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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

EXHIBIT COVER SHEET

1. DESCRIPTION OF EVIDENCE
Notice of Suspension dated September 26, 2007

COPY

ORIGINAL

2. EVIDENCE OBTAINED FROM (Name, address, etc.)

USDA, FSIS, OFO
Mellon Indepenence Center, Suite 4100 A
701 Market Street
Philadelphia, PA 19106

3. NAME OF PERSON OBTAINING EVIDENCE
[redacted]

4. TITLE
Investigator

5. BADGE NO.

6. DATE EVIDENCE OBTAINED
11/15/2007

7. LOCATION OF ORIGINAL(S) (If not attached)

USDA, FSIS, OFO
Mellon Indepenence Center, Suite 4100 A
701 Market Street
Philadelphia, PA 19106

8. EXHIBIT NO. 4

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United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Philadelphia District
Mellon Independence Center
701 Market St. - Suite 4100-A
Philadelphia, PA 19106

September 26, 2007

Certified-Return Receipt Requested

Mr. David Cohen, CEO
Topps Meat Company, L.L.C. (Est. 9748/P-9748)
1161 East Broad Street
Elizabeth, NJ 07207

NOTICE OF SUSPENSION

Dear Mr. Cohen

This letter confirms verbal notification to you by [redacted] District Analyst, from the Philadelphia District Office, the Food Safety and Inspection Service (FSIS) on September 26, 2007, of our decision to withhold the marks of inspection and suspend the assignment of inspectors at **Topps Meat Company, L.L.C. (Est. 9748/P-9748)** located in Elizabeth New Jersey from products produced under your raw ground process HACCP plans. This decision is made in accordance with the Rules of Practice 9 CFR 500.3(a)(1) (4).

Background/Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq) and Poultry Product Inspection Act (PPIA) (21 U.S.C. 451 et seq) provide that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products, or poultry products, to be labeled, marked, stamped, or tagged as "inspected and passed"; and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated; and provides definitions for the term "adulterated". Furthermore, the Acts provide FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. The Acts further provides FSIS program personnel the right to examine and inspect all carcasses and carcass parts that are further treated and prepared, as well as the right to access and examine establishment records. When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

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Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR Parts 416 and 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9 CFR Part 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and/or suspension, with or without prior notification, and for filing a complaint to withdraw a Grant of Federal Inspection.

Findings/Basis for Action

On September 25, 2007, your firm voluntarily recalled approximately 331,582 pounds of frozen beef products produced on June 22, July 12 and July 23, 2007 because they may be contaminated with *E. coli* O157:H7. An investigation into a cluster of illnesses in the Northeast states implicated frozen ground beef patties as a possible source. Some of the case patients reported consuming Topps ground beef patties. Non-intact product (production date of 6/22/07) collected from a patient's home in New York tested positive for *E. coli* O157:H7. Like coded intact product with the same sell by date (production date of 6/22/07) was purchased and tested by the NY State Department of Health. Results from this intact sample that was produced and shipped into commerce with a production date of 6/22/07, have confirmed positive for *E coli* O157:H7. Documentation collected by the FSIS' Office of Public Health and Science provides evidence of epidemiology and lab data regarding *E. coli* O157 illnesses associated with consumption of ground beef patties were produced at Topps Meat Company, L.L.C. (Est. 9748/P-9748) with production dates of June, 22, July, 12 and July 23, 2007.

In the October 7, 2002, Federal Register, titled E. coli O157:H7 Contamination of Beef Products, (67 FR 62329), FSIS 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.

