United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Des Moines District Office
Federal Building
210 Walnut, Room 985
Des Moines, IA 50309-2123

September 19, 2006

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Mr. Tzvi (Heshy) Rubashkin, Plant Manager
Agriprocessors, Inc. Establishment 4653A
220 West Street
P.O. Box 920
Postville, IA 52162

Letter of Warning

Dear Mr. Tzyi (Heshy) Rubashkin,

On March 15, 2006, the Food Safety Inspection Service (FSIS) issued establishment 4653A, Agriprocessors, Inc., a "Notice of Intended Enforcement." This was based on your failure to comply with the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations. Specifically, the failures to meet the requirements of 9 CFR Parts 416.16, 417.2(a)(1),417.2(a)(2), and 417.3(a)

On March 17, 2006, through March 22, 2006 you provided modifications to your Sanitation Standard Operating Procedures (SSOP), and your HACCP plans in response to the issues that were contained in the March 15, 2006, NOIE and on March 22, 2006, a deferral was issued.

On March 28, 2006, a "Show Cause" letter was issued to Agriprocessors, Inc. The Show Cause Letter was based on the sighting of rodents in the establishment (chemical storage area and office area above the beef kill maintenance shop) and the sanitary conditions around the outside of the facility.

In addition to the normal verification procedures that were performed by the in-plant inspection team through the PBIS system, verification checks were also performed on June 28, 2006 and August 10, 2006. The verification checks consisted of reviewing programs for modifications, reviewing all pertinent documentation generated by the plant and FSIS during the Deferral period, and touring the facility and outside premises. The tours also incorporated issues that were contained in the Show Cause letter. The FSIS in-plant verification records indicate that the corrective actions that you have implemented have been effective; however, FSIS will continue to verify the adequacy of your programs through the PBIS system.

Specifically:

9 CFR Part 417.2(a)(1) states: "Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment."

(b)(4)

- During your 1/23/2006 reassessment you identified *Salmonella* and *E. coli* as a "Large Risk" in [redacted] steps in your chicken slaughter process [redacted]. As required by § 417.2(a) you did not identify the preventive measures that you can apply to control the identified hazards.
- The Chicken HACCP plan has been reassessed and was signed on 6/28/2006. During the most recent reassessment references to current SOP's have been up-dated and the flow diagram has been up-dated to accurately reflect the slaughter process. The chicken HACCP plan has been changed to indicate salmonella as a risk, not likely to occur due to new procedures recently put in place. The procedures are as follows; [redacted] All poultry evisceration employees have been retrained on proper product handling and additional [redacted] and wash/sanitizers have been added to the production area. Also, [redacted] is being added to the soak/chill tanks in an effort to reduce the pH of the water thus enhancing the efficacy of the chlorine. Additionally, you are performing in-house testing to monitor the effectiveness of these controls against salmonella.

(b)(4)

9 CFR Part 417.2(a)(2) states, "A flow diagram describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified."

9 CFR Part 417.2(a)(1) states: "Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment."

(b)(4)

- During your 1/23/2006 reassessment you determined *Salmonella* and *E. coli* as a "Large Risk" in [redacted] steps in your turkey slaughter process [redacted] You have included in the flow diagram and hazard analysis of the Turkey Slaughter plan the step of [redacted] as a CCP to address the identified hazards. The spray system is not functional at this time. The flow diagram and hazard analysis are not representative of the system in place as required by § 417.2(a)(2). In addition, you have not implemented the preventive measures you can apply to control the identified hazards, as required by § 417.2(a). Consequently, there are no records for the application of [redacted] as the system is not yet functional.

- The Turkey HACCP plan has been reassessed and was signed on 6/28/2006. During the most recent reassessment references to current SOP's have been up-dated and the flow diagram has been up-dated to accurately reflect the slaughter process. The Turkey HACCP plan has been changed to indicate salmonella as a risk, not likely to occur due to new procedures recently put in place. The procedures are as follows; all poultry evisceration employees have been retrained on proper product handling and [redacted]. Also, [redacted]. Additionally, you are doing [redacted] monitor the effectiveness of these controls against salmonella.

9 CFR Part 417.3(a) states: "The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce."

In records associated with your Raw Not Ground HACCP Plan:

- Records from the monitoring for CCP 2, resulted in product temperatures which exceeded the critical limit on fourteen occasions. These deviations ranged from [redacted] to [redacted] and were documented on your corrective action records called "Food Safety Action Report". These records did not meet the requirements of 9 CFR 417.3(a)(1-4). On all reports from February the form does not specifically identify the products involved in the corrective actions, stating for [redacted]". The cause is identified as [redacted]. The corrective action taken is documented on all February reports as "Will dry ice boxes". Although icing may be an appropriate action, you failed to document product temperatures to show this corrective action was implemented. The February records document measures put in place to prevent recurrence as "Future construction". The recurrence of the elevated temperatures [redacted] creates doubt as to your CCP being under control after the corrective action were taken. Although your records state "No adulterated product", you have failed to show how reducing the temperature after the critical limit has been exceeded can ensure product safety.

