potential hazard to their beef processing operations. The plant created a prerequisite program for purchase specifications for all raw beef entering the establishment. This program has two components, the first requires that their suppliers of beef products fully comply with the contents of Notice 44-02 and provide the establishment how this is accomplished. The second component requires all shipments of beef trim must be accompanied with a negative test result for this pathogen.

Entrance Meeting

An entrance meeting was held at the establishment on October 06, 2005 at 0930 hours. Mr. Anthony D'Urso, Executive Vice President/Chief Operating Officer; Mr. David Cohen, Chief Executive Officer; Dr. John Specchio, (Professor of Food Science, Montclair State University), Establishment Consultant (letter on file); Mr. Geoff Livermore, Plant Manager; Mr. Charlie Chieng, QA Manager; Mr. Charles Harris, Front Line Supervisor; Mr. Louis LaBrutto, CS, JIC; and me, Mr. Thomas Urban, ELAO; were present. At this meeting I informed everyone present how I would be conducting a Comprehensive Assessment of the Food Safety systems in operation and that this would include assessing the Sanitation Standard Operating Procedures (SSOP); the Hazard Analysis Critical Control Point (HACCP) system; any supporting and decision making documents; any pre-requisite programs; any microbiological test data; the past 4 months of records generated by these systems; any pest control program and records; and any other records or documentation needs that may arise during the assessment. I informed everyone this assessment was at the direction of the District Office with emphasis on assuring the establishment is properly addressing *E. coli* O157:H7 in their production practices and programs. I informed plant management that we, USDA and plant personnel, were all part of a total food safety team and that we were all there to ensure that the establishment produces a safe and wholesome food product. Mr. Cohen, Mr. D'Urso, and Dr. Specchio elaborated on the management team's dedication to producing a quality, safe product and would be available to assist me with whatever I needed to perform the assessment. I informed plant management that at the end of my assessment there would be an exit meeting and at that time I would inform them of what my recommendation to the District Office would be as a result of my findings. At this time I answered any questions from the assembled team and informed everyone that I would be available to all as a source of information and guidance. Mr. Harris and Mr. LaBrutto provided closing remarks properly reflecting the FSIS mission and their dedication to ensure the establishment meets all regulatory requirements.

Escherichia coli O157:H7

The establishment has recognized this pathogen, *E. coli* O157:H7, as a potential hazard in the production of their raw meat food products. The hazard analyses identify a "Supplier Certification Program" as a control for incoming beef products. This program requires all suppliers of beef products to adhere to FSIS Notice 44-02 and supply letters outlining how they comply with the Notice for eliminating or reducing this pathogen to undetectable levels. The program also requires suppliers of beef trim to provide certificates of analyses (COA) for each lot shipped to Est. 09748.

A review of all records associated with this program identify that of the thirty-three (33) suppliers of beef products from 7/20/2005 through 10/05/2005 there were four (4) suppliers of foreign beef which had no letters of guarantee. These four foreign suppliers of beef products which failed to provide such letters originated in Australia. The establishment was issued an NR from the LIC for this failure to meet regulatory requirements of 417.5. During a briefing on 10/06/05 of this finding, the management team stated they would not be accepting any beef products from these suppliers until the establishment could verify the appropriate letters are on file.

On 07/01/05 the establishment received ten combo bins of *E. coli O157:H7* positive product from Est. 562M. Topps Meat personnel was notified by Est. 562M that it had inadvertently shipped them this product which was destined for a cooking facility. At the time of notification Topps stopped all production and identified that five of the combo bins of beef trim had been processed into hamburgers in the grinding room. Plant management notified FSIS inspection personnel and requested guidance. Topps did not resume any processing operations for the day (there were other processing rooms which did not have the product but Topps elected not to take any chances). All affected product was condemned. Product processed in other rooms which were not part of the affected lot was put on hold and tested for the pathogen to verify cross contamination did not occur. Intensified cleaning was conducted in all processing areas and any other areas that the contaminated product may have passed through. Investigation by both establishments identified that labeling procedures (size and placement) and shipping procedures were the cause. Topps provided preventive measures included in-depth training of all receiving personnel, personnel who jockey product around the establishment, and supervisors on how to identify all pertinent information which is required on each product box or bin. Corrective actions and preventive measures were evaluated by inspection personnel and found acceptable.

