United States Department of Agriculture

Food Safety and Inspection Service

District Enforcement Operations
665 South Broadway, Suite B.
Boulder, Colorado 80305

CERTIFIED – RETURN RECEIPT REQUESTED & FACSIMILE

July 18, 2002

Mr. Warren Mirtsching
Vice President Quality Assurance & Food Safety
ConAgra Beef Company, Est. 969
One ConAgra Drive
Greeley, Colorado 80634

NOTICE OF INTENDED ENFORCEMENT

Dear Mr. Mirtsching,

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspectors at ConAgra Beef Company, Est. 969, Greeley, Colorado. This notification is based on the following information:

BACKGROUND

On May 14, 2002, a Food Safety and Inspection Service (FSIS) routine monitoring sample of raw ground beef was confirmed as positive for *E. coli O157:H7*. The sample was collected May 9, 2002 at Est. 6475, Galligan Wholesale Meats, Denver, Colorado. Raw materials for production of ground beef by Establishment 6475 on May 9, 2002 were from multiple suppliers, one of which was Est. 969, ConAgra Beef Company, Greeley, Colorado. In accordance with agency policy, FSIS initiated follow-up testing of 15 consecutive days of ground beef production at Est. 6475. Samples collected on June 12, 2002, and June 14, 2002, were confirmed positive for *E. coli O157:H7*. Establishment 6475 provided information indicating that the source of raw materials for ground beef production on June 12, 2002, and June 14, 2002, was product produced May 31, 2002, by Est. 969. It was unclear at that time whether raw materials from other sources had also been incorporated into ground beef production on those dates. Thereafter, on June 19, 2002, a FSIS Compliance Officer located two boxes of Est. 969 frozen ground beef chubs with a production date of May 31, 2002, and Sell/Freeze by date of 6/18 in a freezer at Est. 6475. On June 24, 2002, the Compliance Officer collected and submitted a 10 pound intact chub from each box to the FSIS Western Laboratory in Alameda, CA for microbiological analysis for *E. coli O157:H7*. On June 29, 2002, the samples were confirmed positive for *E. coli O157:H7*. Based on these laboratory findings, on June 30, 2002, Est. 969 initiated a voluntary recall of 354,200 pounds of ground beef produced on May 31, 2002.

On July 10, 2002, the Colorado Department of Public Health and Environment (CDPHE) notified the Centers for Disease Control and Prevention (CDC) of a cluster of 18 culture-confirmed cases of *E. coli O157:H7* infections possibly related to recalled ground beef. This included two cases of hemolytic uremic syndrome (HUS). In addition, two cases of HUS among patients without culture-confirmed infection were reported. Twelve of the patient isolates were

indistinguishable when subtyped with PFGE (Pulse Field Gel Electrophoresis). Isolates matched by two PFGE restrictive enzymes. Dates of illness onset ranged from June 14 to July 5, 2002. Patients ranged in age from 2 – 72 years (median 16 years). Cases were distributed throughout the state, from at least nine different counties.

By July 12, 2002, CDPHE determined that a total of 17 patient isolates had indistinguishable PFGE patterns. Epidemiological case interviews found that 17 of 18 patients reported purchasing ground beef from the same grocery store chain. CDPHE review of grinding logs from the grocery store chain indicated that ground beef repackaged by the grocery chain was from Est. 969, with a production date of May 31, 2002.

Based upon epidemiological evidence suggesting a potential association between consuming ground beef produced at Est. 969 on May 31, 2002, and *E. coli O157:H7* illness, FSIS commenced an in-plant public health investigation on Monday, July 15, 2002, at Est. 969, ConAgra Beef Company, Greeley, Colorado.

The in-plant public health investigation sought to determine the following:

- Are establishment Hazard Analysis Critical Control Point (HACCP) systems, Sanitation Standard Operating Procedures (SSOP), and other establishment process controls adequate to prevent adulterated product from entering commerce?
- Does future production at this establishment pose a public health risk to consumers given current manufacturing practices at this facility?

On Monday, July 15, 2002, PFGE patterns from Colorado patient isolates in this outbreak were found to be indistinguishable from PFGE isolates of Est. 969 ground beef produced May 31, 2002. At least three additional cases of *E. coli O157:H7* in two states (two cases in Arkansas, one in California) are potentially associated epidemiologically with consumption of Est. 969 ground beef produced on May 31, 2002. PFGE results are not yet available.

REVIEW FINDINGS

Based on the team's findings, FSIS has reason to believe that the design, execution and effectiveness of your firm's HACCP and SSOP systems are not effective to prevent the production and shipment of adulterated products. The team's assessment and findings were discussed in detail with you and other ConAgra officials at the exit meeting held today, July 18, 2002. To further assist ConAgra in appropriately addressing this matter, a description of the team's findings that form the bases for issuance of this NOIE are as follows:

The decision to institute enforcement action is based on failure to comply with the following requirements: 9 CFR 417.2; 417.3(b); 417.4(a)(2); 417.4(a)(3); 417.5(a)2); 416.12; and 416.14. Section 417.4(a)(3) requires that every establishment reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. The regulations require that such a reassessment be performed by an individual trained in accordance with Section 417.7. The HACCP plan shall be modified immediately or whenever a reassessment reveals that the plan no longer meets the requirements of Section 417.2(c).

