



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Denver District Office of Field Operations  
Denver Federal Center, Building 45  
PO Box 25387  
Denver, Colorado 80225-0387  
Telephone: (303) 236-9800  
Fax: (303) 236-9794

January 12, 2009

**CERTIFIED RETURN - RECEIPT  
REQUESTED AND FACSIMILE**

Mr. Rick De Los Santos, Owner  
Pecos Valley Meats – Est. 7299  
3845 Cedarvale Road  
Roswell, NM 88023

**NOTICE OF INTENDED ENFORCEMENT**

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 inspection program personnel at Pecos Valley Meats, Est. 7299, 3845 Cedarvale Road, Roswell, New Mexico, 88023.

**Background/Authority**

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products 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 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 establishment are such that products may be rendered adulterated and provide 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. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records. When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to provide inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

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 Part 416 and Part 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**

The following information is provided to support this notification of intended enforcement for your facility:

On January 6, 2009, a PBIS Establishment HACCP Summary report (Attached) for the previous ninety (90) days, October 1, 2008, through December 31, 2008, identified the following noncompliance rates for your establishment:

- 06D01 – 42.9%
- 01C02 – 23.3%
- 03J01 – 14.3%
- 03J02 – 10.7%

On January 6, 2009, review of the noncompliance reports issued at this establishment from October 1, 2008, through December 31, 2008, identified that the establishment has failed to regain compliance for sixty-one percent (61%) of issued NRs identified above:

- 06D01 – 83%
- 01C02 – 28.6%
- 03J01 – 60%
- 03J02 – 66.6%

In addition, prior to October 1, 2008, the establishment has failed to become compliant in response to documented NRs on:

- 08/12/08 (NR #34-2008-13488)
- 09/03/08 (NR #40-2008-11062)
- 09/08/08 (NR #41-2008-13488)
- 09/09/08 (NR #42-2008-11062)
- 09/12/08 (NR #43-2008-13488)
- 09/22/08 (NR #45-2008-11062)
- 09/25/08 (NR #46-2008-11062)

On December 9, 2008, and December 10, 2008, [REDACTED] D.V.M., Frontline Supervisor, performed a review of documented noncompliance as well as a review of the facility, written SSOP and HACCP plans and records for the previous sixty (60) days. This review was initiated based on elevated rates of documented noncompliance for 06D01 and 01C02 procedure codes as well as a lack of response to documented noncompliance from plant management. In addition, the in-plant inspection team has repeatedly discussed trends of noncompliance with plant management, but the establishment has failed to regain compliance with regulatory requirements. Plant management has been provided a copy of the documented weekly exit meeting memoranda.

The firm has extensive HACCP noncompliance due to inaccurate hazard analyses and flow charts, failure to assess for expected hazards, failure to implement critical control points (CCPs) to prevent, eliminate, or reduce identified hazards, failure to maintain supporting documentation in support of the decisions made in the hazard analysis, failure to maintain decision-making documentation supporting critical limits and monitoring and verification procedures and frequencies. In addition, the establishment has failed to implement, and document corrective actions in accordance with regulatory requirements following identification of deviations from a critical limit on numerous occasions.

**The following noncompliance with 9 CFR 417.2(a)(1) was identified:**

The establishment's raw, not ground flow chart identifies a step labeled "Spray Lactic Acid on Carcass" but the establishment failed to incorporate this step into the hazard analysis.

The establishment's raw, not ground hazard analysis failed to consider specified risk materials (SRMs) at receiving.

The establishment's raw, not ground HACCP program identifies production of [REDACTED] which is frequently used for ground beef products. The establishment's hazard analysis identifies *E. coli* O157:H7 as reasonably likely to occur at the first step of the process. However, the establishment has not addressed any preventive measures to control the identified hazard.

The establishment's raw, not ground hazard analysis at the [REDACTED] does not identify any potential hazards. The establishment has not considered any hazards which may occur during this step of the process in the absence of any controls even though *E. coli* O157:H7 and *Salmonella* are identified as reasonably likely to occur at receiving and no CCP to prevent, eliminate, or reduce these hazards is incorporated into the preceding process steps.

**The following noncompliance with 9 CFR 417.2(b)(1) was identified:**

The establishment's raw, not ground hazard analysis identifies BSE as reasonably likely to occur at the [REDACTED] step of the process but the establishment has not incorporated a CCP to prevent, eliminate, or reduce the hazard.

The establishment's raw, not ground hazard analysis identifies *E. coli* O157:H7 and *Salmonella* as reasonably likely to occur at the first step of the process, [REDACTED] but the establishment has not incorporated a CCP to prevent, eliminate, or reduce the hazards.

**The following noncompliance with 9 CFR 417.2(c) was identified:**

The establishment's Slaughter CCP-1, CCP-2, CCP-RP-3 and Raw, Not Ground CCP-RP-3 HACCP plans do not identify the hazards being controlled at the critical control points.

