U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF FIELD OPERATIONS

COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS

EST. NO. 09748 M

DATES CSO VISITED EST. FROM: 09/27/2007 TO: 10/03/2007

NAME AND ADDRESS OF ESTABLISHMENT
Topps Meat Co. Inc.
1161 E. Broad St.
Elizabeth, New Jersey 07207

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NAME OF EIAO:

DISTRIBUTION INSTRUCTIONS:
Submit this report to your District Manager and the Front-Line Field Supervisor via email.

DISTRICT: Philadelphia-60

CIRCUIT VISITED: Elizabeth- 20

REASON FOR VISIT (Check all that apply):

- [✓] A. District Office Direction
- [ ] B. Consumer Complaints
- [✓] C. Foodborne Illness
- [ ] D. Foreign Particle Contamin.
- [ ] E. Repetitive Lm
- [ ] F. STEPS-triggered Sample Form #
- [ ] G. Salmonella Performance Standard Failure
  - [ ] A set
  - [ ] B set
  - [ ] C set
- [ ] H. Other *(Specify)*: E.coli O157:H7

SUMMARY OF DATA ASSESSMENT PRIOR TO VISIT:

Grant of Inspection- dated 5/23/2005- update to show change of officers and to add another name - Butcher's Best.

Application of Federal Meat Inspection- dated 5/13/2005 - updated to show addition of D/B/A Name.

Reviewed prior assessments conducted by EIAOs.

Checked FSIS website for information on illnesses in Florida and positive results for E. coli O157:H7

Reviewed Noncompliance Records from 1/1/2007 to present.

RECOMMENDATIONS:

- [ ] A. No action needed
- [ ] B. 30 day reassessment letter
- [ ] C. NR5 written by in-plant
- [✓] D. NOIE
- [ ] E. Suspension/Withdrawal

F. Summary of reason(s) for recommendation:

See Attachment

NARRATIVE: Attach/Save an MS Word document with the full narrative to this PDF

Entrance Meeting

On Thursday 9/27/2007 I resumed the food safety assessment concentrating on the Raw Not Ground process. My objective was to examine the trimming operation as it related to the production of trimmings that had gone into the raw ground operation. I also focused on the production of steaks and kabobs as it related to the use of mechanical tenderizing equipment and to see if the establishment had conducted reassessment to analyze how they considered E. coli O157:H7 in the use of this type of equipment.

Prologue

On August 31, 2007, a consumer complaint (case # 6096-2007) was filed in Florida reporting an illness from the consumption of a hamburger patty produced on July 12, 2007, at Topps Meat Co. Inc. located in Elizabeth, New Jersey. The illness was reported to be from possible contamination by E. coli *O157:H7*. The illness was confirmed positive for the pathogen by the Florida Dept. of Health on September 4, 2007. During the next few weeks additional illnesses were reported by NY and other States. As a result of these incidents a Food Safety Assessment with emphasis on the raw ground process was scheduled to be conducted at the establishment. NY State reported positive E.coli *O157:H7* results of intact packages collected in response to the illnesses. Topps initiated a voluntary recall of all products produced on production dates June 22, July 12, and July 23, 2007. Subsequently NY tested an intact sample of production for June 21, 2007, which resulted positive for E.coli *O157:H7* and FSIS completed the comprehensive review with emphasis on the raw ground process. The assessment revealed sufficient evidence to support a Notice of Suspension. Topps could not support decisions made in the HACCP plan to prevent the production and shipment of product that is adulterated with E.coli *O157:H7*. The Suspension action was initiated on September 26, 2007. Topps voluntarily expanded the recall to include all products with an unexpired sell-by date in response to these findings. The establishment also produces product under a Raw Not Ground (03C) process. This includes flat ironed and cubed steaks, needle tenderized meat cuts, kabobs and vacuumed tumbled products. They also produce portion controlled products. Kabobs are made from bell peppers, onions, mushrooms skewered with chicken, beef, pork or sausage (raw). On September 27 through October 2, 2007, a comprehensive assessment was performed with emphasis on the raw not ground operation and revealed the following:

Raw Material Handling

Raw materials in the form of sub-primal parts are received in combo bins and used directly in the grinding operation and also in the raw not ground operation. Materials received in combo bins are to be accompanied by a Certificate of Analysis (COA). These certificates support that this particular lot has been tested and found negative for E. coli O157:H7. Boxed sub-primal products received are packaged in cryovac and do not receive any COA's. Letters of Guaranty (LOG) accompany this type of product which state that the producing firm has in place one or more CCPs in their HACCP plan that address E. coli O157:H7 and/ or identify an intervention step for controlling or eliminating the pathogen.

In addition, sub-primal parts from boxed product are used to produce steaks and diced products under the raw not ground process. The trim from this procedure is diverted into the raw ground

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operation. These sub-primal products do not carry COA's and are not subject to any rigorous testing for the presence of E.coli O157:H7, because they are not intended for use in a grinding operation.

The establishment produces trimmings from sub-primal parts in a cutting operation. These trimmings are added to the grinding operations without testing of the trimmings for E. coli *O157:H7*. According to the documented reassessment [redacted] 12/20/02) in response to the October 2, 2002, Federal Notice (67 FR 62329), [redacted] subsequent sanitation and temperature control. A further recommendation was [redacted]

- Testing of the trim that is utilized in the raw ground operation is not being conducted. Topps failed to consider the recommendation of their consultant. Also, there is no supporting documentation to prove that any raw beef used in a grinding operation accompanied by a LOG is sufficient to prove that E. coli *O157:H7* is not present. Letters of Guaranty do not provide any measure of confidence that the product used in the grinding operation has undergone any rigorous testing to prove it is free of the pathogen. This raises concerns as to the safety of these trimmings. The plant has failed to meet the requirements of **9 CFR 417.5 (a) 1.**

E. coli *O157:H7* Testing

The establishment tests for E. coli *O157:H7* [redacted] times per year on incoming raw product to be used in the grinding operation only. There are no documents to show that products used for the manufacturing of raw not ground products are being tested at this facility. This is a concern since the establishment conducts processes using mechanically tenderizing equipment that penetrate the outer surface of the whole muscle and can potentially cross contaminated the interior portion of the product. This fails to meet the requirements of **9 CFR 417.5 (a) 1.**

The establishment processes products using Mechanically Tenderizing equipment. Federal Register Docket # 04-042N HACCP Plan Reassessment for Mechanically Tenderized Beef Products discussed the occurrence of outbreaks of E. coli *O157:H7* as a direct result of beef products that were processed using mechanically tenderizing equipment. Therefore, as part of this concern, establishments were required to perform a reassessment of their HACCP plans in light of the outbreaks of E. coli *O157:H7*. Part of the reassessment was to consider whether the plants adequately addressed biological hazards, in particular E. coli *O157:H7* and evaluate whether these reassessments were adequate. The establishment should also verify with their suppliers that raw material intended to be used in this process re-evaluated their HACCP plans in light of this concern. The plant has failed to meet the requirements of **9 CFR 417.2 (a) 1.**