On October 3, 2005 I was informed that a young child in New York state (NY Outbreak case # 05-01-21) contracted *E. coli O157:H7* and I started my investigation of the incidence. Here is the information and my findings related to the case:

Illness overview:

- A child residing in Albany County, NY, with *E. coli O157:H7* was reported to the New York Department of Health (NYDoH); onset of illness was 09/02/05. Illness is severe, with hemolytic uremic syndrome.
- NYDoH interview with family revealed consumption of undercooked ground beef patty approximately 1 to 3 days prior to illness, with no other likely exposures.
- Family had the remainder of an open container of product and an Albany county environmental health employee delivered it to state laboratory for testing on 9/16/05.
- The product, Topp's 100% Pure Ground Beef Hamburgers, 12 Quarter Pounders, was purchased frozen. The container was embossed with "Sell by July 19 06 1st 08207", this was the identifying lot information for production date July 19, 2005. Also on the container was "BAC-05-6878 Sep 16, 2005", this was a package identifier applied by the NYDoH for laboratory sample identifier purposes.

- The producing establishment, as identified on the container, is Est. #9748, Topps Meat Co., LLC, Elizabeth, NJ.
- The family purchased the product at one of two locations: Price Chopper at 329 Glenmont Road, Glenmont, NY or at Wal Mart located at 311 Rte 9W, Glenmont, NY. Date of purchase was not available.
- NYDoH visited the Price Chopper store and found no like code products. NYDoH also visited distribution centers for both potential source stores and found no like products.
- NYDoH obtained specimens from the patient which tested positive for *E. coli* O157:H7.

Sample testing:

- On 9/29/05 NYDoH stated a product sample was taken from a patty located from the upper row in the product package. Another sample was collected from an "interior" patty on 9/29/05 as requested by the USDA. Results of patient testing and product testing (both product samples) were positive for the pathogen.
- Product samples were confirmed positive for *E. coli* O157:H7 by slide agglutination and stx PCR.
- As of 10/21/2005 NYDoH laboratory stated the positive samples had indistinguishable 2-enzyme PFGE pattern matches.
- This was not an intact product package, arrived at the NYDoH lab cold, not frozen and kept under refrigeration at the lab.
- OPHS Microbiology Division assessed NYDoH laboratory methods as likely less sensitive than FSIS protocols.

Establishment actions:

- The establishment on 10/3/05 initiated a mock recall of all products with the proper code date.
- Investigations made through product distribution and sales people which included on-site visual inspection, revealed no available like coded product in commerce or retail. Company intent was to put any like product on hold, obtain intact packages for pathogen sampling, and direction from FSIS.
- Production records revealed 134,526 pounds of like product were processed on 7/19/05 and shipped. A large portion of this production lot was shipped as fresh. The number of beef patties represented by the production volume was approximately 538,134 patties at 4 ounces each.
- The establishment reassessed their HACCP and SSOP programs for *E. coli* O157:H7 on 10/05/05. Reassessment of the HACCP Raw, Ground plan included reevaluation of the plant pathogen prerequisite program. The establishment determined the programs were current and effective. The plant did identify they lacked four letters from suppliers of foreign beef but no foreign beef was used for the potentially affected production lot.
- Company shipping records were reviewed for completeness with attention to receiving logs for product used on 7/19/05, Certificates of Analysis for product used, and current *E. coli* letters from suppliers. All information was found to be current and complete.

- Establishment reviewed lab analyses from samples collected from the past 12 months and found all samples were negative for this pathogen.
- The establishment increased frequency for verification sampling for the pathogen from four times yearly to monthly.
- The establishment contacted their consultant, Dr. John Specchio, Professor of Food Science, Montclair State University for professional guidance and assessment. Dr. Specchio researched all information provided by the company and assessed the potential of product contamination. Dr. Specchio presented the statistics that of approximately 538,134 beef patties produced on 7/19/05 there was one illness likely from a beef patty and two more patties tested positive for the pathogen in the same three pound box containing 12 patties. No other illnesses were associated with the other 534,131 patties produced by the establishment which he reasoned had more than likely been consumed. Dr. Specchio applied these statistics and the standard deviation and concluded that the likely source of contamination was after package integrity was broken.