The establishment's Slaughter CCP-1, CCP-2, CCP-RP-3 and Raw, Not Ground CCP-RP-3 HACCP plans do not identify a frequency for direct observation of corrective actions.

The establishment's Slaughter CCP-1, CCP-2, CCP-RP-3 and Raw, Not Ground CCP-RP-3 HACCP plans are not signed and dated.

The establishment's Slaughter CCP-1 HACCP plan lists ongoing verification procedures as

[REDACTED] The HACCP plan does not identify specific frequencies for review of records and direct observation of monitoring.

The establishment's Raw, Not Ground CCP-RP-3 HACCP Plan identifies conflicting monitoring frequencies of [REDACTED]

The establishment's Raw, Not Ground CCP-RP-3 HACCP Plan fails to identify a frequency for direct observation of monitoring verification.

**The following noncompliance with 9 CFR 417.5(a)(1) was identified:**

The establishment's Slaughter HACCP hazard analysis identified that the establishment has determined *E. coli* O157:H7 and *Salmonella* are not reasonably likely to occur at receiving. The establishment lacks support for this decision because *E. coli* O157:H7 and *Salmonella* are microorganisms known to be prevalent in livestock.

The Slaughter process flow chart and hazard analysis do address carcass chilling, and include a CCP for [REDACTED] but the establishment has not addressed cold storage of carcasses prior to shipping. The establishment fails to address cold storage in the slaughter flow chart and hazard analysis even though they ship intact carcasses. The flow chart depicts [REDACTED]. However, the establishment [REDACTED].

The establishment has implemented use of a [REDACTED] in the slaughter process which [REDACTED] but has failed to reassess the flow chart and hazard analysis prior to implementing use of this [REDACTED]. The establishment failed to implement any kind of written program addressing procedures for the use of this [REDACTED]. The establishment could not provide any supporting documentation from the manufacturer regarding proper use of the [REDACTED] which [REDACTED]. The establishment has therefore not considered potential spreading of contamination on a single carcass or cross-contamination between carcasses as it has failed to consider any use instructions or sanitation of the [REDACTED] between carcasses. This is also noncompliance with 9 CFR 417.2(a)(1), 417.4(a)(3) and 417.4(b).

The establishment has a single HACCP plan, CCP-RP-3, for the Raw, Not Ground process that addresses the identified hazards of "*E. coli* O157:H7 and *Salmonella*". This same CCP is described in the Slaughter process and is identified by the same name, CCP-RP-3. The CCP identifies the exact critical limits pertaining to the [REDACTED]s. The monitoring procedure references [REDACTED]. The critical limits and monitoring procedures are not relevant to the raw, not ground process.

The establishment's Raw, Not Ground CCP-RP-3 HACCP Plan identifies [REDACTED] in contrast to an identified [REDACTED] in the Slaughter CCP-RP-3 HACCP Plan. The establishment's decision-making is inconsistent and lacks support as the establishment does not have supporting documentation for either frequency.

**The following noncompliance with 9 CFR 417.5(a)(2) was identified:**

The establishment's Slaughter CCP-RP-3, [REDACTED] includes the use of [REDACTED]. The establishment failed to provide any documented calibration procedures in the HACCP plan. When asked, the establishment's [REDACTED] verbally stated that he performed calibrations, but did not have written procedures. He did state that he periodically used the FSIS Food Inspector's thermometer during calibration to compare and make sure the establishment thermometers were accurate. Subsequently, the establishment did produce a facsimile copy, with a copy date of 12/10/08, from the manufacturer of the thermometer utilized which included calibration procedures but the procedures documented are not those utilized by plant personnel. The establishment does not have decision-making documentation for ongoing calibration of process monitoring instruments utilized in both the slaughter, and raw, not ground processes.

The establishment's Slaughter CCP-1, [REDACTED] identifies critical limits as [REDACTED]. The critical limits fail to address milk contamination. The establishment lacks decision-making support for the failure to include milk in the critical limits.

The establishment's Slaughter CCP-1, [REDACTED] monitoring procedures are identified as [REDACTED]. The establishment does not have decision-making support for this monitoring frequency. The establishment changed the monitoring frequency in October 2008 from a monitoring frequency [REDACTED], to monitoring [REDACTED]. Review of records identifies that sequential carcasses are being monitored. The establishment changed the monitoring frequency to a less frequent interval despite the fact that the establishment documented deviations from a critical limit on seven (7) separate occasions in October 2008 and received documented noncompliance relating to zero tolerance/sanitary dressing in July, August, and September 2008.