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There is no documentation to show that the establishment considered this information or re-evaluated their HACCP plan as required by Federal Register Docket #04-042N. There is no documentation to show the plant verified that their suppliers considered this issue in their HACCP plans. The establishment failed to meet the requirements of **9 CFR 417.2 (a) 1.**

Hazard Analysis Critical Control Point (HACCP)

Raw Not Ground (03C)

The establishment produces various products under this process category including beef cubed steaks, beef for stew, beef julienne, beef for fajita, flat iron steak, portion control beef products and kabobs (beef, chicken, pork and sausage). Kabobs are made with bell peppers, mushroom, onion and seasoning. These products are to be cooked prior to consumption. They have a shelf life of 12 months at 0°F or below. They are sold at retail, food service, wholesale and to the general public. Their labeling consists of keep frozen, cooking instructions, safe food handling and nutrition facts.

Raw materials are received into the establishment; either boxes or bins and trimmed. Bins are accompanied by supplier COAs; boxes are not. Boxes have LOG from the supplying firm that indicates that the establishment has CCPs in place that address the control of E. coli O157:H7 in their HACCP plans. Trimmings from the operation are

There were no records to support the company's 12 month sell-by shelf life.

Note: There is no documentation to support the Critical limit and the shelf life. The sell-by contradicts the CCP critical limit. This is a failure to meet the requirements of **9 CFR 417.5 (a) 1.**

Flow Chart/ Hazard Analysis

There are t addressed in this section;
for kabob type products (beef, chicken, pork and sausage
from a federally inspected establishment. The product is th

The flow chart for portion controlled products identifies several key steps in the process including (CCP , (CCP and CCP). The includes not identified as such in the flow chart or hazard analysis). The includes

The flow chart for kabob type products identifies steps such as

The hazard analysis identifies all of the steps listed in the flow chart. However, the following were noted during the review:

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- The [redacted] identifies E. coli O157:H7 as a hazard not likely to occur. This is the only step that the pathogen is addressed.
- The establishment did not take into account the prevalence of E. coli O157:H7 during the summer months in light of Federal Register (67 FR 62329) which informed manufacturers of raw beef products, that they were required to reassess their HACCP plans, in light of certain scientific data on E.coli O157:H7 to determine whether E.coli O157:H7 contamination was a hazard reasonably likely to occur in their production process in the hazard analysis. This fails to meet the requirements of **9 CFR 417.2 (a) 1.**
- The [redacted] identifies microbial growth as a potential hazard that is not likely to occur because the plant's GMP and SSOP will reduce the likely occurrence to an acceptable level. A review of the plant's SSOP describes the [redacted] Floors and drains are sanitized using [redacted] and equipment and product contact surfaces are sanitized using a [redacted] The establishment has produced a document for [redacted] that states that when used as directed the product is an effective sanitizer against Escherichia coli, Escherichia coli O157:H7, Staphylococcus aureus, Yersinia enterocolitica and Listeria monocytogenes.
- The [redacted] used for sanitizing equipment and food contact surfaces can be used in all processing plants. It is accomplished by [redacted] Food processing equipment should be sanitized just prior to use. Contact time should be [redacted] or higher. Plant management states that the sanitizer is being measured and tested daily using a test strip after application to the surfaces but they are not recording the results. Additionally, the time and ambient temperature is not being documented to show that manufacturer's recommendations are being followed. The establishment has failed to meet the requirements of **9 CFR 417.5 (a) 1.**
- There are no documents to support the use of sanitizers ([redacted]) or their strengths as affective agents to control or eliminate E. coli O157:H7. This fails to meet the requirements of **9 CFR 417.2 (a) 1 and 9 CFR 417.5 (a) 1.**
- Allergens are identified at the [redacted] and is a hazard not likely to occur based on an allergen control procedure. This is a pre-requisite program. The written procedure addresses instructions that are to be followed when receiving ingredients that may contain allergens, segregation to prevent cross-contamination, inventory control in storage and proper labeling of product. According to FSIS Notice 45-05 dated 7/7/05 VERIFICATION OF ACTIVITIES RELATED TO AN ESTABLISHMENT'S CONTROLS FOR THE USE OF INGREDIENTS OF PUBLIC HEALTH CONCERN establishments are to identify which products may contain ingredients that cause adverse reactions in their flow chart and hazard analysis and adequately incorporate into its food safety systems (i.e., HACCP plans, Sanitation SOPs, or prerequisite programs) procedures for properly formulating products, applying the appropriate label, and accurately labeling the product to fully disclose the use of all ingredients, particularly those that may cause adverse reactions. The plant has not identified what products contain allergens in their flow chart or hazard analysis as required by FSIS Notice 45-05. They have also failed to meet the requirements of **9 CFR 417.2 (a) 1 and 2.**
- In the [redacted] which includes bell peppers, onions and mushroom the biological hazard states, "none". Because these are fresh vegetables, there

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are inherent hazards associated with them; including E. coli O157:H7. The establishment has failed to address this at this step as required by **9 CFR 417.2 (a) 1.**

- At the [redacted] is one of the activities. Vegetables (onions, peppers and mushrooms) [redacted] This is a unique process and therefore needs to be separated out and a hazard analysis that is specific to the process needs to be conducted. This can be applied to the other processes identified at this step including [redacted] The establishment has failed to meet the requirements of **9 CFR 417.2 (a) 1 and 2.**
- The establishment failed to consider raw vegetables as a potential source of pathogens in the hazard analysis as required by **9 CFR 417.2 (a) 1.**
- The establishment has [redacted] but has not identified hazards likely to occur at that step such as anaerobic pathogens of concern (i.e. C. *botulinum*) and have not met the requirements of **9 CFR 417.2 (a) 1.**
- The flow chart does not include production of "bench trim" from the [redacted] and its inclusion into the [redacted] The plant has failed to meet the requirements of **9 CFR 417.2 (a) 2.**
- The plant has failed to perform a hazard analysis for the production of "bench trim" for the purpose of inclusion into the [redacted] as required by **9 CFR 417.2 (a) 1.**

HACCP Plan

The establishment has identified [redacted] CCPs in the hazard analysis; [redacted]

[redacted]

The hazard identified is Microbial Growth. The Critical Limit is [redacted]
Environmental temperature is obtained by [redacted]
If a deviation from a critical limit occurs, corrective action will be taken to ensure all requirements described in CFR 417.3 are followed. [redacted]

[redacted]

- There are not documents to support the time and temperature ranges identified in the HACCP plan as sufficient to preclude microbial growth or why [redacted] would present a food safety hazard as required by **9 CFR 417.5 (a) 2.**

[redacted]

The hazard identified is Microbial Growth. The Critical Limit is:

- [redacted]

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- Any processing are only work for one kind of meat at one time; change meat can be made after cleaning and sanitizing.
- A maximum of maintained in product handling area.