The FSIS review found evidence that these requirements were not being met. Specifically, during the weeks of May 20, 2002, through May 31, 2002; June 3, 2002, and June 7, 2002; June 10, 2002, and June 14, 2002; June 17, 2002, and June 21, 2002; and June 24, 2002, and June 29, 2002, the establishment received 33 positive E. coli 0157:H7 on trim meat materials produced at Establishment 969. For each positive *E. coli* O157:H7 finding in trim meat materials, the establishment treated this as an unforeseen hazard.

Establishment 969 based this on the premise that their HACCP plans for slaughter, fabrication and ground beef all identify *E.coli* 0157:H7 as a food safety hazard, which must be controlled for each process. However, even though the 33 positive 0157:H7 trim results were considered an unforeseen hazard, they did not result in any modification to the HACCP plan when it was revealed through these results that the plan no longer met the requirements of Sec. 417.2(c) of this part. In reviewing the Unforeseen Hazard-HACCP/SSOP Reassessment Log for Est. 969 Slaughter HACCP Plan records documented for May 27, 2002, through May 31, 2002; June 3, 2002, and June 7,2002; June 10, 2002, and June 14, 2002; June 17, 2002, and June 21, 2002; and June 24, 2002, and June 29, 2002, it was noted that plant management answered the following questions on these records for each positive finding in the same manner.

> "How severe is the food safety risk regarding sickness or injury? Answer High.
>
> What is likelihood of occurrence based on past history and future potential? Answer Low.
>
> Does the program need to be revised? Answer No."

Contrary to plant actions described they did not comply with regulatory requirements. Specifically, Establishment 969 determined that each positive trim sample result of a confirmed finding of *E. coli* 0157:H 7 as an unforeseen hazard. Section 9CFR 417.3(b) states "If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan." The establishment did not perform a review to determine the acceptability of the affected product for distribution or take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce after receiving results of these laboratory samples.

In addition, the Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for May 27, 2002, through May 31, 2002 representing 5 positive E. coli 0157:H7 results, stated the hot water pasteurization cabinet was increased 5 degrees F as of 5/28/02 and the rest of the week was spent perfecting the set point to consistently maintain 230

degrees F at the skids. While it was determined by the plant that this action directly contributes to the efficacy of the critical control point for the slaughter HACCP plan in controlling pathogens, the slaughter HACCP plan was not modified under section 417.4(a)(2) to include an ongoing verification activity. Additionally, this was not validated as being effectively implemented nor is there evidence of review of the records themselves in the context of other validation activities to control the pathogen of concern.

Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for June 3, 2002, through June 7, 2002, representing 3 positive E. coli 0157:H7 results, stated the air flow from the hot water pasteurization wash room was found pulling in from the hot fat trim area. The heating unit in this room was turned on to bring filtered air to push air from the area into the hot fat trim area. Also the scribe saw used on the slaughter floor to saw through the feather bones was moved from before the hot water pasteurizer to after the hot water pasteurizer. These actions were not documented as being effectively implemented nor is there evidence of review of the records themselves in the context of other validation activities to control the pathogen of concern.

Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for June 10, 2002, through June 14, 2002, representing 13 positive E. coli 0157:H7 results, stated "the cattle receiving area at the end of A shift in area below circle pen holding water from cattle wash." Cattle had to walk through the excess water. Start times for employees washing pens for the B shift changed so that the area could be washed prior to any cattle moving into the circle. In addition, the hock blow off cabinet was put on the schedule to be broken down and cleaned every weekend beginning June 15, 2002, and the sanitizing of benches in the cafeteria between breaks was implemented. Neither action was included in the Sanitation Standard Operating Procedures in accordance with 9 CFR 416.12 to describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s). These actions were not demonstrated as being effectively implemented nor is there evidence of review of the records themselves in the context of other validation activities to control the pathogen of concern.

Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for June 17,2002, through June 21, 2002, representing 3 positive E. coli 0157:H7 results, stated modifications were implemented in the slaughter and fabrication area including adjusting hose lengths to prevent rubbing of carcasses, adjusting the stroke on side pullers, replacing wood handle knives with plastic handle knives and removal of all mesh equipment prior to leaving the floor for breaks. The last action identified was not included in the Sanitation Standard Operating Procedures in accordance with 9 CFR 416.12 to describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s). These actions were not validated as being effectively implemented nor is there evidence of review of the records themselves in the context of other validation activities to control the pathogen of concern.

