



Food Safety and
Inspection Service

August 31, 2018

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(b)(6)
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Hand Delivered

NOTICE OF INTENDED ENFORCEMENT

Dear (b)(6):

This serves as an 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 for the Slaughter and Raw Intact processes at your establishment, in accordance with Title 9 Code of Federal Regulations (CFR) Parts 500.4(a), 500.4 (b), and 500.4 (c). This action is based on your establishment's failure to effectively implement and appropriately maintain the required Sanitation Standard Operating Procedures (SSOP) and Hazard Analysis and Critical Control Points (HACCP) programs, in accordance with Title 9 CFR Parts 416 and 417. Furthermore, your establishment failed to implement and maintain the required Sanitation Performance Standards (SPS) in accordance with Title 9 CFR Part 416.

You are required to respond to this notice adequately, in writing, addressing all regulatory noncompliances in this notice. Failure to respond adequately within three (3) business days from the day of receipt of this notice may result in the suspension of the assignment of inspectors at your establishment. FSIS will evaluate your response and will determine if any further administrative enforcement action will be necessary.

Background/Authority

The Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provides that it is essential in the public interest that the health and welfare of consumers be protected, by assuring that poultry and poultry products distributed to them are wholesome, not adulterated, properly marked, labeled and packaged. This Act gives FSIS the authority, as designated by the Secretary of the Department of Agriculture, to issue rules and regulations describing sanitation requirements for inspected establishments. This Act also provides FSIS program personnel the authority to refuse to allow poultry 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, this Act provides FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. This Act also gives 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 inspection and indefinitely withdraw inspection from an establishment, provided the establishment is afforded the right to an administrative hearing.

Under the authorities of this Act, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products including the requirements pertaining to Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS) (Title 9 CFR Part 416) and other matters. FSIS has also developed Rules of Practice regarding enforcement (Title 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 suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal Inspection.

Findings/Basis for Action

From August 14, 2018, through August 23, 2018, Enforcement Investigations and Analysis Officers (EIAOs) conducted a Food Safety Assessment (FSA) at your establishment. The purpose and scope of this assessment was to review the food safety systems for regulatory compliance and to determine if the systems were scientifically sound and supported. During the FSA, the EIAOs reviewed your establishment's HACCP plans, SSOP program, prerequisite programs supporting your hazard analyses, supporting documentation, as well as corresponding records. In review of your establishment's documentation, the EIAOs found your HACCP system to be inadequate. In addition, you failed to maintain sanitary conditions in accordance with the SSOP and SPS regulatory requirements.

On March 30, 2018, FSIS personnel notified your establishment that you failed to meet the *Salmonella* performance standards for Chicken Parts for the sampling period of February 26, 2018, to May 19, 2018. Your establishment exceeded the maximum acceptable percent positive of 15.4%, as defined in the Federal Register Vol. 81 No. 28 "*New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures.*"

From February 1, 2018, through August 13, 2018, FSIS Inspection Program Personnel have issued 126 Noncompliance Records (NRs) for your establishment's continued failure to effectively maintain and implement the required SSOP, SPS, and HACCP programs, in accordance with Title 9 CFR Parts 416 and 417. These recurring NRs indicate your failure to operate and maintain your establishment in a manner to prevent the creation of insanitary conditions and to ensure product is not contaminated or adulterated.

The following are the regulatory noncompliances documented by FSIS Enforcement, Investigation, and Analysis Officers (EIAOs) during the Food Safety Assessment (FSA) at your establishment for the period from August 14, 2018, through August 23, 2018.

Sanitation Standard Operating Procedures and Sanitation Performance Standards – Title 9 CFR 416

1. Your establishment failed to implement pre-operational sanitation procedures to prevent insanitary conditions. Your SSOP pre-operational sanitation procedures state, (b)(4)
(b)(4)
(b)(4) On August 17, 2018, at approximately 0050 hours, in the dark meat room after your establishment Quality Assurance (QA) personnel completed his pre-operational inspection, the EIAO observed product residues in multiple locations inside the thigh hopper. The inside of the hopper is a food contact surface (FCS). Residues such as this can provide an excellent growth medium for many micro-organisms, including pathogens. Your establishment is not implementing your pre-operational sanitation procedures as written to ensure sanitary conditions are maintained. This is a regulatory noncompliance with Title 9 CFR 416.13(a).

In addition, on August 16, 2018, at approximately 2150 hours, in the air chill room, the EIAO observed your establishment employee conduct pre-operational inspection. After your QA personnel completed his pre-operational inspection, the EIAO observed product residue on the floor. Your establishment failed to ensure sanitary conditions prior to the start of operations.

Since February 1, 2018, FSIS Inspection Personnel have issued 14 NRs for your establishment's failure to implement pre-operational sanitation procedures to prevent insanitary conditions as required by Title 9 CFR 416.13(a). FSIS has concerns regarding your establishment's ability to maintain sanitary conditions as evidenced by the ongoing and recurring noncompliance records issued to your establishment.

2. Your establishment failed to implement your written SSOP procedures for your air chill room. Your establishment management indicated that the ceiling in the air chill room is considered a FCS in case condensation occurs and that the air chill room ceiling is cleaned nightly. However, your establishment is not documenting in the "*Preoperational Sanitation Inspection Report*" records that the ceilings are being cleaned and monitored. Furthermore, your SSOP program does not include any procedures for the cleaning of the ceiling, which you have identified as a FCS. Your SSOP do not describe all procedures your establishment is conducting daily, before and during operations, to prevent direct contamination. This is a regulatory noncompliance with Title 9 CFR 416.12(a).

Furthermore, your establishment's SSOP indicate your QA (b)(4)
(b)(4)
(b)(4)
(b)(4) In review of the Adenosine Triphosphate (ATP) testing results provided, your establishment was unable to demonstrate that you are performing any ATP swab tests on the air chill room ceiling. This is a regulatory noncompliance with

Title 9 CFR 416.13(a), 416.13(c), and 416.16(a).

3. Your establishment failed to develop and implement SSOP procedures that your establishment will conduct daily, before and during operations to prevent direct contamination. On August 15, 2018, at approximately 0530 hours, the EIAO observed a combo bin of salvage product near the salvage stations. The EIAO observed yellow hoses touching the inside of the FCS plastic liner of the combo bin. The EIAO notified Director of Food Safety and Quality Assurance, Terry Evans, who indicated that the yellow hoses are considered FCS. However, your establishment is not documenting in pre-operational SSOP records that the yellow hoses are being cleaned and being monitored as a FCS. Furthermore, your SSOP program does not include any procedures for the cleaning of the yellow hoses. Your SSOP do not describe all procedures your establishment is conducting daily, before and during operations, to prevent direct contamination. This is a regulatory noncompliance with Title 9 CFR 416.4(a), 416.11, 416.12(a), 416.13(c), and 416.16(a).

4. Your establishment failed to implement your SSOP "*Salvage Procedure for Carcasses, Parts on the Floor or in Drip Pans*" as written.

- a. Your establishment's SSOP "*Salvage Procedure for Carcasses, Parts on the Floor or in Drip Pans*" states the following: "(b)(4)"

(b)(4)

(b)(4)

On August 20, 2018, at approximately 1130 hours, the EIAO observed half carcass in a drip pan under the "elevator" front-half conveyor in the cone line/white deboning department. The EIAO notified (b)(6)

(b)(6)

, of this finding. However, subsequently, on August 20, 2018, at approximately 1400 hours, after (b)(6)

(b)(6)

, was finished conducting his operational SSOP monitoring check, the EIAO observed that the same product was still in the drip pan under the "elevator" front-half conveyor in the cone line/white deboning department. Your establishment failed to pick up product in the drip pan in a timely manner ("(b)(4)

(b)(4)

"), in accordance with your establishment's written SSOP "*Salvage Procedure for Carcasses, Parts on the Floor or in Drip Pans*". This is a regulatory noncompliance with Title 9 CFR 416.13(c) and 416.4(d).

