

Establishment Inspection Report

Hawkeye Pride Egg Farms, LLP
Corwith, IA 50430

CST JWE

FEI:

3008778825

EI Start:

06/06/2011

EI End:

06/06/2011

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SUMMARY

The initial targeted inspection of this shell egg producer was conducted in accordance with KAN-DO work plans under assignment ID 1271374 Operation ID 5347758 Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFIG Assignment number 11 – 04, ORA Concurrence number 2011012601. The inspection followed the guidance given in the assignment, and the requirements of the “New Egg Rule” written in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. The inspection was pre – announced to the firm’s Complex Manager, Danny L. Snyder on 06/02/2011.

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The main objectives of the inspection were to:

- Assess compliance with 21 CFR 118 including evaluation of the firm's SE prevention plan, egg laying operation, environmental monitoring and response to positive results and documentation.
- Conduct inspections of egg laying facilities to determine if the firm is practicing adequate measures to prevent SE contamination of eggs and egg production areas.

Additionally, the inspection was to determine individual responsibility for the firm's SE prevention plan, who owns the layer hens and who packages the eggs.

Documents/Processes collected/reviewed during the inspection include the firm's SE Plan and Biosecurity Plan, Fly Monitoring reports, Rodent Monitoring reports, pullet procurement reports and laboratory results.

The current inspection was the initial FDA inspection of the firm. The inspection found the firm to have a written SE prevention plan and Biosecurity Plan to cover its production complex.

Assessments were conducted in one house only. The facility has received positive laboratory results indicating birds in barn HP2B01 tested positive for *Mycoplasma synoviae* (MS). Mr. Snyder stated the MS had not been reported to the state of Iowa Veterinarian. Please refer to the section entitled MS/MG for more details.

There was no FDA – 483 issued at the conclusion of the inspection. One item was discussed concerning reportable diseases. Please see the General Discussion with Management section for more details.

No samples were collected during the inspection. There were no refusals encountered during the inspection.

Any documents collected for review and not utilized in this report have been shredded.

The firm stated they are registered b(3) however a post inspectional search of FDA's database did not uncover a current registration.

The firm was warned of their responsibility to adhere to the Food, Drug, and Cosmetic Act and failure to do so could result in an action such as seizure, Injunction or civil penalties.

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Jeffrey W. Eichenberger an FDA Credentialed Investigator from the Iowa Department of Agriculture and Land Stewardship, accompanied me on this inspection. Mr. Eichenberger participated in the inspectional interview and barn assessment.

This report was written solely by Investigator Tucker.

ADMINISTRATIVE DATA

Inspected firm: Hawkeye Pride Egg Farms, LLP
Location: 1275 Deer Ave
Corwith, IA 50430
Phone: 515-583-2600
FAX:
Mailing address: 111 N.W. Elm Street
Corwith, IA 50430

Dates of inspection: 6/6/2011
Days in the facility: 1
Participants: Candace S Tucker, Investigator
Jeffrey W. Eichenberger, Investigator

During the pre – announcement conversation, Mr. Snyder asked that Investigator Eichenberger and I meet him at the corporate office located at 111 N.W. Elm Street, Corwith, IA. Upon our arrival to the corporate office credentials were presented to Mr. Snyder. After signing in, Investigator Eichenberger and I followed Mr. Snyder to the layer farm located at 1275 Deer Avenue, Corwith, IA.

Upon arrival to the layer farm, a completed FDA – 482 Notice of Inspection was issued to Mr. Danny L. Snyder, Complex Manager. Mr. Snyder stated he is the most responsible person on site on a daily basis.

HISTORY

Hawkeye Pride Egg Farms, LLP has been incorporated in the state of Iowa since 2008, **exhibit 1**. The firm's corporate office is located at 111 N.W. Elm Street, Corwith, IA. A copy of the firm's Organizational Chart (Chain of Command) has been attached to this report as **exhibit 2**.