The establishment does not have decision-making documentation for the Slaughter CCP-2 [REDACTED]. The critical limits are [REDACTED]. The establishment is applying lactic acid spray to carcasses, but the establishment has not provided support for the effectiveness of this concentration and the critical limits do not address application, temperature or pressure at application. When asked, the establishment highlighted information on page 20 of the FSIS *Guidance for Minimizing the Risk of E. coli O157:H7 and Salmonella in Beef Slaughter Operations*, but the referenced section summarizes a peer reviewed scientific article which does not match the application used by the establishment. This noncompliance was documented on NR #53-2008-11062 issued on November 7, 2008, by CSI [REDACTED] but the establishment has not answered this NR.

The establishment's Slaughter CCP-2, [REDACTED], HACCP plan, documented monitoring procedures identify that the establishment will monitor [REDACTED]. The establishment does not define or describe [REDACTED] of [REDACTED] in any written documentation.

The establishment's Slaughter CCP- [REDACTED], HACCP plan, critical limits are [REDACTED]. The HACCP plan does not identify procedures addressing preparation or testing to ensure the concentration of [REDACTED] identified in the critical limits is achieved. When asked, the establishment did provide a laminated card documenting procedures for testing [REDACTED] concentration from [REDACTED] but they have not incorporated this testing procedure into the HACCP plan nor provided reference to it.

The establishment's Slaughter CCP-RP-3, [REDACTED] HACCP plan identifies [REDACTED], but under monitoring it specifically states: [REDACTED]. It is not clear at which frequency the establishment has implemented calibration as these are conflicting frequencies.

A review of approximately sixty (60) days of establishment HACCP records from October 2008 and November 2008 identified noncompliance as described below.

**The following noncompliance with 9 CFR 417.2(c)(4) was identified:**

Review of the establishment's "Rail Inspection Audit" records, documenting Slaughter CCP-1 monitoring and verification results, identifies that the establishment is not monitoring at the frequency specified in the plan. Prior to the middle of October 2008, the establishment's documented frequency for monitoring was [REDACTED]. The establishment repeatedly failed to monitor [REDACTED] though total number of livestock slaughtered exceeded the monitoring frequency. For example, on 10/01/08 records identify monitoring results for four carcasses; 10/02/08 records identify monitoring results for five carcasses; 10/03/08 records identify monitoring results for seven carcasses. Records for 10/03/08 document that one carcass was "rejected" with a notation that "fly on carcass removed and passed" but there are no records documenting monitoring results applicable to zero tolerance critical limits. Records for 10/06/08 documented three carcasses as "reject" due to "fly on carcass kill fly trim carcass", "fly on carcass kill and reinspected", and "fly on carcass killed and reinspected". It is not clear if these carcasses were monitored for the identified zero tolerance critical limits and what the results were.

The establishment's Raw, Not Ground CCP-RP-3 HACCP Plan monitoring frequency is identified as "[REDACTED]" while a handwritten monitoring frequency on the same HACCP plan states that [REDACTED]. Review of establishment records for October 2008 and November 2008 reveals that there are no documented monitoring results for the [REDACTED] CCP-RP-3. The establishment does monitor [REDACTED] applicable to the Slaughter CCP-RP-3 HACCP plan, with a monitoring frequency [REDACTED] but is not monitoring at the frequency specified in the Raw, Not Ground HACCP plan.

**The following noncompliance with 9 CFR 417.3(a) was identified:**

Review of the establishment's "Rail Inspection Audit" records for monitoring Slaughter CCP-1, [REDACTED], identify that on repeated occasions the establishment identified deviations from a critical limit but failed to implement, and record corrective actions meeting the requirements of 9 CFR 417.3(a).

On 10/09/08 the "CCP Corrective Action Log" records document deviation from the critical limits: "Fecal on calf breast – stop line, instruct employees to recondition carcass; reinspect and pass; inspect last 3 carcasses to insure zero tolerance"; disposition of product – "trim and pass". The corrective actions do not identify or eliminate the cause of the deviation, fail to demonstrate that the CCP was brought under control, did not address products back to the last acceptable check, and fail to address any measures to prevent recurrence.

On 10/14/08 two deviations from the critical limits were documented. At "1043", the record notes "Reject – fecal on butt retrimmed and passed" and at "1137" the record states "Reject – fecal on brisket retrimmed and passed". The documented corrective actions do not identify or eliminate the cause of the deviation, fail to demonstrate the CCP was brought under control, do not address products back to the last acceptable check, and fail to address any measures to prevent recurrence.

On 10/17/08 two deviations from the critical limits were documented. At "1135" the Rail Inspection Audit states "fecal on back re-trimmed and passed" and at "1153" the record identifies "small piece of fecal trimmed" with no documented corrective actions for either deviation other than the notation indicating products were trimmed. The documented corrective actions do not identify or eliminate the cause of the deviation, fail to demonstrate the CCP was brought under control, do not address products back to the last acceptable check, and fail to address any measures to prevent recurrence.

On 10/23/08 a deviation from the critical limits was documented. At "1042" the record states "small piece of fecal trimmed and past (sic)". The documented corrective actions do not identify or eliminate the cause of the deviation, fail to demonstrate the CCP was brought under control, do not address products back to the last acceptable check, and fail to address any measures to prevent recurrence.