- b. On August 23, 2018, at approximately 0900 hours, the EIAO observed a front-half chicken on the motor, which is not a product contact surface, behind the front-halves rehang table in the cone line room. Your establishment employees picked up this front-half for reconditioning at 0918 hours. Your establishment failed to pick up product in a timely manner ("(b)(4)

(b)(4)

"), in accordance with your establishment's written SSOP "*Salvage Procedure for Carcasses, Parts on the Floor or in Drip Pans*." This is a regulatory noncompliance with

Title 9 CFR 416.13(c) and 416.4(d).

- c. On August 23, 2018, at approximately 0940 hours, in the Cut-up Department, the EIAO observed establishment's employee reconditioning a whole body carcass using the ozone line hose. However, your establishment's written reconditioning procedure states, "(b)(4)"
"(b)(4)"
"(b)(4)" "Your establishment failed to implement the reconditioning procedures in your SSOP as written. This is a regulatory noncompliance with Title 9 CFR 416.13(c) and 416.4(d).

Throughout the FSA, EIAOs observed product on the floor near drains in second processing and on standing platforms and rubber mats, and that the product were there for more than 15 minutes. Your plant management indicated that this product would be condemned. However, it is unclear how your establishment distinguishes between product for reconditioning and product to be condemned. Furthermore, EIAOs observed that your establishment did not pick up product to be condemned in a *"timely manner"*, to ensure that product would not be picked up and reconditioned. In addition, your Salvage procedures do not include any procedures for when products have not been picked up within 15 minutes. Your establishment failed to prevent the creation of insanitary conditions. This is a regulatory noncompliance with Title 9 CFR 416.4(d).

Since February 1, 2018, FSIS Inspection Personnel have issued eight (8) NRs for your establishment's failure to effectively implement your salvage and reconditioning procedures to prevent insanitary conditions. These multiple regulatory noncompliances documented by FSIS personnel and observed during the FSA demonstrate that your establishment has not taken effective corrective actions to prevent insanitary conditions.

5. Your establishment failed to operate in such a way to prevent the creation of insanitary conditions, as required by the Sanitation Performance Standard (SPS) regulations of Title 9 CFR 416. During the FSA, the EIAOs identified the following regulatory noncompliances:
- a. On August 21, 2018, at approximately 0845 hours, in the tub washroom, EIAO observed your establishment employee putting FCS hand tools, such as knives with white handles and knife sharpeners, on the floor. Your employee used his boot to hold down those hand tools, and sprayed the utensils laying on the floor with chlorinated water. The EIAO notified (b)(6)
(b)(6) of these findings.
(b)(6) indicated that the cleaning method was not *"ideal"* and that your establishment stores these hand utensils overnight in peroxyacetic acid (PAA) sanitizer. There was no follow-up or corrective action taken to restore sanitary conditions. EIAO reviewed your establishment's cleaning procedures, which do not cover the cleaning of hand tools. Procedures in the SSOP that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of FCS of facilities, equipment, and utensils. Your establishment failed to provide a cleaning procedure for the FCS hand tools to demonstrate that your establishment is maintaining

sanitary conditions to prevent the contamination of product. This is a regulatory noncompliance with Title 9 CFR 416.12(c), 416.3(a) and 416.4(d).

- b. On August 16, 2018, at approximately 0930 hours, EIAO observed beaded condensation on the ceiling above the transfer conveyor of the front-halves, which transfers chicken front-halves from the cut-up department to the boneless/skinless breast department. Your establishment failed to maintain adequate ventilation to control condensation and prevent insanitary conditions. This is a regulatory noncompliance with Title 9 CFR 416.2(d).

Since February 1, 2018, FSIS Inspection Personnel have issued 10 NRs for similar findings of condensation in your establishment. Your establishment has failed to implement adequate controls to prevent condensation in your facility.

- c. On August 15, 2018, at approximately 0315 hours, the EIAO observed chicken residue and blood on the hand dryer and on the soap dispenser at the hand wash station entering the slaughter floor. Your establishment employees use this hand wash station to wash their hands prior to returning to the slaughter and production floor. EIAO notified plant management of these findings on August 15, 2018. On August 16, 2018, at approximately 1125 hours, the EIAO observed that the hand dryer and soap dispenser still had residue and blood that was observed from the previous day. Your establishment failed to maintain sanitary conditions. This is a regulatory noncompliance with Title 9 CFR 416.4(b).
- d. On August 20, 2018, at approximately 1110 hours, the EIAO observed that your establishment employee was hanging a clear plastic bag near the conveyor where your establishment is packaging product in the cone line department. EIAO observed an establishment employee putting pieces of chicken fat and trim in the plastic bag. Because the plastic bag had no identification or label, the EIAO asked Plant Manager, Daniel Morales, what the raw chicken material in the plastic bag was for. Mr. Morales indicated that the employee was removing trim that would be thrown away. Similarly, on August 21, 2018, at approximately 0732 hours, the EIAO observed that your establishment was hanging a clear plastic bag with no identification on a hook where your establishment employee was standing on the evisceration line. EIAO observed that the plastic bag contained other plastic bags and paper towels. Your establishment indicated that it was trash and that it would go into the trash can after the shift change/break. For both of these instances, your establishment failed to identify the bag with conspicuous and distinctive marking to identify the contents. This is a regulatory noncompliance with Title 9 CFR 416.3(c).
- e. On August 15, 2018, at approximately 0330 hours, while your establishment employees had gone on lunch break during Shift A (Night Shift) and no birds were on the shackles, the EIAO observed a dirty yellow hose, with black unidentifiable foreign material (UFM) hanging above, coming into direct

contact with the FCS shackles (prior to the Inside-Outside Bird Wash (IOBW)). This is a regulatory noncompliance with Title 9 CFR 416.4(a).

- f. FSIS inspection personnel have documented multiple NRs for your establishment's failure to maintain sanitary conditions of equipment used during production. Since February 1, 2018, FSIS inspection personnel have documented nine (9) NRs, for observations of your establishment employees grabbing unclean totes for use in production.

Furthermore, on August 20, 2018, at approximately 1050 hours, EIAO observed FCS tubs turned over on a wooden pallet. (b)(6) indicated that those tubs were designated to go to the tub wash room. On that same day, at approximately 1100 hours, in the dark meat deboning room, the EIAO observed upright FCS tubs on a cardboard slip on a wooden pallet. As there was no label or identification indicating whether the tubs were clean, EIAO asked (b)(6) if the tubs were clean, and (b)(6) indicated that they are usually clean if the tubs are standing upright and not flipped over. (b)(6) indicated that the "assumption" can be made that these tubs are clean since they are right-side-up and that the employees would know if they are clean or dirty. As evidenced by the multiple NRs documented by FSIS personnel, your establishment employees have repeatedly pulled unclean totes for use in production, demonstrating that your establishment does not have effective procedures in place to ensure equipment is maintained in a sanitary condition so as not to adulterate product. This is a regulatory noncompliance with Title 9 CFR 416.3(a).

Since February 1, 2018, FSIS inspection personnel have issued 93 NRs for failure to maintain sanitary conditions. Your establishment has received multiple NRs for unidentified foreign material (UFM) including black specks on product and FCS, product residue on non-FCS, and poor employee hygiene practices that led to direct product contamination. Additionally, FSIS has documented your establishment's failure to maintain your facility in good repair, including findings of mold in the facility and failure to maintain an adequate pest management program to prevent pests in your establishment. These observations indicate your failure to implement your SSOPs to prevent direct contamination or adulteration of products, and your failure to implement the SPS to maintain sanitary conditions in your facility. Your SSOP program and associated records indicate that your establishment has not re-evaluated and revised your SSOP program as needed since 2016, even after your establishment received multiple, repetitive, and recurring sanitation noncompliance records. These findings are regulatory noncompliance with Title 9 CFR 416.14.