(b)(4)

- Reassessment and modifications to the Kosher Beef Raw Not Ground HACCP plan on July 3, 2006 and implanted on July 5, 2006 did not prevent the recurrence of the deviations. Further modifications the Kosher Beef Raw Not Ground HACCP plan were made and implemented on 7/24/2006. Modifications were made to the flow diagram and hazard analysis have been made and accurately reflect the process and product flow through the establishment. The CCP-1 (product temperature) has been moved down stream and is now monitored at the "[redacted] step. The addition of dry ice to the boxes of product as it is packed is included in the "[redacted] step.

§ 416.16(a) states, "Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the

implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date."

- Your operational SSOP records are not reflective of actual in-plant conditions and do not provide sufficient documentation or information to enable you to effectively determine and FSIS to verify if the Sanitation SOP's that you have developed have been implemented and monitored as intended. Your implementation and monitoring of these sanitation programs is called into question based on your failure to document the actual sanitary conditions. Documented FSIS findings (non-compliance records), and observations made during the 3/13/2006 operational tour. Specifically, company records fail to document sanitation issues in the [redacted] boxed product cooler, basement locker room areas and employee traffic ways, as well as throughout the outside premise, even though the same or similar sanitation issues mentioned here have been documented on multiple noncompliance records in the last 90 days. In addition, it has been repeatedly demonstrated through FSIS in-plant documentation that the corrective actions and preventive measures that you have put into place have been ineffective. These findings lead us to question your ability to maintain sanitary conditions, and to produce a safe and wholesome product.
- The records are being maintained at the frequency stated in your SSOP. You have assigned duties and responsibilities for areas of concerns that were noted. Additionally, for the next six (6) months, [redacted] an Operations Manager (if an operations manager is unavailable, the Director of Technical Services may fill in) along with the QA Manager, will tour each department with the manager of that department and perform an Operational SOP audit. The same will be performed [redacted] regarding the outside premises. A review of records generated during the deferral period describe deficiencies, when found, are documented and contain all parts of corrective action. You have developed and implemented new corrective action forms which were attached to the daily records. Training when used as a preventive measure was documented and included in the daily records. In response to the March 28 Show Cause letter you have changed pest control providers and have made improvements that prevent the harborage and breeding of pests on the grounds and within the establishment.

(b)(4)

Although the Notice of Intended Enforcement in deferral at establishment 4653A is no longer in effect, please be advised that we consider violations of this type as serious in nature. As a Federally inspected establishment, you are expected to comply with § 416 and § 417 of the regulations and all other requirements concerning the preparation, sale and transportation of meat and poultry products. Please be advised that failure to comply with these requirements in the future could again lead to the withholding or suspension of inspection or other appropriate action.

We expect persons engaged in the handling of meat and poultry products to comply with all the requirements of the law. We urge your voluntary compliance.

Sincerely,

Dennis Greening
Des Moines District Manager

United States Department of Agriculture | Food Safety and Inspection Service | Field Operations | Des Moines District Office
Federal Building
210 Walnut, Room 985
Des Moines, IA 50309-2123

March 2, 2006

Hand Delivered
Original send US Mail

Mr. Tzvi (Heshy) Rubashkin, Plant Manager
Agriprocessors, Inc. Establishment 4653A
220 West Street
P.O. Box 920
Postville, IA 52162

Letter of Warning

Dear Mr. Tzyi (Heshy) Rubashkin,

On November 23, 2005, the Food Safety Inspection Service (FSIS) issued to your Establishment 4653A, Agriprocessors, Inc., a "Notice of Intended Enforcement" (NOIE). This was based on your establishment's failure to comply with the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations. Specifically, your establishment's failures to meet the requirements of 9 CFR Parts 417.2, 417.2(a)(1), 417.2(a)(2), 417.2(b), 417.2(c)(1), 417.2(c)(3), 417.3, 417.4, 417.6 and Specified risk materials from cattle and their handling and disposition, 310.22(d)(1).

On November 28, 2005 through November 30, 2005 your firm provided modifications to your Standard Operating Procedures, your HACCP plans, and provided documents in response to the issues that were contained in the November 23, 2005, NOIE.

In addition to the normal verification procedures that were performed by the in-plant inspection team through the PBIS system, verification checks were also performed on December 20, 2005, February 6, 2006 and March 2, 2006. The verification checks consisted of reviewing programs for modifications and reviewing all pertinent documentation generated by the plant and FSIS during the Deferral period.

Findings contained in the NOIE that did not meet § 417.2, *specifically:*
9 CFR Part 417.2(a)(1) states: "Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment."