According to your documented reassessment [redacted] in response the October 2, 2002 Federal Notice (67 FR 62329), your consultant recommended [redacted] Additionally, they recommended [redacted] They recommended [redacted] A further recommendation was that [redacted]

According to your hazard analysis [redacted]

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[redacted] This frequency is inconsistent with the recommendations ([redacted]) made by your consultant in response to the 2002 Federal Register Notice (67 FR 62329). Additionally, you have no supporting or decision making documents as required by 417.5 to support the testing frequency of [redacted]

In review of the source material used in the production of Topps ground beef patties; your firm is using source material without the accompaniment of COA's. For example, you receive sub primal cuts from various suppliers that may not have been intended for grinding because they are absent of COA's. In addition, FSIS has documented evidence that you are using trimmings generated from your chuck steak (raw not ground operation) that is used for ground beef [redacted]

Your establishment has not required every supplier of beef products intended to be manufactured into non-intact product to ensure that they are free of *E. coli O157:H7* at undetectable levels. In addition, your plant's verification procedures of [redacted] were ineffective in ensuring that products received from all suppliers were negative for *E. coli O157:H7*. Specifically, your establishment's decision to [redacted] and failure to ensure that you have sampled all potential supplier's source material for each of these tests is an ineffective approach to verification that the supplier's control for *E. coli O157:H7* are effective in reducing the pathogen to undetectable levels.

FSIS expects your documentation to include records that document that your pre-requisite program is effective and that *E. coli* O157:H7 is not reasonably likely to occur. Without this documentation, FSIS would question the adequacy of your establishment's HACCP system and hazard analysis. Therefore, your decision of not requiring Certificate of Analysis (COA's) with negative results for *E. coli O157:H7* or any other supporting documentation to accompany the incoming product intended for grinding showing that the purchase specifications are being met as outlined in the 2002 Federal Register notice (67 FR 62329) lends questions to the adequacy of the design and execution of your prerequisite program and HACCP program. Accompanying documentation and other verification activities are necessary to ensure that the food safety hazard is not reasonably likely to occur. The purpose of purchase specifications is designed to prevent *E. coli* O157:H7-contaminated product from entering your establishment and without accompanying documentations such as COA's with each shipment to ensure that the execution of the purchase specification program is being met, your decision that *E. coli* O157:H7 is not likely to occur is not supportable as required by 417.5(a)(1).

In regards to your verification testing program, FSIS expects an adequately designed verification testing program that is statistically based and sensitive to detect *E. coli* O157:H7 if present to support your decision that the pathogen continues to be not reasonably likely to occur. However without accompanying documentation with your purchase specification, on all incoming raw source material that is used in the manufacturing of raw ground beef, FSIS questions your decisions that *E. coli* O157:H7 is not reasonably likely to occur in your raw ground production process.

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In regards to your consultant's 12/20/02 recommendation [redacted], FSIS questions how these decisions are supportable since you did not specify the controls your supplier had to meet for your establishment to verify if the purchase specifications were being met. Your purchase specifications [redacted]

FSIS has articulated in the October 7, 2002, Federal Register notice that FSIS expects the supporting documentation concerning prerequisite programs to include records that document that the program is effective, and that *E. coli* O157:H7 is not reasonably likely to occur. There is no documentation as required by 417.5 (a) (1) to support the decisions in your hazard analysis that this pathogen is not likely to occur. In the absence of supporting documentation for the decisions in your hazard analysis, FSIS questions the adequacy of your establishment's HACCP system and hazard analysis and have determined it to be inadequate as defined by 417.6(d).

Additionally, there are concerns about the sanitation of your facility. According to your reassessment ([redacted]), they documented that [redacted]

On 9/26/07, during pre-operational inspection, FSIS observed and documented that the patty making machine #[redacted] had gouges, cracks and tears in the neoprene transfer belt used to move raw patties to packaging. The entire belt was affected and the Inspector-In-Charge tagged the equipment to prevent its use in the manufacturing of raw ground beef patties.

Four (4) of the pre-operational NRs (April 2007 to July 2007) relate directly to product residues observed on product contact surfaces of equipment used to manufacture raw beef in the patty room.