Hazard Analysis and Critical Control Points (HACCP) - Title 9 CFR 417

6. Your establishment failed to support the decisions in the Raw Intact hazard analyses that *Salmonella* and *Campylobacter* are not reasonably likely to occur.

Your establishment added PAA sprays as part of your establishment's corrective actions in response to the Performance Standard failure for *Salmonella*. Your establishment provided two studies to support this antimicrobial intervention in second processing. The first study, *"DATA SUMMARY For Beef and Chicken Exposed To PAA Under Various Use Conditions,"* dated October 13, 2015, only provides a summary of the results and does not provide details on how the study was conducted. Furthermore, the document indicates *"Average % Reduction."* However, it is unclear what is being reduced. Therefore, it is unclear how your establishment is using this document to demonstrate that the PAA spray application in your poultry process is effective to address *Salmonella* and *Campylobacter*.

The second study provided is titled *"A study to determine strategies for increasing the antimicrobial efficacy of Peroxyacetic Acid (PAA) and Acidified Sodium Chlorite (ASC) against Salmonella Infantis on chicken,"* dated December 13, 2017. This study was conducted using a PAA dip at various contact times; however, your establishment is using a PAA spray in (b)(4) processing. Your establishment was unable to provide any decision-making document or other support to demonstrate how this study on a PAA dip will support the PAA spray application in your process. In addition, your establishment does not have a designated contact time for your PAA application. During the FSA, the EIAOs observed that your PAA spray does not provide complete coverage of parts as it only sprays the top of the products on the Raw Intact lines of Tray Pack, Repack, and Dark Meat Deboning. Without adequate application of your antimicrobial intervention, it is unclear if your PAA application is effective to address the pathogens of concern. Your establishment failed to provide supporting documentation for your *"Anti-microbial Interventions Prerequisite Program"* to demonstrate that your PAA antimicrobial intervention in second processing is effective and to support the decisions in the Raw Intact hazard analyses that *Salmonella* and *Campylobacter* are not reasonably likely to occur. This is a regulatory noncompliance with Title 9 CFR 417.5(a)(1).

7. Your establishment failed to maintain and implement a HACCP Plan that meets regulatory requirements set forth by Title 9 CFR 417. Your establishment failed to implement CCP 3B for necks at the *"Bulk Packaging: Necks and Giblets"* step. Your establishment's *"Slaughter, Giblets & Necks"* hazard analysis references *"CCP 3B: Giblet and Neck Temps ≤ 55F"* at the *"Giblet & Neck Wrapping," "Giblet Cups or Trays," "Bulk Packaging: Necks and Giblets,"* and *"Weigh & Price."* The HACCP plan for CCP 3B states that your establishment will monitor the product internal temperatures of (b)(4) randomly selected carcasses or parts on (b)(4) packaging line with the *"highest monitoring temperature is documented"* *"randomly (b)(4) times per (b)(4) hour shift (approximately every (b)(4) hours)."* During the FSA, your plant management indicated that your establishment is only monitoring the product temperatures when the necks are used for your Mechanically Separated Chicken (MSC) process and when the necks are packed in whole body birds. Your establishment is currently not monitoring the work in progress (WIP) temperatures of necks at the bulk packaging step. Your establishment therefore failed to monitor necks under the CCP 3B at bulk packaging and failed to monitor each packaging line as indicated in your HACCP plan. This is a regulatory noncompliance with Title 9 CFR 417.2(b)(1) and

417.2(c)(4).

Your establishment failed to support the critical limit in your HACCP plan for CCP 2B. Your establishment's "CCP 2B Master Plan" for "Carcass, Salvage Parts and Feet Water Chilling, Air Chilling, WB Tank Chilling" lists the following critical limit for the "Water Chill Process": "Poultry carcasses, salvage parts and feet shall be chilled to (b)(4) or below within the time allotted by safe harbor rule." The "CCP 2B Master Plan" for the "Air Chill Process" lists the following critical limit: "(b)(4)" (b)(4) "Your establishment management provided FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements, 2014," which indicates that FSIS considers "the former regulatory time and temperature provisions" to be "safe harbors" (page 4) to meet the new chilling regulatory requirement of 9 CFR 381.66(b). Your plant management indicated that your establishment is using the former regulations Title 9 CFR 381.65(a) and 381.65(h) to support these critical limits. However, the temperature parameter (44.6F) of the critical limit of CCP 2B does not match the temperature parameter described in the former provisions, which state:

- "All poultry that is slaughtered and eviscerated in the official establishment shall be chilled immediately after processing so that the internal temperature of poultry carcasses and major portions weighing under 4 pounds was reduced to 40 °F or below within 4 hours of processing; carcasses weighing 4 to 8 pounds, within 6 hours of processing; and those weighing over 8 pounds, within 8 hours of processing unless such poultry is to be frozen or cooked immediately at the official establishment. Once chilled, poultry to be packaged and shipped is to be stored at 40 °F or less."
- "Giblets should be chilled to 40° F or lower within two hours of the time that they are removed from the inedible viscera, except that when the giblets are cooled with the carcass from which they were drawn, the giblets should be subject to the same time and temperatures for carcasses above in paragraphs A and B. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets."
- "In air chilled, ready-to-cook poultry, the internal temperature of the carcasses shall be reduced to 40° F or less within 16 hours."

Your establishment indicated you are using the (b)(4) which states that the minimum growth temperature of *Salmonella* is 44.6F. Therefore, it is unclear what your establishment is using to support both the product temperature and time parameters of your CCP 2B critical limit.

The FSIS compliance guideline you provided as support indicates that "establishments producing ready-to-cook (RTC) poultry can meet the new

chilling requirements by implementing former regulatory time and temperature provisions that the final rule on modernization of poultry inspection removed from 9 CFR 381.66 (b) or by following the time and temperature chilling procedures that FSIS approved under the Salmonella Initiative Program (SIP)."

Your establishment was unable to provide a SIP waiver with time and temperature chilling procedures to support the (b)(4) temperature parameter. Your establishment failed to provide adequate supporting documentation for your critical limit stated in your CCP 2B chilling HACCP plan. This is a regulatory noncompliance with Title 9 CFR 417.5(a)(2) and 417.2(c)(3).

8. Your establishment failed to document a direct observation for an actual monitoring activity. On HACCP record dated June 28, 2018, for CCP 2B Giblet Chilling, your establishment documented from 8:27am to 2:30pm entries indicating that there was no product available. An establishment employee documented a direct observation at 3:21pm on June 28, 2018, on that HACCP record with the result of "compliant." Your establishment documented a direct observation for a monitoring event that never occurred. This is a regulatory noncompliance with Title 9 CFR 417.5(a)(3) and 417.4(a)(2)(ii).
9. Your establishment failed to support the selection of your verification procedure "physical verification" listed in the HACCP plan slaughter CCP 1B for zero tolerance for whole body carcasses, salvage parts, and feet. The HACCP plan for the slaughter CCP 1B lists "physical verification" as a verification procedure in the HACCP plan. The HACCP plan lists the following description for "(b)(4)"
(b)(4)
(b)(4) "In review of your HACCP records, EIAOs observed that your establishment did not document the implementation of this verification procedure. In addition, EIAO's review of your establishment's supporting documentation for your HACCP plan, including decision-making documents, indicate that your establishment did not provide any documentation to support the adequacy of this verification procedure and frequency, including any explanation or definition of "physical verification." This is a regulatory noncompliance with Title 9 CFR 417.5(a)(2), 417.2(b)(1), 417.5(a)(3), and 417.2(c)(7).
10. Your establishment failed to support the decisions in your hazard analyses and failed to consider potential food safety hazards at multiple steps in the Slaughter, Raw Intact, and Raw Non-Intact hazard analyses that can occur before, during, and after entry into the establishment and that can potentially occur in raw poultry products in the absence of any controls. This is a regulatory noncompliance with Title 9 CFR 417.2(a)(1) and 417.5(a)(1).
 - a. Your establishment failed to support the decisions in your Slaughter and Raw Intact hazard analyses. At multiple process steps, your establishment refers to a prerequisite program and/or procedure; however, your establishment failed to identify the hazard you are addressing with the prerequisite program referenced. For example, at the "Inside/Outside Bird Washers (IOBW's)" step in the "Slaughter" hazard analysis. At this step in the hazard analysis, your establishment identifies no hazards and

references “CP 4B: Downstream control point for Sanitary Dressing” as a “Control Point.” Your establishment also references “Monitor and Control IOBW Pressures (a, b, c) and Spray Nozzles” as a measure “to prevent, reduce, or eliminate hazard to an acceptable level.” However, you have not identified the hazard you are addressing at this step.