On 10/27/08 a deviation from the critical limits was documented. At "325" the record states "fecal matter on shank trimmed and passed". The documented corrective actions do not identify or eliminate the cause of the deviation, fail to demonstrate the CCP was brought under control, do not address products back to the last acceptable check, and fail to address any measures to prevent recurrence.

**The following noncompliance with 9 CFR 417.5(a)(3) was identified:**

Review of the establishment's "Rail Inspection Audit" records for monitoring Slaughter CCP-1, [REDACTED] identify that results are being recorded as [REDACTED]. The critical limits are defined as [REDACTED]. The establishment is not recording a quantifiable value when monitoring the CCP.

The establishment has failed to comply with Sanitation Performance Standards (SPS) regulatory requirements as documented by the following noncompliance reports (NRs).

NR #40-2008-11062 (Attached) issued on 09/03/08 documented noncompliance with 9 CFR 416.2(b) due to gaps around the overhead door at the offal load-out area. This NR was linked to NR #17-2008-6305 issued on 06/06/08. The establishment has not responded to NR #40 and has not taken action to ensure all outside openings are sealed to preclude entry of pests and vermin. Wadded up paper towels and gaps were still present around the overhead door as of 01/07/09.

NR #45-2008-11062 (Attached) issued on 09/22/08 documented noncompliance with 9 CFR 416.1, 416.2(b)(1), and 416.2(b)(2) due to extensive rusting and peeling paint on the front cooler door surfaces and supporting structures, extensive rusting of fan shrouds in the holding cooler, extensive rust and peeling paint involving the freezer door and support structures, and door seals to freezer door in disrepair resulting in extensive ice formation. The establishment has not responded to this NR and has failed to take action to correct the identified noncompliance.

NR #47-2008-11062 (Attached) issued on 10/01/08 for noncompliance with 9 CFR 416.1, 416.2(d), 416.2(e)(2), 416.2(e)(3), 416.2(e)(6) and 416.2(h)(2). The specific construction noncompliance identified in this NR included: extensive rust and peeling paint on overhead steel support beams and other overhead structures in the kill floor, extensive rusting of fan shrouds used in the kill floor, extensive rusting of electrical fan metal casings, extensive rusting and peeling paint involving wall surfaces, steel support beams, and other structures attached to walls and extensive rusting of overhead beams and structures in the hot box cooler. The establishment has corrected noncompliance involving the overhead rails and structures in the hot box and has repaired rails on the kill floor. However, the NR remains open as the establishment has failed to correct the additional noncompliance documented.

Noncompliance with SPS regulatory requirements has been discussed repeatedly in weekly exit meetings between FSIS personnel and plant management. For example, the weekly exit meeting, dated 12/04/08 (Attached), identified that NRs #45 and #47 referenced above are still open, that the establishment had agreed to provide FSIS with a plan of action regarding repair of documented facility noncompliance, and that establishment management failed to provide FSIS personnel with that planned action for the week ending 11/28/08. The weekly meeting notes on 12/04/08 regarding these NRs show that FSIS personnel further advised Mr. Rick De Los Santos that continued failure to comply may result in additional regulatory or administrative actions per 9 CFR 500.4. Despite documentation of noncompliance and repeated discussion during weekly exit meetings with FSIS personnel and plant management, the establishment has not yet regained compliance and repaired documented items sufficient to restore sanitary conditions.

The weekly exit meeting dated 01/02/09 (Attached), documents discussion of NR #64-2008-11062 (Attached) issued on 12/31/08 for SPS noncompliance due to an extensive section of the roofing having been blown off by the wind. This NR was linked to NR#43-2008 issued on 09/10/08. As documented in the weekly meeting notes dated 01/02/09: "...concerning wind damage to the raised roof installed directly over the kill floor and offal inedible storage room. CSI [REDACTED] explained that the raised roof had been installed to prevent rain water leakage into the facility as the existing flat roof is not in good repair and was leaking into the facility causing



insanitary conditions that would adulterate product and was a repetitive noncompliance prior to the raised roofs installation. CSI [REDACTED] advised Mr. Rick De Los Santos that the roof had been damaged for approximately ten (10) days with no corrective actions accomplished by the establishment. In addition in the last weekly meeting the roof damage was discussed and the answer was that the roofing company would be contacted to repair the roof during the week of 12/29/2008 thru 01/02/2009. Mr. De Los Santos informed CSI [REDACTED] that he had indeed contacted the roofer and they informed him they would do the repairs as soon as possible." As of 01/07/09, the roof has not been repaired by the establishment.