Additionally, the establishment implemented fogging the fabrication area with quaternary ammonia and added 180 degrees spray to the brush on PC-8D as well as lowering the catch pan

for this brush. Neither action was included in the Sanitation Standard Operating Procedures in accordance with 9 CFR 416.12 to describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

On June 22, 2002, the hot water pasteurization system was modified to have nozzles remain stationary and additional nozzles added to have complete coverage of the carcasses because oscillating arbors may not have had full range. These actions were neither demonstrated as being effectively implemented nor is there evidence of review of the records themselves in the context of other validation activities to control the pathogen of concern. On the evening (10:00 PM-11:30 PM) of July 17, 2002, three members of the team conducted a review of the establishment's slaughter operations. The team members observed two types of scenarios that probably impacted on the effectiveness of the organic acid rinse system. The first scenario, the team observed two times during a 15 to 20 minute interval, where two carcass sides were clumped together that prevented the organic acid spray from hitting areas of both sides of the carcasses. In the second scenario, the team members observed two carcass sides that were much longer than the typical carcass side. Consequently, based on the orientation of the organic acid spray cabinet nozzles, the outside of the neck region wasn't being hit by the organic acid spray. Establishment failed to provide evidence that they have validated the process as required by 417.4 to accommodate these situations.

Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for June 17, 2002, through June 21, 2002, representing 9 positive E. coli 0157:H7 results, stated the hot water pasteurization system was modified to have nozzles remain stationary and additional nozzles added to have complete coverage of the carcasses. This is the same corrective action that was to be implemented on June 22, 2002. Corrective action also included testing to ensure the hot water pasteurization cabinet skids were at 230 degrees F which was proposed as corrective action in the Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for May 27, 2002, through May 31, 20002. Failure to include this action into ongoing verification activity pursuant to 417.4(a)(2) during the week of 5/27/02 resulted in the plant having to re-institute previous corrective action as described on page 3 of this letter.

Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for July 3 "two ground beef chubs with production dates of May 31, 2002, sent in for E.coli 0157:H7 analysis by a Boulder Compliance Officer. On June 29, 2002, the Establishment was notified of the confirmation of E.coli 0157:H7 in the samples. A reassessment of the Ground Beef HACCP plan was performed. A voluntary recall of Ground Beef produced on May 31, 2002, was implemented. Approximately 354,200 lbs. of Ground Beef was effected by the recall. 363 boxes of product are at Millard's Code 42606 on hold. Product returned due to the recall will be condemned. Reassessment of the Ground Beef HACCP plan was performed July 5, 2002. Hazard Analysis for receiving raw ingredients was changed to add a statement to Question #1 under Biological Hazard, and survey sampling of raw material lotted, sampled, and only negative lotted material will be used for ground beef production. Though only negative lotted material will be used, it is not a guarantee that finished product is 100% free of E. coli 0157:H7, this testing of raw materials is not a CCP. This action was not validated as being effective in the context of other validation activities to control the pathogen of concern."

Additionally, the form Unforeseen Hazard-HACCP/SSOP Reassessment Log Est. 969 Slaughter HACCP Plan records for July 3 states both the slaughter and Fab HACCP plans will be reassessed within 30 days from July 8,2002. 9CFR 417.4(a)(3) states every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Conducting reassessment of the slaughter and fabrication HACCP plans 30 days after a recall does not meet the requirements for reassessment whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. In addition, the establishment's reassessment as part of 9CFR 417.3(b)(4) states,

> "How severe is the food safety risk regarding sickness or injury? Answer High.
>
> What is likelihood of occurrence based on past history and future potential? Answer High.
>
> Does the program need to be revised? Answer No."

The decision to institute enforcement action is also based on the failure of the establishment to meet the regulatory requirements of 9 CFR 417.4(a) and 9 CFR 417.5(a)(2). The establishment's documentation used to validate the adequacy of the carcass chill CCP's (CCP3) critical limit was insufficient to address the outgrowth of bacterial pathogens (e.g., *E coli* 0157:H7). The CCP's critical limit is "Carcass internal round temperature at time of transfers are to be 50 degrees F or less." Moreover, the usual time for carcass transfer to occur was 36 hours after the beef carcasses enter the hot box. This CCP's critical limit was to prevent bone sour which is a quality issue that impacts on the grade of carcasses. Consequently, the carcass chill CCP's critical limit was not designed to address the biological hazard of bacterial pathogen (e.g., *E. coli* 0157:H7 and *Salmonella*) growth. Furthermore, the CCP's critical limit does not specify a time that carcasses need to be chilled within to prevent this biological hazard.

The establishment's failure to effectively implement corrective action and to reassess and validate its HACCP programs collaborates findings of fecal and ingesta contamination in trimmings and on carcasses is evidenced by the Noncompliance Records referenced in Attachment I and findings of positive *E.coli* O157:H7 in environmental samples in Attachment II.

Based on the results of this investigation, FSIS has determined that your HACCP Plan does not meet the regulatory requirements of 9 CFR Part and 417.

Before we initiate any enforcement action, we are affording you the opportunity to demonstrate why a SSOP and HACCP system inadequacy determination should not be made or that you have achieved regulatory compliance. Please provide this office a written response within three (3) working days from the receipt of this letter, and no later than close of business Tuesday, July 23, 2002. Your response should include the results of any evaluation or reassessment made to your sanitation SOP and HACCP plans and systems regarding the issues cited above. We will determine further enforcement action to be taken, if any based on your response.

If you have any questions regarding this matter feel free to call the Boulder District Office.

Sincerely,

/s/ Ron Nelson for

Ronald K. Jones
District Manager

Enclosure:

cc: R. VanBlargan, FO/ADA
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