This same “CP 4B” is referenced at process steps where the hazard analysis does identify fecal contamination as a biological hazard not reasonably likely to occur, such as the “Venter” step, “Body Opener” step, “Backup Venter/Body Opener” step, and “Eviscerator” step. During the FSA, Mr. Evans indicated that there are no hazards at the IOBW step because the IOBW equipment does not contain any hazards “in and of itself.” However, your establishment was unable to provide any documentation to support there are no hazards associated with this step when you have a prerequisite program referenced. This similar observation is identified at multiple steps throughout your Slaughter and Raw Intact hazard analyses.

- b. Similarly, at multiple process steps, your establishment references “PR: AMI Step 4”; however, there are no hazards identified to demonstrate what the prerequisite program is addressing. For example, at the “Post-Chiller SANOVA Cabinet” step in the “Slaughter” hazard analysis and at the “SANOVA OLR” step in the “Reprocessing: On-Line, Carcass – Off-Line, Salvage Parts” hazard analysis, your establishment identifies no hazards at these steps and references “PR: AMI Step 4.” However, your establishment references this same “Antimicrobial Intervention System Prerequisite” at the “Receiving Live Poultry” step in the hazard analysis where your establishment identifies *Salmonella* and *Campylobacter* as biological hazards not reasonably likely to occur on the “basis” that “inherent pathogen risk associated with processing poultry mitigated to acceptable level via Antimicrobial Intervention System Prerequisite.” Your establishment is referencing this same prerequisite program at the “Post-Chiller SANOVA Cabinet” and “SANOVA OLR” steps. However, your establishment was unable to provide any documentation to support there are no hazards associated with this step when you have a prerequisite program referenced. This similar observation is identified at multiple steps throughout your Slaughter and Raw Intact hazard analyses.
- c. Similarly, at the “Refrigeration” and “Cut-up Parts from Rework/ Outside Product” steps in this hazard analysis, your establishment identified no hazards and referenced “PR: Temp Control Maintain WIP temperatures < (b)(4) and product stored overnight temperatures < (b)(4)” and “PR: Incoming Materials Prerequisite Program for Outside Product - CCP 3B - WIP temps ≤ (b)(4)” as a “Control Point.” However, your establishment was unable to provide any documentation to support why there are no potential biological hazards of concern at these steps in the “Cut-Up Bulk” hazard analysis. This similar observation is identified at multiple steps throughout your Slaughter and Raw Intact hazard analyses.

Your establishment failed to identify all applicable food safety hazards and did not provide documentation to support the decisions in your hazard analysis. This is a regulatory noncompliance with Title 9 CFR 417.2(a)(1) and 417.5(a)(1).

11. Your establishment failed to support the design of your Control Point (CP) 1B for Venter, CP 2B for Body Opener, CP 3B for Eviscerator, and CP 4B for IOBW performance monitoring evaluations. Your establishment references these performance monitoring evaluations to support the decisions at the “*Venter*,” “*Body Opener*,” “*Backup Venter/Body Opener*,” and “*Eviscerator*” steps in the “*Slaughter*” hazard analysis that the biological hazard “*Fecal Contamination*” is not reasonably likely to occur. Your establishment does not maintain a written program for these control points. Mr. Evans indicated that the columns in the records identifying CP 1B, CP 2B, and CP 3B are what demonstrate that your establishment is implementing these CPs. EIAO identified that there is no column for CP 4B, but that your establishment is documenting the monitoring of the IOBW. In your CP records, your establishment documents a checkmark. However, it is unclear what you are checking and what the checkmark indicates. Your plant management indicated that these columns for CP 1B, 2B, and 3B are for documenting whether “*bird presentation [is] good*.” Your establishment provided no documentation to indicate what “*bird presentation good*” means and how this monitoring check is addressing fecal contamination to support the decision that fecal contamination is not reasonably likely to occur at the “*Venter*,” “*Body Opener*,” “*Backup Venter/Body Opener*,” and “*Eviscerator*” steps in the “*Slaughter*” hazard analysis. This is a regulatory noncompliance with Title 9 CFR 417.5(a)(1).
12. Your establishment failed to implement the test kit instructions for the “*Anti-microbial Interventions Prerequisite Program*” as written to demonstrate that the results of the PAA titration are accurate and valid and to support the hazard analysis decisions in the Slaughter and Raw Intact hazard analyses where this antimicrobial interventions (AMI) prerequisite program is referenced. On August 15, 2018, at approximately 0545 hours, EIAO observed your QA Technician conduct the monitoring of the antimicrobial, which includes titration of PAA to ensure that the chemical is at the target concentration. EIAO reviewed the “*Peracetic Acid Test Kit*,” which instructs to “*swirl 5 seconds to mix*” after a new chemical is added. EIAO observed that your QA Technician did not “*swirl*” for 5 seconds to mix. Your establishment personnel failed to follow your titration procedures as written. Without adequate implementation of your monitoring procedures, your establishment is unable to support the decisions in your hazard analysis. This is a regulatory noncompliance with Title 9 CFR 417.5(a)(1).
13. Your establishment failed to provide an accurate product flow diagram and failed to conduct a hazard analysis on all process steps. In reviewing your establishment’s flow chart, and hazard analyses, EIAOs identified the following noncompliances.
 - a. Your establishment’s flow chart for “*Reprocessing: Off-Line Reprocessing: Whole Body’s with gross contamination, ingesta, kidney pathology and/or broken viscera (feet remain attached)*” includes a “*Hang Back on Evisceration Line After IOBW*” step that is not addressed in the “*Reprocessing: On-Line, Carcass – Off-Line, Salvage Parts*” hazard analysis. This is a regulatory noncompliance with Title 9 CFR

417.2(a)(1).

- b. Your establishment's flow chart for the "*Slaughter Process: Evisceration, OLR And Chilling*" and "*On-Line Reprocessing: Minor contamination, ingesta, digestive tract remnant, etc.*" indicate that the product goes from "*SANOVA OLR Cabinet*" to "*NELS Inspection Station*." Your plant management indicated that the "*NELS Inspection Station*" is the area where your establishment conducts your CCP 1B zero tolerance checks. However, the EIAO observed that your establishment collects the carcass samples for the zero tolerance checks after the birds go through IOBW and before the birds enter the OLR Sanova pre-chill dip tank antimicrobial intervention. The flow charts your establishment provided are not up-to-date and do not accurately reflect the product flow. This is a regulatory noncompliance with Title 9 CFR 417.2(a)(2).
- c. Your "*Whole Body*" flow chart includes the step "*To Cut-Up Process*" that is not addressed in the "*Whole Body*" hazard analysis. This is a regulatory noncompliance with Title 9 CFR 417.2(a)(1).
- d. Your "*Tray Pack*" flow chart includes the step "*Condemn*" that is not addressed in the in the "*Tray Packs*" hazard analysis. This is a regulatory noncompliance with Title 9 CFR 417.2(a)(1).

Your HACCP plans in operation do not meet the regulatory requirements of Title 9 CFR 417.2(a)(1), 417.2(a)(2), 417.2(b)(1), 417.2(c)(3), 417.2(c)(4), 417.2(c)(7), 417.4(a)(2)(ii), 417.5(a)(1), 417.5(a)(2), and 417.5(a)(3). You also failed to meet the sanitation regulatory requirements of Title 9 CFR 416.2(d), 416.3(a), 416.3(c), 416.4(a), 416.4(b), 416.4(d), 416.11, 416.12(a), 416.12(c), 416.13(a), 416.13(c), 416.14, and 416.16(a).