The establishment was issued NR #64-2008-13488 (Attached) on 12/31/08 for noncompliance with SPS regulatory requirements due to failure to provide towels or toilet paper tissue in the employee restroom. This NR was linked to NR #56-2008-11062 (Attached) issued on 12/08/08 for same cause. The establishment has not answered NR #56-2008-11062. In addition, NR #56-2008-11062 was linked to NR #51-2008-11062 (Attached) issued on 11/06/08 also for same cause. The establishment's documented further planned actions on NR #51-2008-11062 state: "Employee restrooms will be checked daily by assigned QC, to insure there is required supplies. Documentation will be done on KF1 sheets." The establishment has been issued three noncompliance reports in the previous two (2) months for insanitary conditions involving employee restrooms demonstrating a failure to consistently ensure cleanliness of all employees handling product.

The establishment has failed to comply with 9 CFR 310.25, Contamination with Microorganisms (Generic *E. coli*) as documented on NR #63-2008-11062 (Attached) issued on 12/15/08. The establishment has not responded to the NR.

**The following noncompliance with 9 CFR 310.25(a)(2)(i) was identified:**

The establishment's Generic *E. coli* written program fails to identify the location of sampling.

**The following noncompliance with 9 CFR 310.25(a)(2)(iii) was identified:**

The establishment is not testing at the required frequency of a one test per 300 carcasses but a minimum of once per week. Review of records indicates no sample results for the week of 12/01/08 through 12/05/08 although review of eADRS data identifies that [REDACTED] head of bob veal were slaughtered during those same dates. Samples submitted the week of 11/28/08 were discarded by the laboratory so no sample results were obtained that week.

**The following noncompliance with 9 CFR 310.25(a)(4) was identified:**

The establishment is not recording results onto a process control chart or table. Review of Generic *E. coli* test results identifies that the last process control chart is dated 2006.

The establishment has failed to comply with 9 CFR 310.22, Specified risk materials from cattle and their handling and disposition as documented on NR #62-2008-11062 (Attached) issued on 12/22/08. The establishment's written SRM program, not dated or signed, is not compliant with 9 CFR 310.22(e)(1), 310.22(e)(4) and 310.22(f). The establishment has not responded to the NR.

**The following noncompliance with 9 CFR 310.22(e)(1) was identified:**

The written program fails to identify all SRMs and therefore the removal, segregation, and disposition of all SRMs is not addressed.

The written program references owner documentation of age, or the use of dentition in the absence of age documentation but no procedures are referenced for how the establishment will determine age by dentition.

The written program does not address segregation of carcasses greater than 30 months age.

The written program identifies that "all heads trimmed to remove tonsils from tongues" but fails to identify specific procedures to ensure adequate removal of lingual tonsils.

**The following noncompliance with 9 CFR 310.22(e)(3) was identified:**

The written program also consists of a "Control of Plant SRMs in Transit" document dated 10/18/05 stating that "all carcasses slaughtered for sale are classified as being 30 months of age or older". However, your establishment primarily slaughters bob veal and this program does not appear to have been reviewed nor made applicable to current slaughter processes.

**The following noncompliance with 9 CFR 310.22(e)(4) was identified:**

Review of establishment records fails to identify how age of cattle were determined. Specifically records labeled "Daily Slaughter Report" and dated 11/03/08 through 11/20/08, document age in the remarks column as "<30" or ">30" but it is unclear how the age was determined. Second, the establishment has failed to document ages of cattle, including bob veal, on a daily basis. While bob veal are certainly less than 30 months age, the establishment is not maintaining any kinds of records documenting the age of these cattle. Review of establishment records fails to identify any records documenting the removal, segregation, and disposition of any SRMs. When asked, Mr. Rick De Los Santos advised CS [REDACTED] that records are kept at the bottom of the operational SSOP records labeled "KF-2". This form does not have any reference to SRMs on the form and review of records identifies that on some dates there is a handwritten record at the bottom of the form identifying "all material denatured and disposed". There are no identified records documenting removal of SRMs on any records examined. Specifically, on 11/04/08 the establishment slaughtered a Jersey cow from [REDACTED] identified as ">30" but review of KF-2 records on that date do not identify removal of any SRMs. Again on 11/18/08 the establishment slaughtered another animal identified as ">30" but no additional documentation demonstrating the removal and disposition of any SRMs was identified. In addition, the establishment has failed to address removal and disposition of SRMs present in all cattle, tonsils and distal ileum.

**The following noncompliance with 9 CFR 310.22(f) was identified:**

The written program does not address segregation of carcasses and parts from cattle 30 months of age and older from cattle younger than 30 months. There are no written procedures addressing sanitation of equipment used on cattle 30 months of age and older and younger than 30 months.