The recurring deficiencies of unsanitary equipment documented by UDSA prior to operations on direct product contact surfaces of equipment used in the raw ground beef process provide evidence that your firm failed to re-evaluate the effectiveness of the Sanitation SOP's. As such, the procedures for preventing direct contamination or adulteration of product(s) were not revised as necessary to keep them current with respect to the changes in the facility, equipment or operations as required by 416.14.

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In addition to the above findings during this food safety assessment, FSIS also identified noncompliance that we believe are serious matters that need to be addressed by your firm to meet the regulatory requirement for 417.

Hazard Analysis/ Flow Chart/

- No supporting documentation for shelf life ([redacted])
- Freezer temperature identified in the hazard analysis is a CCP and the Critical Limit states that [redacted] FSIS questions the decisions you concluded for shelf life ([redacted]) but your freezer CCP is [redacted] which is greater than your required shelf life temperature.
- At the assembling step it identifies cutting/ trimming, flaking, course grinding, mixing, final grind and form patties. 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 (meat and fat from the [redacted] grinder, reground into a fine ground (extruded product from this grind is discarded) and returned to the [redacted] grinder). This is not a CCP because "[redacted]" No supporting documentation to [redacted]
- 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. Your QA Manager informed FSIS on 9/26/07 that Topps' is using rework hamburger from your freezers into production of ground product. This is contrary to your rework policy dated 10/31/05 that states. "[redacted]" [sic] This policy is in response to NR 23-2005-6462 dated 10/20/2005.
- *E.coli O157:H7* is identified in the hazard analysis at the [redacted] only.
- On occasions cryovaced product is received fresh and [redacted] No supporting documentation was provided to support this procedure that hazards are not likely to occur.

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Summary

The documentation supports the conclusion that your establishment has demonstrated a failure to adequately reassess your 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 your 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 your 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).

Your establishment failed to reevaluate the effectiveness of your SSOP. As a result of this, sanitary conditions are not being maintained within your 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).

In the interest of protecting the public's health in accordance with FSIS' Rules of Practice, 9 CFR Part 500 .3(a)(1) and (4), we are notifying you of our decision to withhold the marks of inspection and suspend the assignment of inspectors from your firm for product produced under the raw ground HACCP plans at Topps Meat Company.

The suspension(s) will remain in effect until you provide adequate written corrective and preventive measures to assure FSIS that you can demonstrate a program that meets the requirements of 9 CFR 416, Sanitation Standard Operating Procedures (SSOP) and 9 CFR 417, Hazard Analysis, Critical Control Points (HACCP) .

In order to resume inspected operations, you must submit corrective actions to my attention at the Philadelphia District Office.

You are reminded that as an operator of a Federally inspected plant you are expected to comply with FSIS regulations and to take appropriate corrective actions to prevent the production of adulterated products at your establishment. Please be advised you have the right to appeal this matter. If you wish to appeal you should contact:

Executive Associate for Regulatory Operations
Office of Field Operations
Food Safety and Inspection Service
Room 3157-South Building
14th and Independence Avenue, S.W.
Washington, DC 20250
Phone: (202) 720-
Fax: (202) 690-3287

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In addition, you may also request a hearing regarding this determination pursuant to FSIS Rules of Practice (9 CFR Part 500). The Rules of Practice were published in the Federal Register, Vol. 64, No. 228, on November 29, 1999. As specified in Section 500.5(d), should you request a hearing, FSIS will file a complaint that will include a request for an expedited hearing. If you wish to request a hearing regarding this determination, you should contact:

Director
Evaluation and Enforcement Operations
Food Safety and Inspection Service
United States Department of Agriculture
Congressional Quarterly Building, Room 300
Washington, DC 20250
Telephone No.: 202-418-8872
Fax No.: 202-418-8896

We urge your cooperation and voluntary compliance. Please direct any questions to [redacted] District Analyst (DA) at: 215-597-4219, ext. [redacted]

Sincerely,

[redacted]

Mr. Jan T. Behney
Philadelphia District Manager