For the reasons stated above and in accordance with Title 9 CFR 417.6(a), 417.6(b), and 417.6(d), FSIS has determined your HACCP system is inadequate. Your establishment failed to support the decisions in your hazard analyses and you failed to adequately implement your HACCP plans and maintain adequate records. FSIS is unable to determine that your establishment's HACCP system is safe, scientifically supported and sound.

Pathogens such as *Salmonella* and *Campylobacter* are of serious public health concern that can cause a variety of serious illnesses. The organisms can cause a serious infection which can lead to illnesses, including death. Without adequate implementation and supportable design of your HACCP program that would support the control of *Salmonella* and *Campylobacter* in your process, FSIS cannot determine that you have adequately addressed the hazards of concern to ensure you are producing safe and wholesome product.

Supporting documentation is an important recordkeeping component necessary to show that the implemented HACCP plan will ensure the production of safe food. Without documentation that adequately supports the HACCP plans, FSIS cannot determine that

the selection and development of the CCPs and critical limits would result in safe and wholesome products.

Poorly maintained facilities and equipment can and do harbor foodborne pathogens, which can then multiply and be dispersed throughout the food processing environment increasing the chances of product contamination rendering the product unsafe. Furthermore, dripping condensation can be a source of direct product contamination which can render product adulterated.

The Poultry Products Inspection Act, 21 U.S.C. 456, states “*the Secretary shall refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.*” Perdue Foods, LLC, Est. 2882, failed to maintain sanitary conditions at your establishment, creating insanitary conditions that could result in the production of products, which may have been rendered injurious to health.

The Poultry Products Inspection Act, 21 U.S.C. 463 states that “*the Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this Act.*” Perdue Foods, LLC, Est. 2882, failed to abide by the rules and regulations of the Poultry Products Inspection Act.

Establishment process controls are essential to product safety and wholesomeness and all meat and poultry producing establishments must have written HACCP and SSOP programs that address all food safety hazards that are reasonably likely to occur in the process. FSIS affirms that proper process controls are an important and integral part of every food process and fundamental requirement of the inspections laws that FSIS administers and enforces.

In accordance with FSIS’ Rules of Practice, Title 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 within three (3) business days from the date of your receipt of this letter. We will determine if we will take any further administrative enforcement action based on your response. You may submit your response by facsimile to (844) 622-0081, or by electronic mail (e-mail).

In accordance with Title 9 CFR 500.5(b)(4), you may contest the basis for the proposed action by contacting:

Dr. Keith Gilmore
Executive Associate for Regulatory Operations
210 Walnut St
Room 923
Des Moines, IA 50309
Phone: 515-727-8970

If you have any questions, please call the Alameda District Office at (510) 769-5712.

Sincerely,

*/s/ Virginia Felix, DDM
(for)*

Yudhbir Sharma, DVM
District Manager

cc:

V. Felix, DDM
S. Beckett, DDM
A. Amin, DDM
F. Gillis, DDM
L. Wang, DCS

(b)(6)

(b)(6)

K. Gilmore, EARO

(b)(6)

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P1480	Tip Top Poultry, Inc.	JBA362 109060 4N-1	09/04/2018	04C05	381.65(b)	<p>On 08/17/2018 after a review of trailers on the yard it was found that a trailer and a half would be left over the weekend to be slaughtered on Monday 08/20/2018. One trailer had a total of approximately (b)(4) birds and the second trailer contained approximately (b)(4) birds. I, (b)(6) (b)(6) conducted a GCP Saturday 08/18/2018 to assess the condition of the birds that had been left over the weekend. I observed 4-5 coops at the top of the rigs where birds in each coop were dead. I observed other coops where some of the birds were dead, not moving around or making any noise. I observed other coops with the birds hunkered down and heads hanging low. I observed other birds making noises. On Monday Morning 08/20/2018 there was a 21.5% death rate on the load of 3,456 which is approximately 743 birds. Based on the DOA's rate, the establishment lost process control and the birds died by other means rather than slaughter. This is a failure to meet the requirements of 381.65 (b). Continued failure to meet the requirements of 381.65 (b) may lead to further regulatory requirements.</p>
P4734	New Lee's Live Poultry Market Inc.	XKD360 909230 5N-1	08/28/2018	04C05	381.65(b)	<p>On Tuesday 08/28/2018, at approximately 11:15am, while performing an unscheduled Good Commercial Practice PHIS task in order to verify the establishment was conducting daily inspections and meeting with regulatory requirements of CFR 9(416), the following incompliance was observed. In the live holding /killing floor area, six geese slaughter and bleeding out inside shipping crate, twenty geese bleeding out in required designated equipment. (b)(6) the establishment's Person in charge was notified of these incompliance both verbally and in writing with this NR the establishment was in violation of regulations indicated on section (#6) of this document , and reoccurrences of this malpractice can lead to agency disciplinary action.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P18414	MB Consultants LTD	JYI0513- 063426 N-1	06/26/2018	04C05	381.65(b)	At approximately 1345, while inspecting the live poultry hang area, I observed the following noncompliance. The turntable past the shackling station where the empty crates enter the water bath had a crate with live birds in it still. The employee who pushes the crates into the water bath removed three chickens and threw them over to the shackler employees. One of the chickens that he threw hit a crate before falling onto the floor and the other two landed in the shackling area. It is about seven feet in distance from where the chickens were thrown. Throwing chickens as I observed is inhumane and contrary to good commercial practices. I notified (b)(6) (b)(6) of the noncompliance.