Monitoring is accomplished by:

Corrective actions are followed in accordance with 9 CFR 417.3 and

- There are not documents to support the time and temperature ranges identified in the HACCP plan as sufficient to preclude microbial growth or why would present a food safety hazard as required by **9 CFR 417.5 (a) 2.**

The hazard identified is foreign materials and the critical limit is

The HACCP monitor records the results If a deviation from a critical limit occurs, corrective action will be taken to ensure all requirements described in CFR 417.3 are followed.

The hazard identified is microbial growth. The critical limits :

The environmental temperature is monitored by

If a deviation from a critical limit occurs, corrective action will be taken to ensure all requirements described in CFR 417.3 are followed.

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After review of the HACCP plans for this process, the following were noted;

- There are not documents to support the time and temperature ranges identified in the HACCP plan as sufficient to preclude microbial growth or why would present a food safety hazard as required by **9 CFR 417.5 (a) 2.**
- There are no documents available for review to show a correlation between the with coding, wrapping, strapping, vacuum packing and labeling with metal detection. This fails to meet **9 CFR 417.5 (a) 2.**
- The critical limit identified at the In that document it identifies The document also describes instructions for performing a test to However, there are no documents to support the sample sizes and that they are a food safety hazard. This fails to meet **9 CFR 417.5 (a) 2.**
- The verification activities include direct observation of monitoring procedures at a frequency of This frequency fails to meet the requirements of **9 CFR 417.4 (a) (2) (ii)** in that direct observations are to be conducted at each CCP at a frequency determined by the establishment as opposed to randomly selecting one CCP from all the HACCP plans.

Records

Records from 6/1/2007 to 8/31/2007 were reviewed and the following were noted:

- At the metal detection line in the HACCP monitoring & verification record the entries made are the word "good". This fails to meet **9 CFR 417.5 (a) 3** in that "good" is not a quantifiable value.

Sanitation Standard Operating Procedures (Sanitation SOP)

The establishment's Sanitation SOP describes the cleaning and sanitizing of all equipment used during the production day. The plant has contracted an outside firm to clean and sanitize the facility. The Sanitation SOP was signed and dated 4/10/2003. The procedure was last revised 7/10/2006.

The cleaning company maintains a manual of cleaning procedures and frequencies the are followed and apply to each piece of equipment within the establishment. Included are walls, doors, floors, entranceways, overheads, sinks, cords, lugs, baskets and conveyors.

No specific mention is made to individual equipment cleaning and sanitizing particularly those involved with mechanical tenderizing The company uses as their sanitizer on equipment and food contact surfaces. They also use for sanitizing floors and drains.

The supervisor of each processing room will be responsible for performing organoleptic inspection and final cleaning prior to start of the operation. Before release each processing room

for operation, the assigned QC personnel will perform pre-operational inspection on the room to ensure satisfied sanitation works in all areas and good physical conditions of all equipment. All results of the inspection are recorded and signed on a Pre-operational Sanitation Checklist Form by assigned QC personnel for each room and send to QC office for audit review. The Sanitation SOP is addressed as a decision making document in the two HACCP plans (Raw Ground and Raw Not Ground) at the [redacted]

Corrective Action/ Record Keeping

When monitoring personnel have determined that the equipment does not meet acceptable sanitary standards by organoleptic examinations, operations will be suspended in the affected area. The equipment will be tagged and unacceptable facilities or equipment will have to be re-cleaned, sanitized and, re-cleaned, sanitized and re-inspected by QC manager or assigned official to make sure that they are acceptable. Any possible contamination of products being observed, production or QC manage will be notified and the products will be discarded or retained for further investigations, if applicable. Any deviation observed will be forwarded to the cleaning crew employees for preventive measures. If deviations are noticed continuously for several days at a time, the QC manager will confer with managers from the cleaning company and review all cleaning and sanitizing procedures. The QC manager will review the record for any deviation observed and corrective action taken. To prevent recurrence of direct product contamination or adulteration, appropriate improvement in the execution of SSOP procedure(s) will be addressed. All audit results will be recorded on Pre-operational/ Operational Sanitation Deficiency Report with on day after the incident. All records are signed, dated and audited by QC manager and kept in the establishment QC file.

Operational Sanitation is performed following Good Manufacturing Practices guidelines. They address employee hygiene, direct product contamination and handling of product that falls on the floor, overhead structures, product handling and product storage. It is monitored [redacted] daily and recorded on the Operational Sanitation Checklist Form.

Analysis

The plant has several pieces of equipment that are used for mechanical tenderizing [redacted] This equipment carries inherent risk to raw not ground product in that their use may compromise the safety of the product introducing E. coli O157:H7 into the interior portion of the meat product and preventing the complete destruction of the organism by cooking. The establishment has not considered this in their hazard analysis and the implications if the equipment is not thoroughly cleaned and sanitized in a manner that would preclude contamination with E. coli O157:H7. Additionally, the establishment has no verification procedure in place to show that these pieces of equipment are free of E. coli O157:H7. Since the plant has the Sanitation SOP as a decision making document for E. coli O157:H7 not being a hazard in the hazard analysis, then they have failed to meet the requirements of **9 CFR 417.2 (a) 1.**

Records

Sanitation records from 6/1/2007 to 8/28/2007 were reviewed. Of the approximately 72 days that were reviewed, there were 2 deficiencies were documented that were related to the raw not ground

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operation.. No deficiencies were entered that indicated mechanically tenderized equipment were insanitary during the reviewed period.
The plant records the sanitizer strength of the hand dip station each day. There are no records available to determine the sanitizer strength when applied to the equipment or product contact surfaces.

Analysis

This is significant since the plant is using GMPs and the Sanitation SOP as decision making documents to show that microbial growth is a hazard not likely to occur. Sanitizers are important components in eliminating bacteria and other microbes (including E.coli O157:H7) from food contact surfaces prior to operations. If the strength of the sanitizer is not being documented, it calls into question whether the documents generated by the Sanitation SOP will support the decision made in the hazard analysis.