The establishment has failed to comply with 9 CFR 416.11 through 416.16 pertaining to Sanitation SOPs. The establishment has received multiple, linked, noncompliance reports identifying repetitive noncompliance with SSOP regulatory requirements due to direct product contamination from flies. The establishment had a written Pest Control Program incorporated into the written SSOP plan. The establishment was issued a total of fifteen (15) NRs dating from April 22, 2008, through November 5, 2008, documenting failure of the establishment's written SSOP procedures from preventing direct product contamination, failure to implement effective pest control, and/or failure to implement effective SSOP corrective actions. Based on this trend of noncompliance, specific documented discussion has occurred in weekly exit meetings between FSIS personnel and establishment management beginning on September 10, 2008 and weekly thereafter in which issuance of NRs and linkage of NRs was discussed including specific notification to you that continued failure to meet regulatory requirements could result in further regulatory or administrative actions per 9 CFR 500.4. You repeatedly indicated to FSIS personnel that you understood the ramifications of continued failure to meet regulatory requirements; despite this acknowledgment additional noncompliance has been documented and the establishment has failed to achieve regulatory compliance and respond to NRs.

The following NRs document repetitive noncompliance due to direct product contamination with flies on edible product during the slaughter process have been issued. The documentation history demonstrates failure on the part of the establishment to implement SSOP procedures sufficient to prevent direct product contamination, failure to implement corrective actions effective in preventing recurrence, and failure to maintain an effective SSOP program.

NR#10-2208-6305 (Attached) issued on 04/22/08 due to noncompliance with 9 CFR 416.4(d) resulting in direct contamination of four carcasses with flies. The ISP code cited SSOP monitoring and the narrative cites the establishment's written "SSOP Fly and Pest Control Program". The narrative referenced verbal measures to prevent recurrence proffered by the establishment including use of a black light insect zapper during lunch break. The establishment's written response to this NR states: "new spray bottles put at trim station to control any flies; lunch time lights will be turned off on kill floor to gather flies to disposal area at head wash station; found source where flies were entering kill floor, knocking chute has gap over it ... will be fixed this weekend 4/26/08".

NR #14-2008-6305 (Attached) issued on 06/05/08 due to noncompliance with 9 CFR 416.4(d) resulting in direct contamination of edible product with flies. The narrative also identified numerous gaps present allowing entry of pests into kill floor. This NR was linked to NR #10-2008. The NR was not signed by plant management, but an attached "Daily Operational Procedures/Corrective Actions" dated 06/05/08 stated: [REDACTED]

NR #19-2008-6305 (Attached) issued on 06/17/08 for SSOP monitoring due to noncompliance with 9 CFR 416.13(c) due to direct contamination of edible product with flies. This NR was linked to NR #14-2008 and identified that previous measures to prevent recurrence were incomplete or ineffective. The narrative also documented additional contamination of products with flies one hour following the first notification of noncompliance. The narrative identifies verbal measures to prevent recurrence including spray for flies, keeping double doors near knock box closed and locked during slaughter, installation of a water mister over the double doors, and re-evaluation of "the situation". The documented response from establishment management on the NR states: "exhaust fan installed on 06/18; water misters installed in knocking chute area; doors on west side will be kept closed; rubber seal over knocking box reinstalled".

NR #21-2008-6305 (Attached) issued on 06/26/08 for SSOP monitoring noncompliance due to direct contamination of edible product with flies. This NR was linked to NR#19-2008 and identifies previous measures to prevent recurrence which were ineffective and included statement providing notification that additional noncompliance may lead to additional regulatory or administrative action. The narrative describes verbal measures to prevent recurrence including assign a fly monitor; pest control company hired to fog pens outside area and inside plant Saturday; fly control in the area to the runway to the knocking box will be done as often as needed; slaughter floor will be fogged before pre-op. The establishment's documented measures to prevent recurrence provided on the NR states: "QC has assigned a fly monitor as needed on K.F., Our pest Control Company has come in on Saturday to fog outside areas. K.F. will be fogged before pre op."

NR #22-2008-6305 (Attached) issued on 06/30/08 due to fly contaminating carcass at final rail. This NR was linked to NR #21-2008. The narrative described implementation noncompliance due to inadequate monitoring and previous corrective actions were not effective in eliminating the ongoing fly problem. The NR narrative included a statement referencing continued noncompliance may lead to additional regulatory or enforcement action. The establishment's documented response on the NR states: "QC will continue to have an employee monitor flies. In the event flies are found to be in K.F. QC will shut down slaughter area and fog area. Doors will continue to be closed and locked during operations."

NR #23-2008-6305 (Attached) issued on 07/07/08 due to flies on the slaughter floor contaminating edible product. The SSOP - Implementation trend indicator and 9 CFR 416.13(c) was cited. The NR was linked to NR #22-2008 and identified that the previous measures to prevent recurrence were ineffective. The NR included a statement that continued noncompliance may lead to additional regulatory or administrative action. The establishment's documented response on the NR states: "hired employee responsible for monitoring and killing flies; fluorescent lights on K.F. and in inedible areas to help control flies; outside premises are also sprayed; fly baited daily".