Management stated Hawkeye Pride Egg Farms, LLP (Hawkeye Pride) is managed by Center Fresh Group located at 241 St. Andrews Way, Sioux Center, IA 51250. Management stated there is no

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available organizational chart for Center Fresh Group, although Mr. Snyder stated Mr. James R. Dean is CEO/President of Center Fresh Group and also the most responsible for Hawkeye Pride Egg Farms, LLP. Management stated Center Fresh Group also oversees/manages Center Fresh Farms, (b)(4)

This is the initial inspection of Hawkeye Pride.

Hawkeye Pride began construction around June of 2009. Houses were populated in January 2010. Currently there are eight houses constructed and populated, with a ninth currently under construction.

Hawkeye Pride employs a staff of (b)(4). All except (b)(4) are (b)(4) employees. Hours of Operation are (b)(4) p.m. (b)(4) days per week. (b)(4) staffing was explained to me as the farm is staffed (b)(4) but to a lesser degree.

FMD – 145 SHOULD BE ADDRESSED TO

Hawkeye Pride Egg Farms, LLP
Danny L. Snyder, Complex Manager
111 N.W. Elm Street
Corwith, IA. 50430

POST INSPECTIONAL COORESPONDENCE SHOULD BE ADDRESSED TO

Center Fresh Group
James R. Dean, CEO/President
241 St. Andrews Way
Sioux Center, IA 51250

INTERSTATE COMMERCE/JURISDICTION

Hawkeye Pride Egg Farms, LLP (Hawkeye Pride) is a shell egg producer of approximately (b)(4) dozen eggs per day. The firm mills feed on site for on site use only. All birds at the facility and the land are owned by Hawkeye Pride Egg Farms, LLP.

There are two areas of processing located in the main building. One side of the building processes shell eggs, in that the eggs are washed, graded and packed. The other side of the building is a breaking facility. The two areas are separated by a wall.

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Approximately b4 of the facility's production is in liquid egg. The liquid egg is shipped for further processing only to b4 located in b4. The remaining b4 of the firm's production is shell eggs which are shipped to b4 located in b4.

The firm packs under the following brands:

b4

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Danny L. Snyder, Complex Manager. Mr. Snyder is the most responsible individual on site on a day to day basis and has been employed by the firm since 01/2010. He oversees every aspect of operation including grading, breaking, barns and the flock, ensuring each department is running properly and required tasks are completed. He reviews documents, performs scheduling and is responsible for hiring and firing. He has b4 total reports and reports directly to Mr. Ross Sharp. Mr. Snyder was present for the entire inspection and provided much of the information in this report.

Nicholas H. Alt, Production Manager/SE Administrator. Mr. Alt has been with the firm since 06/07/2010. Mr. Alt manages the SE and Biosecurity program for the firm and supervises all aspects of the flock including feeding, watering and bird health. He oversees environmental sample collection, manure removal, fly/rodent control and SE control. Mr. Alt has approximately b4 direct reports and reports directly to Mr. Snyder. Mr. Alt was present for the entire inspection and provided much of the information in this report.

John A. Vanden Hoek, QA/Environmental Compliance Manager. Mr. Vanden Hoek has been with Center Fresh Group since Feb. 2011. He is responsible for all aspects of quality assurance for the firm which includes writing, approving and implementing procedures. Mr. Vanden Hoek is the firm's HACCP coordinator and performs audits for HACCP and SQF (Safe Quality Food). Mr. Vanden Hoek has b4 people who he oversees, but states he has no direct reports. He reports directly to J.T. Dean located at the corporate office. Mr. Vanden Hoek's office is also located at the corporate office in Sioux Center, Iowa. Mr. Vanden Hoek was present throughout the entire inspection and provided some of the information in this report.

Ross D. Sharp, Operations Manager. Mr. Sharp has been with Center Fresh Group since November 2009. He was not present at the beginning of the inspection, but arrived approximately one to two hours into the inspection. Mr. Sharp provides oversight to b4 egg laying and processing operations, traveling between the facilities. He approves procedures and processes and has the authority to hire and fire complex managers. Mr. Sharp has b(4) direct reports and reports directly to J.T. Dean whose office is located at the corporate office. Mr. Sharp's office is also

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located at the corporate office in Sioux Center, Iowa. Mr. Sharp provided some of the information in this report.