Conclusion/ Recommendation

The establishment has not demonstrated that their HACCP plan for this process meets the requirements of Part 417 of the Regulations in that the flow chart does not identify key components of the process, specifically the use of trim from the butcher table and their inclusion into the raw ground process. This is significant in light of concerns with source materials and the prevalence of E. coli O157:H7 that may be present in them. In addition, the establishment has failed to consider the use of mechanical tenderizing equipment on raw not ground product and the implications for the possible contamination of product by E. coli O157:H7 in light of Federal Register Docket No. 04-042N HACCP Plan Reassessment for Mechanically Tenderized Beef Products.
The firm has failed to perform a proper hazard analysis as required by 9 CFR 417.2 (a) 1 in that processes such as [redacted] were identified under one step; [redacted]. Because each of these processes have their own specific and unique attributes, the establishment failed to address them as individual steps and thereby did not determine the implications for product contamination from these types of equipment.
The establishment also failed to show support for microbial growth being a hazard not likely to occur at the [redacted] and referencing their SSOP as the basis for the decision. There were no documents to support that the plant's Sanitation SOP contained documents to show that sanitizers used by the plant were at the required strengths to be effective controls to eliminate micro-organisms or pathogens of concern.
The establishment's HACCP plan for raw not ground has numerous design problems that include but are not limited to:

- Missing documents to support decisions made in their hazard analysis and HACCP plan.
- Failing to meet the requirements for verification frequencies in that the plant is randomly selecting CCPs to be verified rather than performing verification on all CCPs at a determined frequency.
- Failure to identify what products contain allergens in their flow chart or hazard analysis.
- Failure to identify the hazards associated with vacuum packaging in their hazard analysis.
- Failed to consider the use of raw vegetables in their process as a potential source of pathogens.

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- Failed to identify in the flow chart the production of trim from the butcher line and diverting them into the raw ground operation.
- Failed to take into account the prevalence of E. coli O157:H7 during the summer months in light of Federal Register (67 FR 62329) which informed manufacturers of raw beef products, that they were required to reassess their HACCP plans, in light of certain scientific data on E.coli O157:H7 to determine whether E.coli O157:H7 contamination was a hazard reasonably likely to occur in their production process.

The establishment has failed to properly address these and other concerns as documented in this report that are of a food and public safety concern. It is therefore my recommendation that a Notice of Intended Enforcement be issued for this process.

Exit Meeting

On 10/3/2007 an exit meeting was conducting in Est. 9748 at 1:00 PM. Those in attendance were; Mr. Anthony D'urso, Executive Vice President/ COO, Mr. Jeff Rohach, Vice President, Finance, Mr. Geoff Livermore, Vice President, Operations, [redacted] Quality Assurance Manager, [redacted] Legal Consultant (via teleconference), [redacted] Consumer Safety Inspector, [redacted] Consumer Safety Inspector, [redacted] Consumer Safety Inspector and [redacted] Enforcement Investigation and Analysis Officer (EIAO). The purpose of the meeting was to discuss the findings of the food safety assessment for the raw not ground process and to inform them of my recommendation for a Notice of Intended Enforcement (NOIE).
I began by introducing myself to [redacted] since he was not present at the meeting location. I informed the panel that I was recommending an NOIE be issued to the establishment for their raw not ground process. I explained to them what a Notice of Intended Enforcement was and how it differed from a Suspension. I also brought [redacted] up to date on the chronology of events related to the first assessment for raw ground. I explained that based on an illness for E. coli O157:H7 in Florida, I was dispatched to Est. 9748 to complete a Food Safety Assessment (FSA) concentrating on the raw ground process. The result was a suspension of that operation and a recall of their product. I then continued to perform an FSA on the raw not ground and found numerous design problems related to the production of trim that was to be used in the raw ground operation and the use of mechanical tenderizing equipment. Other noncompliances were noted in the discussion, including lack of supporting documentation for decisions made in their hazard analysis and HACCP plans, lack of testing of raw materials used in the raw not ground process, not identifying products with allergens in their hazard analysis and flow chart, failure to address vegetables in their hazard analysis, failure to identify the trim production step for the raw ground process and how it moves to that process, overloading of processes into one hazard analysis that are not similar ([redacted] and [redacted] I went on to outline and describe each noncompliance. Mr. D'urso questioned why and how personnel from his company, outside auditors or consultants failed to find these noncompliances. I gave no response but to say that I could not answer for them.

I thanked plant management for their cooperation and help and that I understood the difficult situation they were in and how diligent they were in responding to my requests for information. The meeting was adjourned at 1:35 PM.

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Raw Ground (03B)

1. Are bench trimmings from products without COAs being used in grinding operations? YES
2. Are bench trimmings being tested for E. coli O157:H7? NO
3. Are trimmings produced from cut up operation being used in grinding operation? YES
4. What does "random cut" mean as it refers to the testing program of raw materials used for hamburger?

Random cut refers to the sampling conducted on raw material from boxes and bins. [redacted] whole muscle samples (clods, chucks) are from bins are taken from the top middle and bottom of the bin at the trimming table (one piece cut from the outermost area of the muscle). [redacted] is taken from [redacted] boxes. Samples are measured in [redacted] increments and sent to an outside lab as whole pieces for analysis.

5. Explain AOAC method 2000.13 for testing of sampling at outside lab.

[redacted] (Additional information is available for review via fax)

6. What are the supporting documents for the frequency of sampling [redacted] times per year?

The plant has a document from an auditor, [redacted] dated 12/20/2002 in which an audit was conducted at the request of the establishment to evaluate their food safety systems. In [redacted] is not being performed by the plant as prescribed in the audit.

Hazard Analysis/ Flow Chart/

- No supporting documentation for shelf life (12 months at 0°F or below)
- [redacted] identified in the hazard analysis is a CCP and the Critical Limit states that [redacted]
- At the [redacted] step it identifies [redacted] Each of these pieces of equipment are unique and specific operations and should be addressed separately in the hazard analysis. Cross contamination with E. coli O157:H7 is a factor for these types of equipment and each need to be addressed as a separate issue because of the different use, function and operation.
- The establishment reprocesses extruded meat [redacted]
- They are not processing rework into the product. According to their rework handling procedures ground product from previous days' production are never put back to production line and won't be used as rework. However, they may be packed into boxes

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- E.coli O157:H7 is identified in the hazard analysis at the step only.
- On occasions it is This product is then brought out use in the raw not ground operation. The trim from this process is used in the raw ground operation. is accomplished by From 11/2005 to 1/2006 the establishment performed an in house study to ensure that the water temperature was being maintained under so that product would not exceed Critical limit of as prescribed in their HACCP plan for storage.

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COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS

EST. NO. 09748 M

DATES CSO VISITED EST. FROM: 09/25/2007 TO: 09/27/2007

NAME AND ADDRESS OF ESTABLISHMENT
Topps Meat Co. Inc.
1161 E. Broad St.
Elizabeth, New Jersey 07207

NAME OF EIAO:

DISTRIBUTION INSTRUCTIONS:
Submit this report to your District Manager and the Front-Line Field Supervisor via email.