NR #34-2008-13488 (Attached) was issued on 08/12/08 for SSOP - Monitoring noncompliance and cited 9 CFR 416.13(c); 416.2(a) due to a fly identified within the muscle folds on belly region of a carcass presented at final rail inspection. The NR was linked to NR #23-2008 with same root cause written on 7/7/08. The narrative identifies that the establishment's previous

corrective actions were inadequate or ineffective to control flies within the harvest area. The narrative includes a statement that failure to comply may result in additional regulatory or administrative action. This NR has not been answered by establishment management.

NR #41-2008-13488 (Attached) was issued on 09/08/08 for SSOP Monitoring noncompliance and cited 9 CFR 416.13(c) and 416.14, Maintenance, due to a fly "stuck on veal carcass at the final rail" and the Food Inspector reported seeing another carcass in same condition. The narrative describes plant management "stated door to loading chute was out of order and was the cause of the problem, and would be fixed tomorrow; would re-fog area before resuming operations in the morning." This NR was linked to NR #34-2008 dated 08/12/08 "for same cause as your corrective/preventive actions proposed were ineffective in preventing reoccurrence". The narrative included a statement notifying the establishment that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. This NR has not been answered to date and no SSOP corrective actions are identified.

NR #42-2008-11062 (Attached) was issued on 09/09/08 for SSOP Monitoring noncompliance as well as noncompliance with grounds and pest control SPS regulations citing 9 CFR 416.13(c) and 416.2(a) due to fly on carcass (stuck to carcass). The narrative described that this was the second occurrence in two days and linked to NR 0041-2008 dated 09/08/08 for "same cause due to ineffective corrective actions to prevent flies from entrance into the facility and contamination of product." The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. This NR has not been answered to date and no SSOP corrective actions are identified.

NR #43-2008-13488 (Attached) was issued on 09/12/08 for SSOP Monitoring and SPS Pest control noncompliance citing 9 CFR 416.13(c) and 416.2(a) due to identification of flies landing on exposed edible products of two carcasses, one at final rail inspection. The narrative identified that this NR was linked to NR #42-2008 due to "same cause due to ineffective corrective actions to prevent flies from entrance into the facility and contamination of product." The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. This NR has not been answered and no SSOP corrective actions are identified.

NR #46-2008-11062 (Attached) was issued on 09/25/08 for SSOP Monitoring and Recordkeeping noncompliance citing 9 CFR 416.13(b), 416.13(c) and 416.16(a) due to review of the establishment's written Fly control SSOP and identification that the establishment was not spraying premises as described in the plan and was not documenting implementation and monitoring results of outside premises fly control. This NR was linked to NR #43-2008 due to failure of the establishment to implement the verbal measures identified in that NR which included fogging the premises. The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. This NR has not been answered to date.

NR #47-2008-13488 (Attached) was issued on 10/07/08 for SSOP Implementation, SSOP Monitoring, SSOP Corrective Action, and SPS Grounds and Pest Control noncompliance citing 9 CFR 416.13(b), 416.13(c), 416.15(a), and 416.2(a) due to observation of a plant employee

slapping a fly and smashing it on a veal carcass. The verbal measures to prevent recurrence included stating that the employee would be properly trained concerning proper SSOP procedure to be followed. The narrative also describes notifying establishment manager Rick De Los Santos "that due to swarming flies in and around holding pens and plants inability to control flies from entering the facility the slaughtering operation would not be allowed to continue" and further identified that prior corrective actions were not effective. This NR was linked to NR #46 dated 09/25/08 for same cause as the establishment's further planned action to fog outside and inside premises at a more frequent rate was not effective. The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. The establishment has not signed the NR but has responded by attaching a corrective action record stating that the employee was verbally disciplined and that the establishment identified spray misters at the knocking chute were not properly working and instructing the pen employee to monitor the misters to ensure they were functional.

NR #49-2008-11775 (Attached) was issued on 10/16/08 for SSOP Corrective action noncompliance citing 9 CFR 416.15(a) and 416.15(b) due to a fly on edible product of a carcass. Verbal preventive measures are described in the narrative as installation of ventilation system on the kill floor to prevent flies entrance. This NR was linked to NR #47 issued on 10/07/08 and identified that the plant had not yet responded to that NR. The narrative also states that "This trend of noncompliance was also discussed during the weekly meetings." The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. The NR has not been signed but has been returned with attached corrective actions identifying that "misters were off outside will turn back on".

NR #49-2008-11062 (Attached) was issued on 10/28/08 for SSOP Corrective Action, SSOP Monitoring, and SPS Grounds and Pest control noncompliance citing 9 CFR 416.13(c), 416.15(a), 416.13(b), and 416.2(a) based on observed fly on carcass presented for final rail inspection. The narrative identifies that Mr. De Los Santos was "advised that the facility has failed to prevent the noncompliance numerous times and that corrective/preventive actions have not been effective. In addition, the establishment was setting a trend of failure to correct and prevent reoccurrence." The narrative further identifies that "Mr. De Los Santos was also notified in the last three (3) weekly meetings that the corrective actions proposed by the facility were ineffective in preventing reoccurrence." The NR was linked to NR #48-2008-12969 dated 10/16/08 (*Note – this should have documented linkage to NR #49-2008-11775 which was issued on 10/16/08*). The narrative identifies that "your verbal measures were to reassess the plant pest control SSOP and increase fogging of inside and outside areas was ineffective" in preventing recurrence. The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. This NR has not been answered.