(6)(4)

- {Beef Slaughter Plan} You have designed and implemented a CCP to address [redacted] present on the carcass. You have addressed the pathogens that may reside in [redacted] as required on the carcass (through zero tolerance). However, you have failed to address the same hazards in your

(b)(4) hazard analysis that may be present on the head meat and cheek meat. [redacted]

(b)(4) ↓ You have modified your HACCP plan to include a zero tolerance cheek/head meat step and this has been added to your flow diagram and hazard analysis. You have also modified [redacted] to include cheek and head meat.

- {Poultry Slaughter – Chicken Plan} You have identified hazards and designed measures to control those hazards at the [redacted] steps. The plan as written fails to determine hazards and controls associated with the parameters in use for the production of organic chicken. Control limits that have been designed are not applied to the organic chicken production. The flow diagram and hazard analysis do not describe the organic chicken production.

(b)(4) ↓ Production of organic and standard poultry has been addressed in your flow diagram and the hazard analysis. (*Salmonella* issue is being addressed through the 30-Day reassessment letter).

- {Beef Fabrication Plan} You have developed and implemented a SOP designed to address the reconditioning of product that may have contacted the floor or another insanitary surface. The process fails to consider all possible hazards that may exist with product that has contact with the floor or another insanitary surface. The hazard analysis and procedure as written do not address any possible biological hazards that may exist.

(b)(4) ↓ You have modified your written reconditioning procedures to include the application of [redacted] after trimming of visible contamination and rinsing with potable water.

- {Beef Fabrication Plan} Specified risk material associated with carcasses derived from cattle that are 30 months of age or older (spinal cord, vertebral column, and dorsal root ganglia) slaughtered at your establishment and received from your [redacted] are known hazards. You have failed to include these in the hazard analysis of your HACCP plan. Records documenting the removal of SRM's from +30 month of age cattle slaughtered at your establishment were complete. Carcasses from this establishment and from your [redacted] were observed in the cooler. The carcasses were segregated and the vertebral columns were colored with blue ink as stated in your SOP.

(b)(4) ↓ You have modified the raw not ground HACCP plan to include the hazard of BSE in the [redacted] step and [redacted] You have provided documentation for the receiving of +30 month carcasses. Your SOP's for the Kosher and non-Kosher boning procedures have been followed and you are generating documentation that demonstrates SRM's that may be present are removed and disposed of as inedible.

Findings that were contained in the NOIE that did not meet § 417.2(a)(2), *specifically:*
9 CFR Part 417.2(a)(2) states: "A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified."

- {Lamb Slaughter Plan} The intended use and the consumers of the finished product have not been identified in the HACCP plan as written.

↓ You have completed a product description for Lamb slaughter process which does describe the intended use and consumers of the finished product.

- {Fully Cooked RTE HACCP Plan} Your flow diagrams and hazard analyses for both ground products and whole muscle products fail to include the process step of shipping.
  - You have added the shipping step to the flow diagrams and hazard analysis for your ground products and the whole muscle products.

Findings that were contained in the NOIE that did not meet § 417.2(b)(1), *specifically:*
9 CFR Part 417.2(b)(1) states: "Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:"

- {Beef Fabrication Plan} Veal front quarters and lamb fronts are fabricated with the application of the CCPs contained in the beef fabrication plan. The HACCP plan as written does not include veal and lamb as required.
  - You have modified the Beef Fabrication plan which is now the raw not ground HACCP plan. The description has been up-dated (modified) and now includes all species that are produced with this plan.
- {Raw Ground HACCP Plan} Your critical limit as written is specific to ground beef and does not include the ground chicken and ground turkey products produced under this plan as is required.
  - Your Raw Ground HACCP plan and description have been up-dated (modified) to reflect all species that are being processed under this plan.

Findings that were contained in the NOIE that did not meet § 417.2(c)(3), *specifically:*
9 CFR Part 417.2(c)(3) states: "List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirements set forth in this chapter to the specific process or product, are met;"

- {Beef Slaughter Plan} The spray pressure parameters associated with the critical limit established for the [redacted] application to the carcass are not utilized for the step of [redacted] application to offal and head products. The pressure readings observed and recorded at the offal and head products cabinet exceed the upper limit stated for the critical limit.

(b)(4)

  - You have made adjustments to your [redacted] application system for offal and head products. You are now monitoring the same parameters used for the carcass cabinet ([redacted]). You have modified CCP-2 in the beef slaughter plan to ensure that it is monitored and verified at the same frequencies.

Findings that were contained in the NOIE that did not meet § 417.4(a)(2), *specifically:*
9 CFR Part 417.4 (a)(2) state: "Ongoing verification activities include, but are not limited to: (i) The calibration of process-monitoring instruments; (ii) Direct observations of monitoring activities and corrective actions; and (iii) The review of records generated and maintained in accordance with 417.5(a)(3) of this part."