DISTRICT: Philadelphia-60

CIRCUIT VISITED: Elizabeth- 20

REASON FOR VISIT (Check all that apply):

- [✓] A. District Office Direction
- [ ] B. Consumer Complaints
- [✓] C. Foodborne Illness
- [ ] D. Foreign Particle Contamin.
- [ ] E. Repetitive Lm
- [ ] F. STEPS-triggered Sample Form #
  - [ ] A set
  - [ ] B set
  - [ ] C set
- [ ] G. Salmonella Performance Standard Failure
- [ ] H. Other *(Specify)*: E.coli O157:H7

SUMMARY OF DATA ASSESSMENT PRIOR TO VISIT:

Previous FSA performed October of 2005

See Attached

RECOMMENDATIONS:

- [ ] A. No action needed
- [ ] B. 30 day reassessment letter
- [ ] C. NRS written by in-plant
- [ ] D. NOIE
- [✓] E. Suspension/Withdrawal

F. Summary of reason(s) for recommendation:

See attached

NARRATIVE: Attach/Save an MS Word document with the full narrative to this PDF

FSIS FORM 5000-8 (07/03/2007) REPLACES FSIS FORM 5000-8 (9/15/2005), WHICH MAY BE USED UNTIL EXHAUSTED.

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Background from cover page

Fifteen E.coliO157:H7 case-patients with indistinguishable PFGE pattern combinations have been reported from 6 states (NY 6, NJ 3, CT 2, PA 2, OH 1 and IN 1).

The PFGE pattern combinations are EXHX01.4214/EXHA26.2331and considered rare in CDC's PulseBNet database.

Onset dates range from 7/5/07 to 9/9/07

Case-patients' age ranges from 8 to 77 years old with median of 20.

Eight are male and 7 are female.

12 case-patients reported consuming ground beef products during the potential incubation period.

Five out of 12 case-patients reported consuming Topps brand preformed frozen ground beef patties.

Three case-patients (1 NJ, 1 NY and 1 PA) were able to provide leftover ground beef patties for testing.

Both NY and NJ health departments collected the leftover patties from their case-patients' home and state health laboratories performed the test.

PA health department is sending an officer to collect the leftover ground beef patties on 9/24/07. PA state lab will perform the test.

The test methods for NJ and NY were verified by FSIS/OPHS microbiology division. MIB will contact PA lab to verify the testing methods.

NY laboratory reported that each of the 5 patties from the patient's home tested positive for E.coliO157:H7. The PFGE pattern from 1 patty is indistinguishable to this cluster and 4 patties' pattern is very similar to the cluster (pending upload and CDC review). The box of the patties shows 20 quarter Pounders 100% ground beef produced by Est. # 9748 and sell by date 6/22/2008. Box code is #100000416

A box of like coded product with same "sell by date" was purchased and tested by NY health department. The preliminary result indicated that 4 patties are Positive of E.coliO157 with Shiga toxin II. Final result will be available on 9/25/07 or 9/26/07. Box code is #100011390

NJ state lab tested leftover ground beef product collected from the patient's home. The result was negative. The box of the patties shows 20 quarter Pounders 100% ground beef produced by Est. # 9748 and sell by date 7/5/2008.

PA health department is sending an officer to collect the leftover ground beef patties on 9/24/07. PA state lab will perform the test. The product is Topps frozen hamburger patties, 100% pure ground beef (32 count), Quarter pound patties, Sell by date: June 22, 2008, Lot code (hard to decipher): 56T-5748 # 100000212

On Friday September 21, 2007, the recall committee conducted a preliminary discussion regarding the plan of action regarding Topps Meats. During the weekend Topp's was actively assembling source material information for 6/22/07, 7/5/07 and 7/23/07. On Monday September 24, 2007 EIAO [redacted] arrived at the firm to gather source material information.

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Entrance Meeting

On Tuesday 9/25/2007 an entrance meeting was held in Est. 9748 Topps' Meat Co. Inc. The meeting was held at 1:45 PM. In attendance were, David Cohen, CEO, Anthony D'urso, EVP/ COO, Geoff Livermore, VP of Operations, Jeffrey T. Rohach, VP Finance and Administration, [redacted] QC Manager, [redacted] Ph.D., Consultant, [redacted] Consumer Safety Inspector (CSI) and [redacted] Enforcement Investigation and Analysis Officer (EIAO).
I explained that the purpose of the assessment was in response to a recent illness in Florida associated with the consumption of one of the establishment's products (hamburger patty) and that it was District initiated. I told them that I would be examining their Hazard Analysis Critical Control Point (HACCP) plans and specifically the raw ground process from which the patty was derived. I also would be looking at their raw not ground process in light of the fact that source materials for the raw ground products were produced there as well as from outside suppliers. I informed them that I would be at the plant for several days. I asked for their cooperation during my visit and that I appreciated their help in completing the assessment. They were very receptive and would help out in any way possible.
[redacted] stated that the plant has been cooperative in complying with the regulations and that he would be available for consultation if needed. I thanked him for his offer and told him that if any questions needed to be addressed I would not hesitate to contact him.
I thanked plant management again and the meeting was adjourned at 2:05 PM.

On 9/26/2007 I handed Mr. David Cohen a pamphlet during a discussion with him about findings made during a review of the HACCP plan for raw ground product. The pamphlet included the following information:
Keep America's Food Safe Pamphlet
FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products Booklet
Food Safety Resource Pamphlet
Regulations 416, 417 and 500 Booklet
Regulations 430 and 310.25 Handout
Office of the National Ombudsman Contact List
Compliance Guideline Links
Food Safety Guideline Links
HACCP Contacts and Industry Representatives
Compliance Guideline for Small and Very Small Plants Appealing Inspection Decisions
Thermy® Magnet
What is a Food Safety Assessment? Handout
Tompkins' Guidelines for Controlling Pathogens
My Business Card

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Prologue

On August 31, 2007 a consumer complaint (case # 6096-2007) was filed in Florida reporting an illness from the consumption of a hamburger patty produced on 7/12/2007 at Topps Meat Co. Inc. located in New Jersey. The illness was reported to be from possible contamination by E. coli *O157:H7*. The illness was confirmed positive for the pathogen by the Florida Dept. of Health on 9/4/2007. As a result of the incident a Food Safety Assessment was scheduled to be conducted at the establishment where the product was produced. During the next few weeks additional illnesses were reported in New York State. These illnesses were found to be from hamburgers produced on 6/22/2007 and 7/23/2007. An investigation and review of the plant's HACCP plan for the production of the raw ground product, sanitation procedures and records was conducted from 9/25/2007 to 9/27/2007 revealed the following:

Raw Material Handling

Raw materials in the form of sub-primal parts are received into the establishment daily for use in ground product. Materials received are accompanied by either Letters of Guaranty (LOG) which state that the supplying firm has in place one or more CCPs in their HACCP plans that address E. coli O157:H7 and/ or identify intervention steps for controlling or eliminating the pathogen (boxed product) or they are accompanied by Certificates of Analysis (COA) which analyze lots of production (bins) for the presence of E. coli O157:H7.
In addition, sub-primal parts are trimmed to produce steaks and diced products. The trim is diverted into the ground operation as a component of those products. None of these products do not carry COAs.
The establishment also [redacted] beef that is included in the production of ground products. They are accompanied with letters from the supplier indicating that raw material has been tested for E. coli O157:H7 and/ or have intervention steps to control or eliminate the pathogen.