My investigation included:

- Review of company records including information of source material suppliers (National Beef Packing, est. 208A; Moyer packing, est. 1311; and Beef Products, Inc., est. 19872) with current guarantee letters on file and certificates of analyses on product of trimmings used.
- I verified that Topps generic *E. coli* test results for 7/19/05 were not excessive (Less than 3 colony forming units).
- Lab analyses from the NYDoH associated with the identified *E. coli O157:H7* positive case patient (NYDoH outbreak #05-01-21)
- Information provided by the NYDoH laboratory and Albany county health officials from their investigations related to outbreak #05-01-21.
- Company HACCP and SSOP plans and associated programs.
- Company HACCP and SSOP records and in particular for the day of 7/19/05.
- Production records and shipping records.
- Information provided by the department of Health and Human Services from both the headquarters office and the Omaha office.
- Plant history and proactive actions related to this production date.

My evaluation of all company records, programs, and materials identified there were no weaknesses or failures in their *E. coli O157:H7* programs or controls for the day of 7/19/05, all company records were complete, and though the company found no evidence that Topps was the direct or root cause of the pathogen source, they took a proactive approach.

SSOP

The current SSOP plan was initiated on 04/10/03. The latest reassessment was 10/28/04. The establishment utilizes an outside contractor for post production cleaning and sanitation procedures. Establishment management verifies the daily sanitation pre-operational and operational practices and procedures are applied and effective.

The programs and procedures met regulatory requirements and were easy to understand. Establishment inspection personnel identified some facilities deficiencies in the past 10 months which provided potential sanitation issues. The company addressed all issues through immediate corrective actions and an ongoing Plant Improvement Program (PIP). The company PIP program is discussed with inspection personnel during regular meetings and updates are provided in writing.

HACCP

The establishment produces ground beef, mainly in patty form, ground turkey, portion controlled cuts of beef, and shish-kabobs. The process categories are: Raw, Ground; and Raw, Not Ground. Product is shipped fresh or frozen. Grinding operations produce between 130,000 -- 160,000 pounds of ground beef per production day, five days per week. Poultry processing is very limited with ground turkey produced only 3-4 days per year in 115,000-120,000 pound lots, and chicken kabobs produced on limited seasonal occurrences. Beef and poultry is not produced in the same rooms on the same days.

Revisions on HACCP plans were conducted on: 07/05/05 for the unintended receiving of *E. coli* O157:H7 positive product; 08/22/05 for the use of allergens; and on 10/05/05 to reassess the est. *E. coli* O157:H7 programs and controls.

The plan CCPs were:

- CCP1B -- Monitoring meat storage of all coolers and freezers.
- CCP1P -- Monitoring foreign material during processing.
- CCP2B -- Monitoring temperature during processing.
- CCP2P -- Metal Detection.
- CCP3P -- Monitoring foreign material at packaging.
- CCP3B -- Monitoring finished product storage.

Both HACCP plans met regulatory requirements and were well written.

In regards to Poultry Processing:

BACKGROUND AND HISTORY

The reason for the FSA was District direction to ensure *E. coli* O157:H7 was properly addressed.

Poultry Processing information:

- a. Chicken and turkey are processed
- b. Turkey is limited to grinding 3-4 days per year
- c. Chicken is limited to kabob production on a limited seasonal basis.
- d. further processing: Simple