- {Beef Slaughter Plan} Your records associated with the monitoring of the application of [redacted] on offal and head products are not included in the records review. You also fail to include direct observation of the monitoring activities.
  - You have modified CCP-2 in the beef slaughter plan to ensure that the application of [redacted] is monitored and verified at designated frequencies.
- {Beef Slaughter Plan} Beef slaughter HACCP records for 8/28/05 through 11/11/05 were reviewed. On 8/28/05, the conductivity reading taken with a meter for the monitoring procedure was documented with a value below the critical limit [redacted] As a follow up activity to determine if the [redacted] concentration was below the critical limit, titrations were performed. The records did not determine the cause of the equipment's failure but you provided information to support that the on-going monitoring using the conductivity meter effectively determined acetic acid concentration.
  - You have retrained the employee responsible for the monitoring and provided documentation of the retraining. Your training included the proper completion of deviations and training for determination of when they are required.

Findings that were contained in the NOIE that did not meet § 417.5(a)(1), *specifically:*
9 CFR Part 417.5(a)(1) states: "The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;"

- {Beef Slaughter Plan} Your hazard analysis has many steps in the slaughter process which have identified biological hazards of [redacted]" The justification for the risk of these identified hazards not being large is supported with [redacted] These procedures are SOPs that identify each step of slaughtering and dressing beef carcasses. The plant does not have any documentation or records to show the procedures are implemented as written.
  - You have developed a form that documents a weekly review of [redacted] kill floor procedures to ensure that proper procedures are being followed. You have also provided a space on that form to document corrective actions in the event that proper procedures are not being followed.

Findings that were contained in the NOIE that did not meet § 417.6(b), *specifically:*
9 CFR Part 417.6(b) states: "Establishment personnel are not performing tasks specified in the HACCP plan;"

- {Fully Cooked RTE HACCP Plan} Records you have generated for dry and semi-dry sausage on 10/07/05 show you failed to document the [redacted] The scientific documentation supporting this critical limit is specific [redacted] Your monitoring during [redacted]
  - You have modified your record keeping and monitoring to reflect the correct limit of [redacted]

(b)(4)

Findings that were contained in the NOIE that did not meet § 417.6(c), *specifically:*
9 CFR Part 417.6(c) states: "The establishment fails to take corrective actions, as required by § 417.3 of this part;"

- {Poultry Slaughter HACCP Plan – Turkey} On 10/11/05 and 11/01/05, gizzards that were being harvested failed to meet the chilling critical limit. You failed to implement corrective actions to include; identifying the cause of the deviation and establish measures to prevent the recurrence. Affected product was condemned.
- You have retrained the employee responsible for monitoring this critical limit and provided documentation of the retraining. Your training included the proper completion of deviations and training for determination of when they are required.

Findings that were contained in the NOIE that did not meet § 310.22(d)(1), *specifically:*
9 CFR Part 310.22(d)(1) states: "Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program."

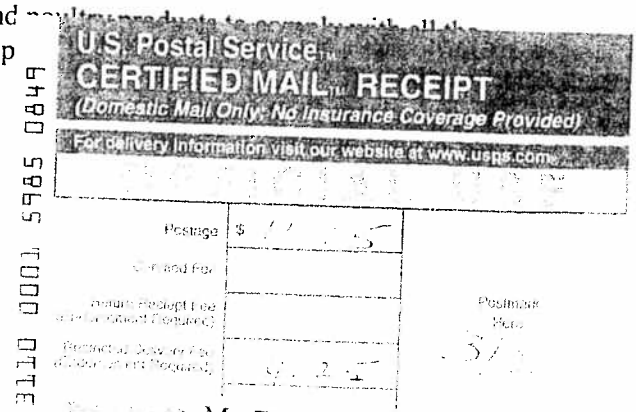
- {Beef Slaughter HACCP Plan} Your [redacted] SOP fails to describe how beef heads from cattle that are 30 months of age or older will be segregated and processed. When asked your Quality Control Manager described the procedures that are followed, however the procedures were not included in your SOP.
- You have modified your beef slaughter SOP which now includes the segregation and processing procedures for heads from cattle which are +30 months of age.

Although the Notice of Intended Enforcement in deferral at establishment 4653A is no longer in effect, please be advised that we consider violations of this type as serious in nature. As a Federally inspected establishment, you are expected to comply with § 417 and § 310.22 of the regulations and all other requirements concerning the preparation, sale and transportation of meat and poultry products. Please be advised that failure to comply with these requirements in the future could again lead to the withholding or suspension of inspection or other appropriate action.

We expect persons engaged in the handling of meat and [illegible] requirements of the law. We urge your voluntary comp

Sincerely,

Dennis Greening
Des Moines District Manager



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