E. coli O157:H7 Testing

The establishment has several testing protocols for the control of E. coli *O157:H7*. They are as follows:

Raw Material Components

This sampling is performed [redacted] times per year as a verification of incoming suppliers. On a random day the plant will sample each supplier that comprises the source material of that day's production. It is tested for E. coli *O157:H7*. Samples taken on 5/1/2007 and 7/18/2007 were found negative for E. coli *O157:H7*.
NOTE: On 6/6/2007 15 bins of [redacted] were shipped to the establishment. The load was to be 20 bins. However, five bins were found positive for E. coli *O157:H7* at the supplying plant and were held. The receiving establishment selected the bin after the five and before the five, boxed them up and tested them for E. coli *O157:H7* and found them to be negative. The other 13 bins were processed that day.

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On July 12, 2007 as similar incident occurred where 20 bins were to be shipped and five were held at the supplying plant because they tested positive for E. coli *O157:H7*. However, in this case the receiving plant did not test the remaining bins for the pathogen. They were processed that day.

Additionally, the establishment produces trimmings from sub-primal parts in a cutting operation. These trimmings are added to the grinding operations without testing of the trimmings for E. coli *O157:H7*. According to their documented reassessment (12/20/02) in response the October 2, 2002 Federal Notice (67 FR 62329), their consultant recommended Additionally, they recommended They recommended that you could accomplish this by A further recommendation was

Finished Product Testing

Finished product is sampled for E. coli *O157:H7* a minimum of times per year to determine the presence of E. coli *O157:H7* in finished product. Samples tested from 2/1/2007 to 9/10/2007 resulted in negatives. The samples were taken from a variety of hamburger products.
The establishment also tests finished product for aerobic plate count, coliform, salmonella and generic E. coli. The tests are conducted to determine in house sanitation controls and procedures. Tests are performed and analyzed in plant and samples are sent to an outside lab for analysis
In house results from 5/1/2007 to 7/31/2007 were acceptable. Samples sent to the lab from 1/19/2007 to 8/10/2007 were acceptable.

Environmental Microbiological Testing Program

The establishment has a testing program to verify effectiveness of the cleaning work performed after production. This method was found to be unreliable for determining cleaning effectiveness because the results were not consistent from day to day. The method was found to be more accurate and consistent for their purposes and has been used from 6/8/2007 to 9/17/2007. Results have been acceptable. On 7/26/2007 the butcher knives showed a plate count of

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Hazard Analysis Critical Control Point (HACCP)

Raw Ground (03B)

The establishment produces raw beef patties, hamburgers, ground beef, and turkey burgers. They are to be cooked prior to consumption. They have a shelf life of 12 months at 0°F or below. They are sold to retail, food service, general public and wholesale. They have keep frozen, cooking instructions, safe food handling and nutrition facts as part of their labeling. Beef patties contain ingredients such as soy flour, salt, hydrolyzed soy protein and flavoring. Turkey burgers contain turkey skin.

Flow Chart/ Hazard Analysis

The flow chart lists various steps in the production of raw ground product;

- The step includes; and This is identified as a Critical Control Point (CCP).

Analysis

This step consists of several different kinds of steps within the process. Each step is unique in how product is handled, the types of equipment and each has its own specific hazards associated with them. It is not reasonable to conclude that the various equipment mentioned in this step would have the identical hazards associated with their use. They would therefore need to be separated and a hazard analysis would need to be performed on each step. The CCP for this step is

- The step includes This is also a CCP ( ). Again, the only CCP here is have nothing to do with detection.

The establishment has failed to meet the requirements of **9 CFR 417.2 (a) 2 and 3.**

Hazard Analysis

A review of the hazard analysis revealed the follow:

The hazard analysis identifies E. coli *O157:H7* at the step for meat. It is a hazard not likely to occur based Review of your testing program titled " " identifies a frequency of times per year for testing raw material suppliers used for hamburgers. This frequency is inconsistent with the recommendations (of testing) made by your consultant in response to the 2002 Federal Register Notice (67 FR 62329). Additionally,

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they have no supporting or decision making documents as required by 417.5 to support the testing frequency of [redacted] times per year. This does not meet the requirements of **9 CFR 417.5 (a) 1.**

Analysis

Products produced on 6/22/2007, 7/12/2007 and 7/23/2007 were reported to be contaminated with E. coli O157:H7 by FSIS initiating a voluntary recall of the product. this indicates that the plant has failed to prevent product from being contaminated and shows that the identified basis for the unlikelihood of E. coli O157:H7 from occurring in the product is invalid. The establishment has failed to meet the requirements of 9 CFR 417.2 (a) 1.

- In the [redacted] product is [redacted] product is received [redacted] This product is then brought out [redacted]. The trim from this process is used in the [redacted] From 11/2005 to 1/2006 the establishment performed an in house study to ensure that the water temperature was being maintained under [redacted] so that product would not exceed Critical limit of [redacted] as prescribed in their HACCP plan for storage. There is no document to support that there are no hazards likely to occur at this step as required by **9 CFR 417.5(a) 1.**
- The establishment reprocesses [redacted] There is no data to show that this product [redacted] has low levels of microbial growth and does not meet the requirements of **9 CFR 417.5 (a) 1.**
- At the [redacted] the plant has a rework handling procedure and according to the document states, "[redacted]." However, on 9/26/2007 management informed EIAO that ground finished product from freezer was being reworked into production and that a rework reporting sheet was being produced to track that usage. This fails to meet the requirements of **9 CFR 417.2(a) 1.**

HACCP Plan

There are [redacted] CCP's in this HACCP plan; [redacted]

The hazard identified is microbial growth. The critical limit is [redacted] The inside temperature of [redacted] The environmental temperature is monitored by [redacted]

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Corrective actions when there is a deviation from a critical limit are to and to follow requirements of 9 CFR 427.3(a). Verification activities are;

- There are no documents to support the time and temperature ranges as stated in the HACCP plan. This does not meet the requirements of **9 CFR 417.5 (a) 2.**

The hazard identified is microbial growth. The critical limit is Monitoring is done by Product handling area temperature is obtained by Corrective actions when there is a deviation from a critical limit are to and to follow requirements of 9 CFR 427.3(a). Verification activities are;

- There are no documents to support the time and temperature ranges as stated in the HACCP plan. This does not meet the requirements of **9 CFR 417.5 (a) 2.**

The hazard identified is microbial growth. The critical limit is Monitoring is done by The environmental temperature is obtained by Corrective actions when there is a deviation from a critical limit are to and to follow requirements of 9 CFR 427.3(a). Verification activities are;

- There are no documents to support the time and temperature ranges as stated in the HACCP plan. This does not meet the requirements of **9 CFR 417.5 (a) 2.**

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The hazard identified is foreign material. The critical limit is [redacted] Monitoring states, [redacted] Corrective actions when there is a deviation from a critical limit are to [redacted] and to follow requirements of 9 CFR 427.3(a). Verification activities are: [redacted]

- The procedure for monitoring the CCP does not appear in the HACCP document. However, it does appear in the written procedure that is referenced in the monitoring column.