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P7669	Turkey Valley Farms LLC	RZB171 407540 5N-1	07/04/2018	04C05	381.65(b)	<p>At approximately 1240 hours while performing a routine Good Commercial Practices task on heavy toms the following noncompliance was observed. When entering the picking room, I observed 13 cadaver carcasses, with a cherry-red appearance of the skin, no cut present on the neck, and significant blood pooling in the neck region, lying on the floor of the picking room, near the hock cutter. I then proceeded to observe birds entering the scalding and observed 1 bird showing signs of consciousness (blinking eyes, open mouth breathing, and raised head) proceed into the scalding. During this time I also observed 3 out of 100 birds hanging by one leg in the shackle. I immediately notified (b)(6) (b)(6) of my findings. He informed me that he was aware that there was an issue with too many cadavers and that he would replace the back-up cutter immediately. I took a regulatory control action to reduce the line speed from (b)(6) birds per minute down to (b)(6) birds per minute. At approximately 1300 hours I performed a recheck and I observed 4 additional cadaver carcasses that had a cherry-red appearance of the skin, no cut present on the neck, and significant blood pooling in the neck region lying on the floor of the picking room, near the hock cutter. I also observed 3 out of 100 birds hanging by one leg in the shackle. Again, I immediately notified (b)(6) (b)(6) of my findings and he informed me that he had not removed the back-up cutter as previously stated. I took a regulatory control action to reduce the line speed from (b)(6) birds per minute down to (b)(6) birds per minute. At approximately 1315 hours I went to perform a recheck but the establishment had changed lots to a different class of birds (breeder toms). (b)(6) (b)(6) and (b)(6) were notified of the noncompliance. The establishment's corrective actions taken to ensure carcasses were slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding were either ineffective or not implemented. Therefore, the establishment is not in compliance with 9 CFR 381.65(b).</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P5787	Pilgrim's Pride Corporation	DEB190 807202 7N-1	07/26/2018	04C05	381.65(b)	<p>#154 On July 26, 2018 at approximately 0950 hours, I observed 5 cadavers in a yellow condemn can by the Meyn line 1 rehang table in the picking room. All of the cadavers had the heads on the carcasses with no evidence of any cut having been made. All the carcasses were bright red to purple in color. The appearance of such birds is indicative that they had entered the scald vat and drowned. (b)(6) was notified of the presence of these cadavers on Meyn line 1. The previous week on July 19, 2018 while performing a Poultry Good Commercial Practices task during observation of the steps of stunning, kill blade and back up on Meyn line 1, I noted that the back-up missed a bird as it went past him. I alerted (b)(6) and he was able to remove the bird from the line before it entered the scald tank. The presence of the 5 carcasses that entered the scald tank alive indicated a loss of process control at that time. Poultry must be slaughtered in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Carcasses of poultry that die from drowning in the scald vat result in an unwholesome/adulterated carcass. Birds that die by means other than slaughter represent a failure of the establishment to comply with 9 CFR 381.90 and 381.65(b). (b)(6)</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P5787	Pilgrim's Pride Corporation	DEB0904094222N-1	09/21/2018	04C05	381.65(b)	<p>#210 On September 22, 2018 at approximately 0310 hours, I observed 9 cadavers in a yellow condemn can by the Meyn line 1 rehang table in the picking room. All of the cadavers had the heads on the carcasses with no evidence of any cut having been made. The carcasses were bright red to purple in color. All of these cadavers were removed from the top part of the barrel and were still warm to the touch. The plant had just returned from break and had resumed operations at approximately 0305. The appearance of such birds is indicative that they had entered the scald vat and drowned. (b)(6)</p> <p>(b)(6) was notified and shown these cadavers on Meyn line 1. The presence of these 9 cadavers that entered the scald tank alive indicated a loss of process control at that time. Poultry must be slaughtered in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Carcasses of poultry that die from drowning in the scald vat result in an unwholesome/adulterated carcass. Birds that die by means other than slaughter represent a failure of the establishment to comply with 9 CFR 381.90 and 381.65(b). Please refer to NR issued on 7/26/18 #DEB1908072027N/1 for a similar noncompliance. (b)(6)</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P7156+V7156	Tyson Foods, Inc.	JTF5818083617N-1	08/17/2018	04C05	381.65(b)	<p>On 08/17/2018 at approximately 1540 hours SCSI was notified by (b)(6) who was performing postmortem inspection in line (b)(4) station (b)(6) that she identified 12 cadavers. Five of them were hung on the rack behind the inspector station. When verified the hung carcasses, their necks were red uncut, and their heads were engorged. The viscera parts related to the carcasses appeared congested more than the other passed carcasses. SCSI asked food inspectors (b)(6) on station (b)(6) and (b)(6) Young on station 1 and found that they identified a total of 3 cadavers. The line was stopped for 3 minutes to notify (b)(6) (b)(6) of the noncompliance. (b)(6) (b)(6) notified SCSI that they experienced equipment default in the kill area. While was walking toward the kill machine SCSI observed that other carcasses that had red, uncut necks, engorged red heads which were coming down stream in line (b)(6) SCSI found that kill machine was not operating and 2 back up team members were bleeding birds. Two birds were passed back up kill persons without being properly bled, SCSI applied control action and ensured birds were properly bled before the line allowed to operate back. SCSI was notified by Maintenance personnel that birds hanging was stopped to fix the kill machine. SCSI verified no birds were hung until Kill machine was fixed. Total of 25 cadaver were reported on tally sheets on inspection stations of line (b)(6) before kill machine back to operation. FSIS Directive 6110.1 states that repeated occurrence of birds that dying otherwise than by slaughter or not being appropriately bled represents a noncompliance of Good Commercial Practices. Kill machine was verified at 2018 hours and was found working properly.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P7156+V71 56	Tyson Foods, Inc.	JTF581 808361 7N-2	08/17/2018	04C05		<p>On 08/17/2018 at approximately 1540hours SCSI was notified by (b)(6) who was performing postmortem inspection in line (b)(4) station (b)(6) that she identified 12 cadavers. Five of them were hung on the rack behind the inspector station. When verified the hung carcasses were their necks uncut, red very engorged heads. Viscera parts related to the carcasses appeared congested more than the other passed carcasses. SCSI asked (b)(6), (b)(7)(C) on station (b)(6) and (b)(6) on station 1 and found that they identified a total of 3 cadavers. The line was stopped for 3 minutes to notify (b)(6) (b)(6) of the noncompliance. While was walking toward the kill machine SCSI observed that other carcasses that were with red, uncut necks, engorged red heads coming down stream in line (b)(6). SCSI found that kill machine was not operating and 2 back up team members were bleeding birds. Two birds were passed back up kill persons without being properly bled, and SCSI applied control action and ensured birds were properly bled before the line allowed to operate back. SCSI was notified by Maintenance personnel that birds hanging was stopped to fix the kill machine. SCSI verified no birds were hung until Kill machine was fixed. Total of 25 cadaver were reported on tally sheets on inspection stations of line 2 before kill machine back to operation. FSIS Directive 6110.1 states that repeated occurrence of birds that dying otherwise than by slaughter or not being appropriately bled represents a noncompliance of Good Commercial Practices. Kill machine was verified at 2018 hours and was found working properly.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P206+V206	Pilgrim's Pride Corporation	KCC491 306460 6N-1	06/06/2018	04C05	381.65(b)	<p>On June 6, 2018 (b)(6) observed the following GCP noncompliance. At approximately 1400 hours the east evisceration line was stopped due to a maintenance issue. At 1435 (b)(4) went to the live hang room to verify live birds were being handled appropriately. The employees in the live hang room had stopped hanging birds and the birds prior to the stunner had been removed from the line. Upon inspection of the stunning and kill equipment there were approximately 20 dead birds inside of the stunner. (b)(6) was called to the area and shown the noncompliance. The dead birds had drowned in the stunner and (b)(6) (b)(6) was instructed to remove the dead birds from the line to be properly disposed of. Failure to implement procedures for preventing accidental injury and/or death inconsistent with 9CFR 381.65(b) in regards to birds presented for slaughter, resulted in a lack of response to a known GCP failure, and birds were allowed to die by a means other than slaughter. The establishment was notified that the USDA expects the establishment to employ handling methods consistent with Good Commercial Practices. Plant Management is asked to consider these USDA concerns and prevent future occurrences. Copies of this noncompliance will be distributed to the establishment, inspection file and District Veterinary Medical Specialist per FSIS Directive 6100.3. The establishment is also reminded that NRs and MOIs documented for GCP issues can be FOIA requested and made available for viewing by FSIS. Documented by (b)(6)</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P206+V206	Pilgrim's Pride Corporation	KCC070 906461 4N-1	06/14/2018	04C05	381.65(b)	<p>At approximately 0630 hours, I observed a cadaver at the Pinner/Sorting station on the East line. The carcass was bright cherry red with no bleeding cut on the neck. Within 2 minutes, I observed another cadaver arrive at the Pinner/Sorting station, also with no bleeding cut on the neck. At that time, I saw (b)(6) and showed him the 2 cadavers. He informed his Back Dock Supervisor. On her way to the Pinner/Sorting area, the Back Dock Supervisor removed another cadaver from the line. I then took regulatory control action and I instructed (b)(6) to decrease the line speed from (b)(4) birds per minute to (b)(4) bpm. The plant had increased the linespeed on the East line because the West line was having mechanical issues and was not operating at the time. I went to the Kill Machine and observed that there were 2 employees backing up the Kill Machine. These 2 employees were not effective in backing up the machine to prevent live birds from entering the scalders. While at the Kill Machine area, I also observed that paws that were not being unloaded properly at the Paw equipment were not being removed before hanging chickens on the same shackle, possibly causing stunning issues. I pointed this out to (b)(6). I then proceeded back to the Pinner/ Sorting area where 2 more cadavers were removed from the East line. I then notified Tonya Byers, Plant Manager of the numerous cadavers found at sorting (8 total in an approximately 20 minute period) and that the finding would be documented on a noncompliance record. The establishment did not meet 9 CFR 381.65(b) which states: "Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding." The PPIA (21 U.S.C. 453(g)(5)) and 9 CFR 381.90 provide that poultry carcasses showing evidence of having died from causes other than slaughter are considered adulterated and must be condemned.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P206+V206	Pilgrim's Pride Corporation	KCC071 306182 2N-1	06/22/2018	04C05	381.65(b)	<p>On June 22, 2018, (b)(6) observed the following GCP noncompliance. At approximately 0816 hours, I was going to live hang just before break and noticed that the West line had stopped. I arrived at the stunner about 0819 hours and the stunner was full of birds with about 10 birds in shackles behind the stunner. The East line continued to run and the back-up killer left the East line. The West line back-up killer finally cut the necks of the birds between the stunner and kill equipment about the time the line restarted. The line stopped again with one bird still in the stunner. I walked to the back of the stunner and the bird was struggling to get its head out of the water. (b)(6)</p> <p>(b)(6) walked by me and I told him he had a bird drowning in the stunner. I watched the bird drown from behind the stunner before the line started back up. I went to the back-up killer and had him remove the bird from the line and watched him dispose of the cadaver carcass. Failure to implement procedures to prevent the accidental drowning of birds in the stunner is a violation of 9 CFR 381.65(b) and a GCP failure. On Tuesday, there were multiple stoppages due to equipment problems and I mentioned to (b)(6) and Plant Manager Tonya Byers that plant employees were not taking care of birds in the stunner when the lines were stopped. Corrective actions and preventative measures given for a similar incident on June 6, 2018, states that the plants standard procedure is to turn off the stunner and lower the stunner water to allow the birds to breathe when the line stops for more than two minutes. On Tuesday I was monitoring multiple stoppages of one or both lines and the lines might be stopped for more than two minutes, including several close to three minutes. There was not any plant employee activity to turn off the stunner and lower the stunner water. Plus the back-up killers did not always cut the necks of the birds between the stunner and kill equipment after the two minutes. USDA expects the establishment to implement handling procedures consistent with Good Commercial Practices. I urge the establishment to consider a program that prevents birds from drowning in the stunner before slaughter. Copies of this noncompliance will be distributed to the establishment, inspection file and the District Veterinary Medical Specialist per FSIS Directive 6100.3. The establishment is also reminded that NRs and MOIs documenting GCP issues can be FOIA requested</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
						and made available for viewing by FSIS. Documented by (b) (6)