FIRM'S TRAINING PROGRAM

Mr. Alt stated all flock personnel are trained for the first [redacted] days in the barns with one or more of the firm's trainers. Each employee is also required to go through safety training. Each employee has a document they follow on a daily basis which lists daily tasks to be completed. The firm goes over issues on an as needed basis to refresh skills that may not be used daily.

MANUFACTURING/DESIGN OPERATIONS

Hawkeye Pride produces approximately [redacted] eggs per year. The firm consists of a USDA monitored shell egg processing plant and breaker plant located in a common building, a feed mill and a manure storage building. The processing plant is connected to the layers by a system of common egg conveyors. Eggs are graded prior to packaging by Mr. Pat Douthit, the USDA grader on site. During the inspection, we introduced ourselves to Mr. Douthit and explained our presence as a routine targeted inspection.

The firm has nine double decked belted houses completed; additionally a tenth house is under construction. Eight houses currently house birds; as one house experienced cage collapse recently and was depopped. Re – construction of the house is in progress at this time. When the re – construction has been completed, the house will be repopulated.

Houses are connected by a [redacted] as in exhibit 3. A [redacted] system is the only way to enter and exit each house separately, as the front entrance to the block of barns has a [redacted] between each barn so entering and exiting one barn at a time is not possible.

Each house has an upper and lower level. Each level contains [redacted] rows, each row having [redacted] tiers.

Feed is deposited in troughs by the use of [redacted] which is a [redacted] comprised of a [redacted] suspended on an [redacted] by [redacted]. Feed in the [redacted] to a [redacted] at the lower end of the [redacted]. Proximity switch and [redacted] control [redacted] movement of the [redacted] on the [redacted] as well as operate the [redacted]. The [redacted] is fitted with a [redacted] that determines which [redacted] feed is deposited.

The carts move up and down the aisle [redacted] times per day. [redacted] b(4) the end of each aisle where employees can pan and toss the debris.

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There is b4 per barn to complete barn/bird daily operations. There are b4 maintenance and b4 manure employees who can float from barn to barn as needed, and b(4) Pod Leader whose function is to oversee all of the above employees.

Eggs roll to an escalator belt which transports the eggs to a main conveyor belt. The main conveyor belt continually moves throughout each house transporting the eggs into the main building which houses the processing and breaker areas. b

Pullets are purchased from a facility contracted by Center Fresh Group.

SALMONELLA ENTERITIDIS/ BIOSECURITY PLAN

The firm provided a copy of their SE/Biosecurity Plan. Investigator Jeffrey W. Eichenberger and I reviewed documents to assess compliance with the final egg rule, 21 CFR 118.

The plan covers the following:

- Biological Security Plan
- Procedures to Reduce the Threat of SE Contamination
- Testing Policies

In addition, forms created for required documentation are also included in the plan.

Mr. Snyder reported the firm has no current SE positive houses and have never had any positive houses. Mr. Snyder also explained biosecurity is not conducted in the usual manner at this firm.

b4

Trucks entering the facility must be accompanied by wash tickets. Wash tickets from July 2010 were reviewed with no objections noted.

Visitors entering the facility are directed to the corporate office located at 111 N.W. Elm Street, Corwith, IA. The corporate office contacts Mr. Snyder by phone or radio and he travels to the corporate office to meet with the visitor.

All mortality is covered and composted after b4 removal from the egg production barns. If a rendering truck is utilized, it must be accompanied by a wash ticket prior to entering the facility.

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Feed is milled on site and trucked from the feed mill to the houses. Feed trucks do not deliver off the facility grounds.

If one or more barns would become SE positive, Mr. Snyder stated employees would be assigned to SE positive houses only and should not move between SE negative and positive houses.