NR #50-2008-11062 (Attached) was issued on 11/05/08 for SSOP Monitoring noncompliance citing 9 CFR 416.13(c) due to an observed fly on carcass at final wash area at 0935 hours. The plant verbally stated that "mister located on outside chute leading to knock area had been turned off". The narrative identifies that on the same date at 1300 hours, a fly was observed on a carcass at final rail inspection and was "notified plant second occurrence on this date." The narrative further identifies that verbal measures to prevent recurrence included "would install two large fans in critical areas on the kill floor to prevent entry of flies". This NR was linked to

NR #48-2008-12969 on 10/17/08 for flies. (Note – this should have documented linkage to NR #49-2008-11062 which was issued on 10/28/08). Measures to prevent recurrence were ineffective. The establishment was advised that continued noncompliance may result in additional regulatory or administrative action per 9 CFR 500.4. The establishment's documented SSOP Corrective Action attached to the NR in response identifies measures to prevent recurrence as: "2 large fans were installed on K.F. to circulate air and control any flies."

Despite repetitive, linked noncompliance identifying Sanitation Performance Standard and SSOP noncompliance, the establishment has demonstrated failure to effectively address documented SPS and SSOP noncompliance. Review of establishment "Rail Inspection Audit" records (CCP-1) for the month of October 2008 identifies that on eleven separate dates the establishment identified flies on sixteen (16) separate carcasses. Your firm also has a responsibility per 9 CFR 416.14, Maintenance of Sanitation SOP's, to routinely evaluate the effectiveness of the SSOPs and to revise the SSOP and procedures therein as necessary to keep them effective and current with respect to changes in facilities, operations, or personnel. In response to a documented trend of noncompliance identified by FSIS personnel and the establishment's own findings, the establishment did reevaluate their SSOP procedures and, in response to repetitive documented noncompliance, advised SPHV/EIAO Dr. [REDACTED] that they removed their Pest Control Program from the SSOP plan because of an understanding that by leaving it in the SSOP they were obligated to maintain records and lack to do so would result in issuance of NRs. According to 9 CFR 416.15(b), as part of SSOP corrective actions, the establishment is expected to reevaluate and modify the SSOP as needed. In response to a documented trend of noncompliance clearly identifying a trend of direct product contamination with flies, the only modification to your SSOP was to remove the Pest Control Program from the SSOP.

In addition, the documented trend of noncompliance repeatedly references noncompliance with 9 CFR 416.2(a), Grounds and Pest Control. Documented noncompliance references swarming flies around antemortem pens, insanitary conditions in the offal load-out area including a large gap between the flat roof and peaked roof providing harborage to pigeons, and dead calves and cows in the area of the garbage dumpster. The establishment was repeatedly notified of noncompliance due to an ineffective pest control program which resulted in entry of flies into edible product areas and direct contamination of edible product.

The establishment was issued NR #60-2008-12323 (Attached) on 12/12/08 due to SPS noncompliance with 9 CFR 416.2(a) due to failure of the establishment to denature carcasses piled near the holding pens. The carcasses were not protected from vermin attack or attraction of flies. The narrative describes the creation of insanitary conditions. The establishment has not answered this NR.

On 01/06/09, during on-site visit to the establishment, FLS [REDACTED] and James Adams, Deputy District Manager, observed three (3) bob veal carcasses in the antemortem pens with several chickens having free range of the premises and pecking on the dead carcasses. This demonstrates failure to maintain sanitary conditions of the grounds around the establishment which is noncompliance with 9 CFR 416.2(a).

In accordance with FSIS' Rules of Practice, 9 CFR Part 500, we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility. Please provide this office with a written response concerning this notice of intended enforcement (NOIE) within three (3) working days from the date of your receipt of this letter, no later than the close of business, on Thursday, January 15, 2009. We will determine further action, if any, based on your response.

If you have questions regarding this matter, please feel free to contact me, Dr. Ron Nelson, District Manager, or Dr. James Adams, Deputy District Manager, at 303-236-9800.

Sincerely,

A handwritten signature in black ink, appearing to read "Ron Nelson", followed by the word "Fork" written in a cursive script.

Dr. Ron Nelson  
District Manager  
Denver District

Cc: J. Adams, DDM  
A. Gallegos, DDM  
R. Reeder, DDM  
S. Symons, DCS  
[REDACTED] FLS  
Establishment File  
Reader File