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P7044	Tyson Foods, Inc.	GJJ172 005262 2N-1	05/22/2018	04C05	381.65(b)	<p>At approximately 2150-2200 hours, while leaving the chiller area (b)(6) observed a head-on cadaver on the floor under the evisceration equipment for Line 1. This area is closest to the rehang line for Line 1. (b)(6) pointed out the cadaver to (b)(6) and proceeded to (b)(4) the Live Hang area to conduct a GCP task. On approach to the Live Hang area she observed a live chicken standing in-between the Line 1 and Line 1 scald tanks in the Picker Room. On entry to the Live Hang area, the Live Hang Supervisor was observed to be leaning on a fan watching the hangers. (b)(6) motioned for him to come over and showed him a pile of paws/litter at the door, the live birds on the floor and the live bird in the Picker Room. (b)(6) stated that someone was coming to clean the area. (b)(6) went to find (b)(6) to notify (b)(6) of (b)(6) concerns. During conduction of the GCP task, other conditions were observed that describe failure of the establishment to comply with Good Commercial Practices. These items were shown to establishment management: (b)(6)</p> <p>(b)(6)</p> <p>(b)(6)</p> <p>(b)(6) proceeded to complete the remainder of the GCP task. At 2210 hours, (b)(6) observed two additional head-on cadavers on Line 1 in the Picker Room. (b)(6) followed the cadavers to the evisceration rehang table and had them removed. At that time (b)(6) notified the Evisceration lead to slow the line speed on Line 1 to 126 BPM to allow the Live Hang/Picker Room Supervisor to regain process control in his area. The establishment stated that the root cause of the cadavers was due to the Line 1 kill machine lowering when the line was stopped; the establishment did not state at what time it lowered. The backup cutter was unable to catch all of the birds before they entered the scald tanks. (b)(6) asked that the establishment encourage the backup cutters to stop the line or notify management before birds are allowed to enter the scalders breathing. Establishment management stated the employee issue would be addressed at the end of the shift. The backup cutter was observed to be ensuring all birds missed by the autoknife had a cut applied to severe the major arteries of the neck before they entered the scald tanks. No additional cadavers were observed after monitoring the line (in the Picker Room) for approximately 5 minutes. Regulatory control action was released to the establishment at 2138 hours, when sanitary operations were regained in the Live Hang and</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
						Picker Room areas. A similar noncompliance was documented on May 9, 2018 (NR GJJ5208055209N-1). The root cause of that incident was also determined to be failure to maintain equipment in a manner that resulted in the proper bleed out of poultry slaughtered at the establishment, as well as failure of supervision to maintain control of the area. The requirements of 9CFR 381.65(a) and 9CFR 381.65(b) were not met. Documented by (b)(6) Nacogdoches Circuit 4029
P517	Mar-Jac Poultry-MS	QOO3216081521N-1	06/22/2018	04C05	381.65(b)	<p>approximately 0906 hours on June 22, 2018, while verifying Good Commercial Practices in Poultry (GCIPI) verification task at 00517P (Mar Jac), in Hattiesburg, MS, the following less than GCIPI incident was observed at the cage dumper for live birds. An employee was observed grabbing several (approximately three in each hand) birds, that had not fallen onto the conveyor, out of the cages and throwing them onto both the North and South conveyors leading to the hanging pens. A similar incident was written (QOO4209050524G) on May 24, 2018 with the respect of mishandling live birds at the dumper. Throwing birds is not consistent with GCIPI. Establishments are responsible for birds entering the official premises and must employ GCIPI to prevent unnecessary suffering, injury or death. This issue was discussed with (b)(6) (b)(6) on June 22, 2018 at 0920. As per Federal Register Notice Docket 04-037N, dated September 28, 2005, "Treatment of Live poultry Prior to Slaughter", the 4 Food Safety Inspection Service (FSIS) strongly encourages all establishments engaged in the slaughter of poultry to abide by Good Commercial Practices (GCP's) as described in industry guidelines.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P509	Koch Foods LLC	IPG230 208173 ON-1	08/29/2018	04C05	381.65(b)	<p>The following occurred on the shift beginning 08/29/2018 while performing Good Commercial Practices. At approximately 0132 hours, I observed less than good commercial practices. While I was performing a 500 bird count after the back-up killer, I had observed eight (8) birds travelling to the first scalding, each one unwounded and retaining consciousness (blinking, attempting to right themselves), some of which were hung overlapping another bird or with two legs in one half of the shackle. Birds that drown in the scalding have not been slaughtered in accordance to the GCP, per 9 CFR 381.65(b). Before performing the count, I had observed the picking line speed at (b)(4) birds per minute. During the count, I observed the back-up killer trying to keep up with the number of birds that the kill machine had missed. No one else was present, as it was later told to me that the maintenance personnel assigned to the Kill Room/Picking Area was at lunch. Production was halted, and (b)(6)</p> <p>(b)(6)</p> <p>(b)(6)</p> <p>(b)(6) were immediately summoned to the Kill Room. The Halal representative also came to the Kill Room. Adjustments were made to the kill machine, and the picking line was slowed to (b)(4) birds per minute. Another 500 bird count was performed, with no live birds entering the scalding. The area was back in compliance at approximately 0146 hours. A copy of Federal Register / Vol. 70, No. 187 Docket No. 04-037N titled "Treatment of Live Poultry Before Slaughter" can be made available to the Establishment.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P1307	Mar-Jac: Poultry-AL	KIL0215 090914 N-1	09/14/2018	04C05	381.65(b)	<p>At approximately 13:45 while monitoring operations in the rehang area of the evisceration department, I observed 8-10 cadavers in the drip pan near the line (b)(4) auto-rehanger. As I continued to observe, I saw the back-up employee remove 6 more cadavers from the line and dispose of them in the condemn barrel within a short time span. At 13:47, I proceeded to the scalding area to observe birds entering the scalders. I observed for one minute, and within that time, I observed four birds enter the scalders with their eyes blinking and their necks arched, which is an indication that the birds were alive. I concluded that the establishment's process was out of control. At 13:49, I immediately went to the live hang room, and took regulatory control action by instructing the employees to stop hanging chickens on line (b)(4). As I looked around in the live hang area, I observed approximately 20-25 live chickens which were loose on the floor of the hanging pen. There were piles of chicken litter, feathers and fecal material mixed with piles of dead and dying birds at the end of each of the live conveyor belts. The piles were approximately 2 feet in diameter and approximately 2 feet high on each line. As the plant employees dug through the piles of debris, there were 2 or 3 live chickens found on each line. The live chickens were euthanized by cervical dislocation.</p>