A copy of the SE and Biosecurity Plan was provided by the firm and can be reviewed attached to this report as **Exhibit 8**.

MANUFACTURING CODES

Manufacturing codes are the plant number along with the Julian date of packaging.

PEST CONTROL

Exterior pest control is monitored and maintained by [b4] located in [b4] Bait stations are placed every [b4] feet around the exterior.

Interior pest control is the responsibility of a Hawkeye Pride employee. There are [b4] interior rodent monitoring stations which are checked [b4]. Rodent monitoring forms for 2011 were reviewed. A completed form dating 1/5/11 from house 1A has been attached to this report as **exhibit 4**. In the event an increased rodent index is experienced, corrective actions are documented on these forms.

Fly monitoring is handled by the use of [b4] [b(4)] are picked up [b4] and spots are counted to determine an action plan. Fly monitoring forms for 2011 were reviewed. If an increase in fly activity is experienced corrective actions are documented on the form. A completed form dating 12-16-10 attached to this report as **exhibit 5** shows an increase in fly activity and corrective actions taken.

MYCOPLASMA SYNOVIAE

The firm was unaware MS and/or MG were reportable diseases. I explained the state of Iowa's veterinarian had adopted the OIE (World Organization for Animal Health) for the list of reportable diseases in the state of Iowa and referred the firm to the website for confirmation. Mr. Alt stated it is the testing laboratory's responsibility to report diseases to the state of Iowa. He called Dr. Schmidt (State Veterinarian for the state of Iowa) during the inspection to clear up some confusion about the reportable diseases and reporting responsibility. He returned to say Dr. Schmidt does get monthly reports concerning MS and MG from laboratories in the state and determines the need to follow up

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positives from those reports. Mr. Alt stated Dr. Schmidt told him he does not follow up on cases of MS and/or MG because there are too many within the state and would require much of his time. Mr. Alt also called (b) (7)(C) of the (b) (4) Mr. Alt stated (b) (7)(C) said he was uncertain as to why FDA was interested in other diseases as the egg rule inspections should cover S.E. only. I explained to Mr. Alt our interest and request for information concerning other diseases was to allow FDA personnel to exclude areas from inspections (such assessments of barns with positive disease results) in order to prevent cross contamination. Please refer to the section heading entitled **Post Inspectional Information** for more details.

Test results received from (b) (4) located at (b) (4). (b) (4) have been attached to this report as **exhibit 9**. Column 5 contains the plate results for MG (Mycoplasma Gallisepticum) and MS. 14+/50 means 14 of 50 samples were found positive. The flock identified as HP2 B01 shows plate tests as 19+/19, or 19 positive results were found from 19 samples.

Mr. Alt stated the birds are vaccinated for MS/MG, so the positive results mean the birds have been challenged (exposed) to the viruses therefore increasing the titer, which is what the firm wants to see happen post vaccination. Vaccinations used in layers are to prevent drops in egg production and also egg quality.

COMPLAINTS

Complaints are received via email or phone calls. The firm refers to this as "Customer Care". An investigation is conducted on pertinent issues and the firm replies with any necessary follow up. A Customer Care procedure was provided for review and is attached to this report as **exhibit 6**.

RECALL PROCEDURES

The firm maintains a recall procedure which can be reviewed attached to this report as **exhibit 7**.

REFUSALS

There were no refusals encountered during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Those present for the inspectional close were Danny L Snyder, Nicholas H. Alt, John A. Vanden Hoek and Ross D. Sharp. One item was discussed concerning reporting diseases listed on the state

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of Iowa’s Veterinarian’s website. Mr. Alt explained testing laboratories report all reportable diseases to the state veterinarian. Post inspectional information from Iowa state veterinarian, Dr. Schmidt revealed this to be factual.

No FDA – 483 List of Observations was issued at the close of the inspection. Management was warned of their responsibility to adhere to the Food, Drug, and Cosmetic Act and failure to do so could result in an action such as seizure, Injunction or civil penalties.