Records

Records from 6/1/2007 to 8/30/2007 were reviewed and the following were noted:

- Monitoring of product temperatures and room temperatures are being performed as required in the HACCP plan.
- Monitoring of Metal detection is being performed by the HACCP monitor at the frequency specified in the HACCP plan.
- Verification activities are being documented including the time of the occurrence and the initials of the verifying. The verification does coincide with the times that monitoring is performed.
- The auditor's signature and date is the pre-shipment review.

They meet the requirements of 9 CFR 417.5 (a) (b) and (c).

Sanitation Standard Operating Procedures (Sanitation SOP)

The establishment's Sanitation SOP describes the cleaning and sanitizing of all equipment used during the production day. The plant has contracted an outside firm to clean and sanitize the facility. The Sanitation SOP was signed and dated 4/10/2003. The procedure was last revised 7/10/2006.

The cleaning company maintains a manual of cleaning procedures and frequencies the are followed and apply to each piece of equipment within the establishment. Included are walls, doors, floors, entranceways, overheads, sinks, cords, lugs, baskets and conveyors.

The supervisor of each processing room will be responsible for performing organoleptic inspection and final cleaning prior to start of the operation. Before release each processing room for operation, the assigned QC personnel will perform pre-operational inspection on the room to ensure satisfied sanitation works in all areas and good physical conditions of all equipment.

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All results of the inspection are recorded and signed on a Pre-operational Sanitation Checklist Form by assigned QC personnel for each room and send to QC office for audit review.

Corrective Action/ Record Keeping

When monitoring personnel have determined that the equipment does not meet acceptable sanitary standards by organoleptic examinations, operations will be suspended in the affected area. The equipment will be tagged and unacceptable facilities or equipment will have to be re-cleaned, sanitized and, re-cleaned, sanitized and re-inspected by QC manager or assigned official to make sure that they are acceptable. Any possible contamination of products being observed, production or QC manage will be notified and the products will be discarded or retained for further investigations, if applicable. Any deviation observed will be forwarded to the cleaning crew employees for preventive measures. If deviations are noticed continuously for several days at a time, the QC manager will confer with managers from the cleaning company and review all cleaning and sanitizing procedures. The QC manager will review the record for any deviation observed and corrective action taken. To prevent recurrence of direct product contamination or adulteration, appropriate improvement in the execution of SSOP procedure(s) will be addressed. All audit results will be recorded on Pre-operational/ Operational Sanitation Deficiency Report [redacted] All records are signed, dated and audited by QC manager and kept in the establishment QC file.

Operational Sanitation is performed following Good Manufacturing Practices guidelines. They address employee hygiene, direct product contamination and handling of product that falls on the floor, overhead structures, product handling and product storage. It is monitored [redacted] and recorded on the Operational Sanitation Checklist Form.

Records

Sanitation records from 6/1/2007 to 8/28/2007 were reviewed. Of the approximately 72 days that were reviewed, there were only 4 days that had deficiencies and one of them had three. Sanitation Deficiency Reports were filled out properly and no reports of contaminated product were reported.
Requirements of 9 CFR 416 have been met.

Recommendation

A Suspension Action is warranted.

The documentation supports the conclusion that the establishment has demonstrated a failure to adequately reassess the HACCP plan based on scientific data related to the prevalence of *E. coli O157:H7* in raw beef products and failure to support decisions that controls are in place for controlling *E. coli O157:H7* in your production process.

Theses findings are consistent with a determination that the HACCP plan is inadequate based on the design and execution of the program as defined in 9 CFR Parts 417.6 whereas adulterated product was produced and shipped into commerce and the HACCP plan in operation does not meet the requirements set forth in part 417. Therefore, product produced could bear or contain

poisonous or deleterious substance which may render it injurious to health as defined in the Federal Meat Inspection Act (FMIA) 21 U.S.C. 601(m)(1).

The establishment failed to reevaluate the effectiveness of the SSOP. As a result of this, sanitary conditions are not being maintained within the facility and meat products produced may become adulterated if it has been prepared, packed, or held under insanitary conditions, whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health as defined in Federal Meat Inspection Act (FMIA) 21 U.S.C. 601(m)(4) and 21 U.S.C. 608 and 21 U.S.C. 453(g) (4).

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Topps' Meat Co. LLC Est. 9748

A tour of the facility was conducted on Monday 9/24/07 with the assistance of in plant Inspector [redacted] During the tour the following were observed:

- A single entrance for the employees into the production area has a foot bath and hand sanitizing trough. Employees are required to wear clean smocks, hairnets, gloves, plastic helmets and aprons.
- There are three areas of production; the raw not ground room where boneless meat is trimmed, and cut and mixed with spices to form "flat iron" steaks for restaurants and grills. Some of the steaks are cubed or tenderized. The finished product is vacuumed packed and boxed.
- The main beef patty production area takes several source materials, grinds them, mixes them and places them through patty former machines (3). They are packaged, boxed and placed on racks. The racks are placed into a blast freezer overnight. From there they are shipped to outside storage until sold.
- The source materials come from domestic as well as foreign suppliers.
- The third area is a vacuum tray pack area where whole muscle meat is cut-up, vacuum tumbled with spices or portioned and packaged using a vacuum tray pack machine.
- All rooms are refrigerated.

Suppliers of raw materials for product produced 7/23/2007

Supplier	COA	Type of Product	State	Origin	PO #
[redacted]	Yes	Boneless Clods (Bin)	[redacted]	[redacted]	T-1925
	Yes	Boneless Clods (Bin)			T-1925
	No	Textured Beef (Boxes)			T-1845
	Yes	Boneless Beef (Boxes)			T-1903
	Yes	90% Lean Beef (Boxes)			T-1728
	Yes	90% Lean Beef (Boxes)			T-1479
	Yes	50/50 Trimmings (Boxes)			T-1642
	Yes	65% Trimmings (Bins)			T-1959
	No	50/50 Trimmings (Boxes)			T-1973
	No	Clods (Boxes)			T-1972
	No	Sirloin (Knuckle Trim) Boxes			T-1954
	Yes	Head Meat (Boxes)			PFSN*

NOTE: Unused bins, pallets and bench trimmings (those produced from trimming knuckles and chucks) are carried over to the next production day.

[redacted] Product shipped from there to plant.