ASSESSMENT OF POULTRY FINDINGS

a. SSOP

- i. The facilities were very well maintained and kept in a sanitary manner and were addressing some facilities issues on a Plant Improvement Program.
 - ii. Production processes were adequate to prevent the adulteration of products and provided a flow that was free from product pile-ups or mutilation.
 - iii. No reprocessing or salvage operations are conducted. Contaminated products are plant condemned.
 - iv. Processing operations is limited to very simple cut-up and grinding. The minimal processing of product limits the potential sanitation problems.
 - v. Records show no history of microbial problems at the establishment.
 - vi. *Salmonella* is not identified as a pathogen of particular concern in the SSOP, the establishment identifies all pathogens as food safety concerns.
- b. Assessment of the SPS through plant tours, observing sanitation procedures and records, microbial sample results, and the aggressive nature of plant management in applying proper sanitary practices reflects an effective SSOP and dedication in meeting the SPS.
- c. The flow charts for the (2) HACCP plans are all complete with no steps missing and is clear and easy to follow the flow of processes.
- d. The Hazard Analyses for the HACCP plans meets regulatory standards for all process steps.
- f. HACCP monitoring activities meet or excel expectations for the processes involved. Frequencies for monitoring activities meet proper guidelines and support.
- g. Verification activities for CCPs are at a frequency which excels. Verification activities are almost as frequent as monitoring. Management stated that this is to ensure that there is no question about monitoring results and provides an effective means of checks and balances.
- h. Records for monitoring and verification reflect no recordkeeping failures for paperwork reviewed from 04/03/05 through 10/06/05. All other associated records for HACCP and SSOP document a very prudent Quality Control department which is supported by a very "hands on" management team.
- i. Corrective Actions are properly addressed during HACCP deviations and any monitoring findings. The HACCP plans fully meet regulatory requirements for corrective actions.
- j. The establishment conducts proper reassessments. During production modifications reassessments were also properly performed and documented. All team members have been thoroughly trained on-site and through certified HACCP courses to provide the establishment a very well informed team.
- k. The Generic *E. coli* process meets Agency guidelines.
- l. *Salmonella* is addressed in the establishment's HACCP plan within the hazard analysis. USDA *Salmonella* Performance Standards are being met at this establishment with no findings of "Set" failures.
- m. General Microbial Testing at the establishment confirms the establishment is maintaining proper sanitary standards and properly addressing biological hazards within its processes.

n. The establishments antimicrobial processes are effective in keeping biological hazards in check. Due to aggressive sanitation and processing procedures, biological hazards are maintained at very low levels so the use of antimicrobials is mainly to minimize growth potential of pathogens.

IV. CONCLUSION

Due to several factors which include a hands on, dedicated management team; professionally trained Quality Control department; properly trained processing employees; regular reassessments/audits from a consultant; and overall pride in the products they produce this establishment meets or exceeds regulatory requirements and guidelines. Sanitation and HACCP concerns are fully meeting and properly address pathogens of concern. The establishment was provided a prior CSO assessment followed by a 30 Day Reassessment Letter issued on June 12, 2003 for limited basic design issues. All concerns were properly addressed. Audits by a third party professional consultant also have identified minor deficiencies which immediately get addressed. This has provided very well rounded plans that meet all concerns. The establishment only accepts turkey products from two suppliers and one chicken supplier. This establishment is in the development stage of implementing a poultry program similar to a beef E. coli O157:H7 program for suppliers. They intent do have the program in place by year end. This program would require suppliers of poultry products to provide a letter to Topps which outline how the supplying company identifies, controls, reduces, and records the practices and programs in place to reduce or eliminate *Salmonella* and other pathogens in processing operations. The company is excited about working on this project and how they might be able to help improve standards and concern related to poultry processing operations nationwide by being a cutting edge leading example.

V. RECOMMENDATION

No further action is recommended at this establishment by our program personnel.

Exit Meeting

An exit meeting was held at the establishment on October 24, 2005, at 1300 hours. Mr. David Cohen, Chief Executive Officer; Mr. Anthony D'Urso, Executive Vice President/Chief Operating Officer; Dr. John Specchio, (Professor of Food Science, Montclair State University), Establishment Consultant (letter on file); Mr. Geoff Livermore, Plant Manager; Mr. Charlie Chiong, QA Manager; Mr. Charles Harris, Front Line Supervisor; and me, Mr. Thomas Urban, EIA(); were present (Mr. Louis LaBrutto, PIC, CSI, was attending a funeral). Mr. Harris opened the meeting commending the open working relationship plant management maintains with inspection personnel and as witnessed during the assessment. Mr. Harris also acknowledged the quick response by the company to NYDoH case #05-01-21 and the company's proactive approach. During this meeting I presented my findings and observations. I thanked the inspection team and management team for their help and support during the assessment. Mr. Cohen stated his

company's position as it relates to the dedication to his customers, the public welfare, and in producing a quality product. Dr. Specchio emphasized the pride he and plant personnel have in their facility and products. I closed with providing an invitation to call upon me for future reference and guidance to regulatory issues and for the establishment to also use the local inspection team and the Technical Service Center.