Table: Noncompliance Reports in Response to FOIA_2019_18

EstNbr	EstName	NR#	Date	Task	Regs	Description
P6164A	Foster Poultry Farms	OIJ1815 094313 N-1	09/13/2018	04C05	381.65(b)	<p>On September 13, 2018, at approximately 0950 hrs, I, (b)(6) of P6164A, was performing inspections of the scalding tank areas as part of a routine Good Commercial Practices (GCP) verification task. When I approached the pre-re-hang sorter station, I observed the establishment sorter remove a bird from the line and toss it into a red establishment condemn barrel without logging the disposition. Noticing that the condemned bird was brightly red-tinged with a purple-colored head, I searched the condemn barrel. Inside the barrel on top of approximately fifteen birds, I found the bird and observed its head fully intact without cuts. Examining the remaining birds, I found three other birds similarly with head and necks engorged with blood and no sign of slaughter. Two of the four birds had two minor nicks about the head which, in addition to the eyes and mouth were congealed with blood, but nevertheless were also insufficiently bled out. The signs of death by means other than slaughter defined the four birds as cadavers. I notified (b)(6) of the finding who promptly segregated the birds for examination and began to attend the issue. (b)(6) (b)(6) stated to (b)(6) that the barrel was last emptied at the 1st break at approximately 0820; therefore, the period over which the four cadaver birds had occurred was bracketed between approximately 0820 hrs and my inspection at 0950 hrs. That resulted in a rate of a cadaver occurring approximately every twenty two minutes for at least an hour and a half. Additionally, an ongoing pattern of birds dying otherwise than slaughter had been documented by five recent GCP MOIs (9/11/18, 8/3/18, 5/3/18, 4/23/18, 4/20/18) written by four different inspection personnel each observing live birds approaching or entering the scalding tanks. I informed (b)(6) that that current rate of cadavers coupled with the history of ongoing pattern of live birds entering the scalders indicated that the process was out of control and a noncompliance would be documented. No indication of deliberate mistreatment of poultry by establishment personnel was observed. As all the adulterated product was appropriately removed from the process, no product was tagged/retained, and therefore no adulterated product entered commerce.</p>

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EstNbr	EstName	NR#	Date	Task	Regs	Description
P44947	Two Brothers for Wholesale Chicken, Inc.	TRR360 807461 7N-1	07/17/2018	04C05	381.65(b)	While performing a routine GCP task at 920 on 7-17-18, and walking over the kill floor, I saw that one of the barrels used to wheel the bled-out birds from the killing area to the scalding was covered by an empty chicken crate. I removed the crate, and then observed that several chickens were breathing and flapping their wings inside the barrel, and were trying to escape. I pointed this out to one of the kill floor employees, who immediately removed the live birds from the barrel and dropped them back into the cones so that they could be thoroughly and properly bled out. Production was not halted, because the est. had already finished killing before its 930 break. Because the floor manager was not in the building, I notified one of the kill floor employees that, because this was the third instance in the last month in which I had observed birds being dropped inside the barrels before they had been thoroughly bled, and then left in the barrels either to finish bleeding out or to die by suffocation, I would be writing a noncompliance report. The est. is noncompliant with 9 CFR 381.65(b), which states that poultry must be slaughtered 'in a manner that will result in thorough bleeding of the carcasses and that will ensure that breathing has stopped prior to scalding.'
P45045	Bee Bee Farms, LLC	BGI501 306072 2N-1	06/20/2018	04C05	381.65(b)	On 6/20/2018 at approximately 1020 hours, I, (b)(6), (b)(6), conducted an Poultry Good Commercial Practice task. While observing birds hanging on the chill rack, several birds had fecal material on them. I, (b)(6), immediately notified (b)(6) of the deficiency. (b)(6) inquired about the issue. I, (b)(6), explained that there is fecal on the birds. Upon further inspection of the chill rack, (b)(6) (b)(6) observed fecal material on the birds. The chiller was washed out and refilled. All birds since the beginning of production were reworked. (b)(6) lowered the line speed to 25. I informed (b)(6) (b)(6) that an noncompliance report would be generated for violation of 9 CFR 381.65(B).

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EstNbr	EstName	NR#	Date	Task	Regs	Description
P46869	Carrol Poultry, LLC	DLA161 805252 9N-1	05/29/2018	04C05	381.65(b)	<p>On 5/29/2018 approximately 17:23 while performing a Good Commercial Practice task I observed an alive (controlled movements, blinking eye and rhythmic breathing) at the entrance to the scalding and proceeded into the scalding. I noticed a second alive bird on the line and the bird was removed from the line. Six more alive birds were observed and removed from the line before entering the scalding. I also observed seven more alive birds piled in the sink adjacent to the blood tank. In less than a minute three more live birds were observed on the line just prior to entering the scalding. Regulatory action was taken by stopping the line to prevent live birds from going into the scalding. I notified (b)(6) of the systematic failure of the plant's Good Commercial Practice 381.65 (b) and the regulatory action taken. 9 CFR 381.65(b) states the regulations also required that poultry be slaughtered in accordance with Good Commercial Practices, in a manner that results in thorough bleeding of the poultry carcass and ensures that breathing has stopped before scalding so that the birds do not drown. . Further investigation I observed a full barrel of cadaver birds at the rehang table exit, two on the rehang hang table, and one on the line after the pickers on the same production day. The preventive measure is to conduct training prior to the start of production on May 30, 2018. The establishment reviewed their procedure and found it to be not detailed on specific on the knife cut. The procedure will be updated to be more detailed. Training will be signed off on and QA will verify and audit against the effectiveness. Any employee found not following the procedures will be disqualified and not allowed to perform the job until they can requalify and retested. Employees will be trained on the new updated procedure prior to start of shift on May 30th. Operations resumed once the plant had given and implemented their preventative measures.</p>

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P46869	Carrol Poultry, LLC	DLA021 706390 7N-1	06/07/2018	04C05	381.65(b)	<p>On 6/07/18 while performing a GCP, I observed at the end of the blood tunnel before the scalding a live bird (controlled movements, blinking eye and rhythmic breathing). The bird was removed from the line. I also observed seven more alive birds removed from the line. There was a large gap in the line (no birds were on shackles), line was not stopped no birds were hung. I notified (b)(6) of the non-compliance 9 CFR 381.65(b). I observed the preventive measure described in the GCP noncompliance on 5/28/2018 was not being implemented. Further investigation I observed a half full barrel of cadaver birds at the rehang table in EVIS. All the birds in the barrel did not have a cut on the throat to allow proper bleeding before entering the scalding. I observed, while giving breaks, a cadaver bird at the inspection stand and 3 more cadaver birds were documented on the USDA lot sheet. I also observed eight cadavers being removed from the line after pickers before the hock cutters. The establishment's preventive measure is to enforce the preventive measure described in the last noncompliance on 5/28/2018 and to monitor the cutters throughout the shift. They also placed skilled cutters toward the beginning to decrease the amount of birds needing a backup cut from the back up killers. Establishment preventive measure was given before hanging more birds on to the line.</p>