Raw materials are received into the establishment and logged in by the receiving employee. Multi-page tags are applied to each bin or pallet received and is marked with the following information: Name of the supplier, product identification, the date received, whether bin or pallet, weight, whether fresh or frozen and the date the bin or box was produced. The tags follow the raw material through the entire process and are

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collected and filed. They can be referred to when tracking back to the supplier of the product. This procedure was determined ineffective as the company was not able to provide accurate trace-back information using this process. FSIS had to actually verify the company paperwork to make a determination.

Supplier of raw materials for product produced 6/22/2007

Supplier	COA	Type of Product	State	Origin	PO #
	Yes	Beef Trimmings 65/35 (Bin)			T-1872
	Yes	Beef Trimmings 65/35 (Bin)			T-1783
	Yes	Beef Chucks (Boxes)			T-1889
	Yes	Beef Chucks (Boxes)			T-1851
	No	Choice Clods (Boxes)			T-1850
	No	Choice Clods (Boxes)			T-1852
	Yes	Beef Trim 65/35 (Bin)			T-1828
	Yes	Lean Beef 90% (Boxes)			T-1491
	Yes	Lean Beef 90% (Boxes)			T-1733
	Yes	50/50 Trimmings (Boxes)			T-1640
	No	Top Sirloin Beef (Boxes			T-1856

Suppliers of raw materials for product produced 7/5/2007

Supplier	COA	Type of Product	State	Origin	PO #
	Yes	Beef Trim 65/35 (Bins)			T-1787
	Yes	Beef Trim 65/35 (Bins)			T-1788
	Yes	Lean Beef 90% (Boxes)			T-1494
	Yes	Lean Beef 90% (Boxes)			T-1732
	Yes	Beef Trim 65/35 (Bins)			T-1911
	Yes	Beef Trim 50/50 (Bins)			T-1919
	Yes	Beef Clods (Bins)			T-1896
	Yes	50/50 Beef Trim (Boxes)			T-1643
	Yes	Textured Beef Chips (Boxes)			T-1843

The plant had a power failure during the week of August 5, 2007. The plant power was down for approximately 4 hours and then restored. No production was done during that time.
According to the completed report on the day of the incident, August 8, 2007, the establishment monitored the temperatures of the coolers and the freezers during the down time. The power was off from 7:30 AM to 10:45 AM. The meat in the cooler was still lower than 35°F and in good condition.

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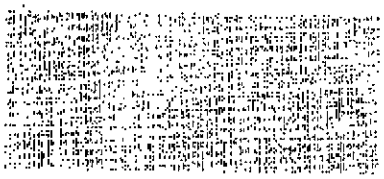

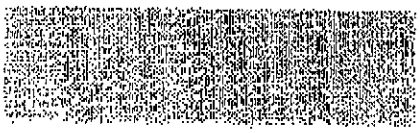

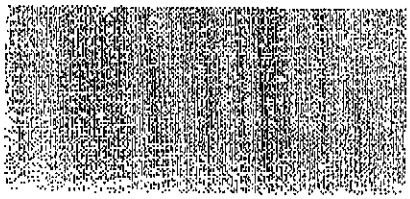

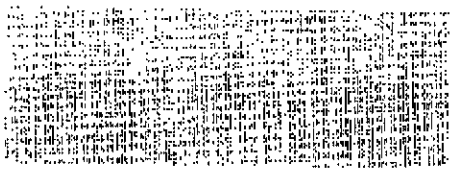

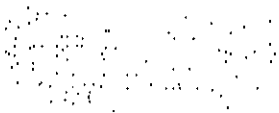

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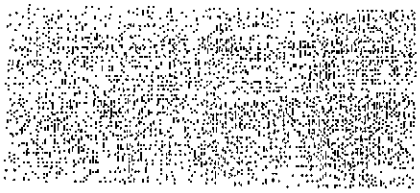

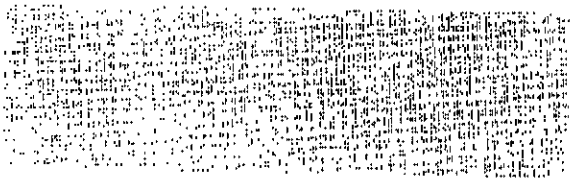

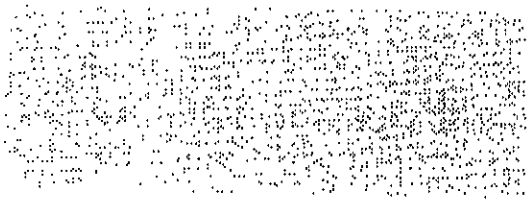

Sampling

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The establishment has several testing protocols for determining the effectiveness of controlling or eliminating E. coli *O157:H7* from their raw ground products. They are as follows:

Raw Material Components

This sampling is performed times per year as a verification of incoming suppliers. plant will sample each supplier that comprises the source material of that day's production. It is tested for E. coli *O157:H7*. Samples taken on 5/1/2007 and 7/18/2007 were found negative for E. coli *O157:H7*. Plant management has not to date tested any of their trimmings produced from the trimming operations that are being used to produce raw ground product.

NOTE: On 6/6/2007 bins of were shipped to the establishment. The load was to be bins. However, bins were found positive for E. coli *O157:H7* at the supplying plant and were held. The receiving establishment selected the bin after the and before the boxed them up and tested them for E. coli *O157:H7* and found them to be negative. The other bins were processed that day.
On July 12, 2007 as similar incident occurred where bins were to be shipped and were held at the supplying plant because they tested positive for E. coli *O157:H7*. However, in this case the receiving plant did not test the remaining bins for the pathogen. They were processed that day.

Finished Product Testing

Finished product is sampled for E. coli *O157:H7* a minimum of times per year to determine the presence of E. coli *O157:H7* in finished product. Samples tested from 2/1/2007 to 9/10/2007 (8 samples) resulted in negatives. The samples were taken from a variety of hamburger products.
The establishment also tests finished product for aerobic plate count, coliform, salmonella and generic E. coli. The tests are conducted to determine in house sanitation controls and procedures. Tests are performed and analyzed in plant. and samples are sent to an outside lab for analysis.
In house results from 5/1/2007 to 7/31/2007 were acceptable. Samples sent to the lab from 1/19/2007 to 8/10/2007 were acceptable.

Environmental Microbiological Testing Program

The establishment has a testing program to verify effectiveness of the cleaning work performed after production. from each room is collected at least for total aerobic plate count. This is used as the index bacteria. The acceptable limit is and the unacceptable limit is When limits are exceeded the production supervisor is notified and cleaning procedures are assessed to find the cause and take the necessary steps to correct the deficiencies. Additional samples are The method is currently being used to determine effectiveness of cleaning procedures. But from 6/8/2007 to 7/7/2007 the was also being used. This method was found to be unreliable for determining cleaning effectiveness because the results were not consistent from The method was found to be more accurate and consistent for their purposes and has been used from 6/8/2007 to 9/17/2007. Results have been acceptable. On 7/26/2007 the butcher knives showed