ADDITIONAL INFORMATION

b5 & b7E



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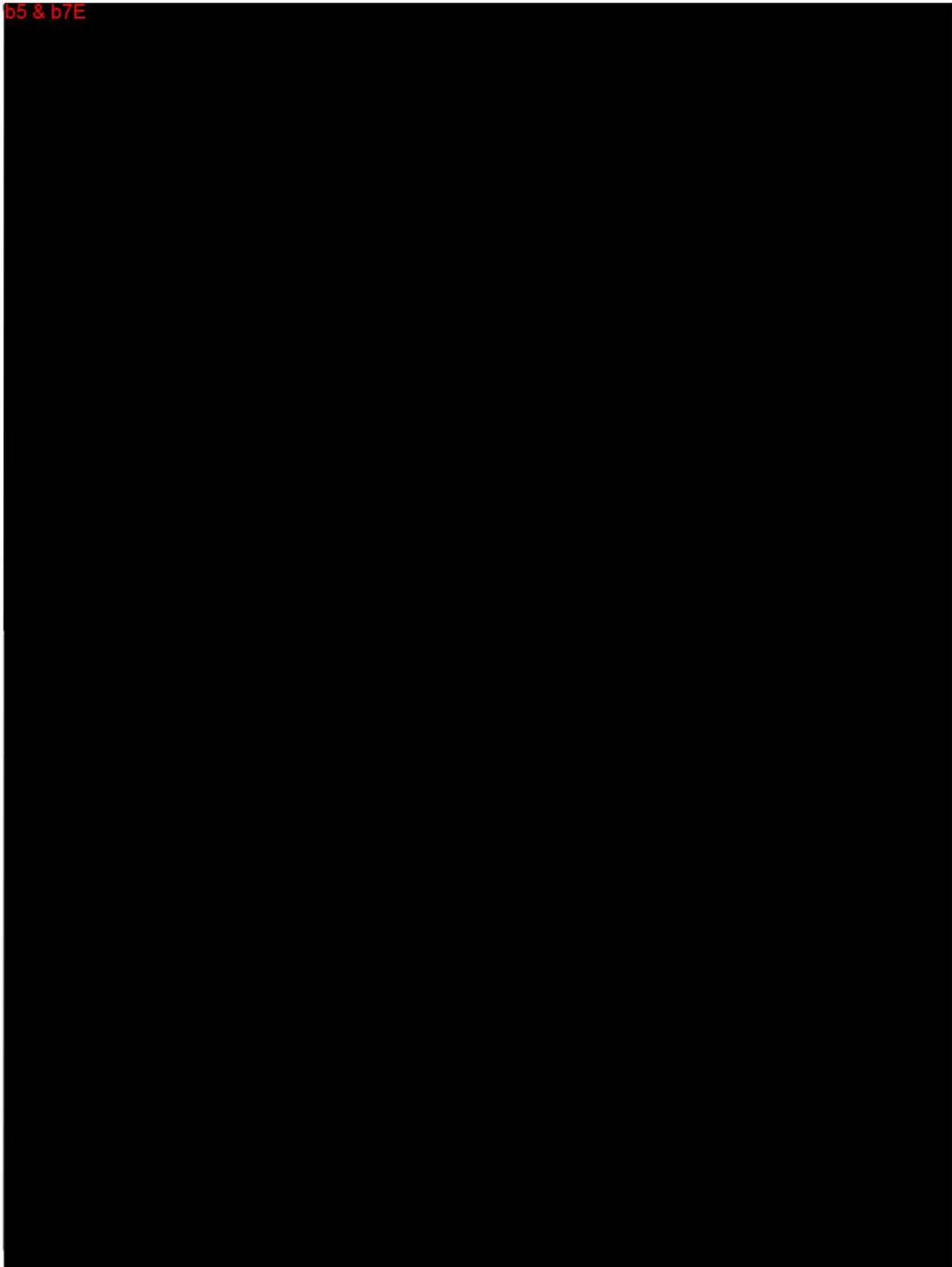
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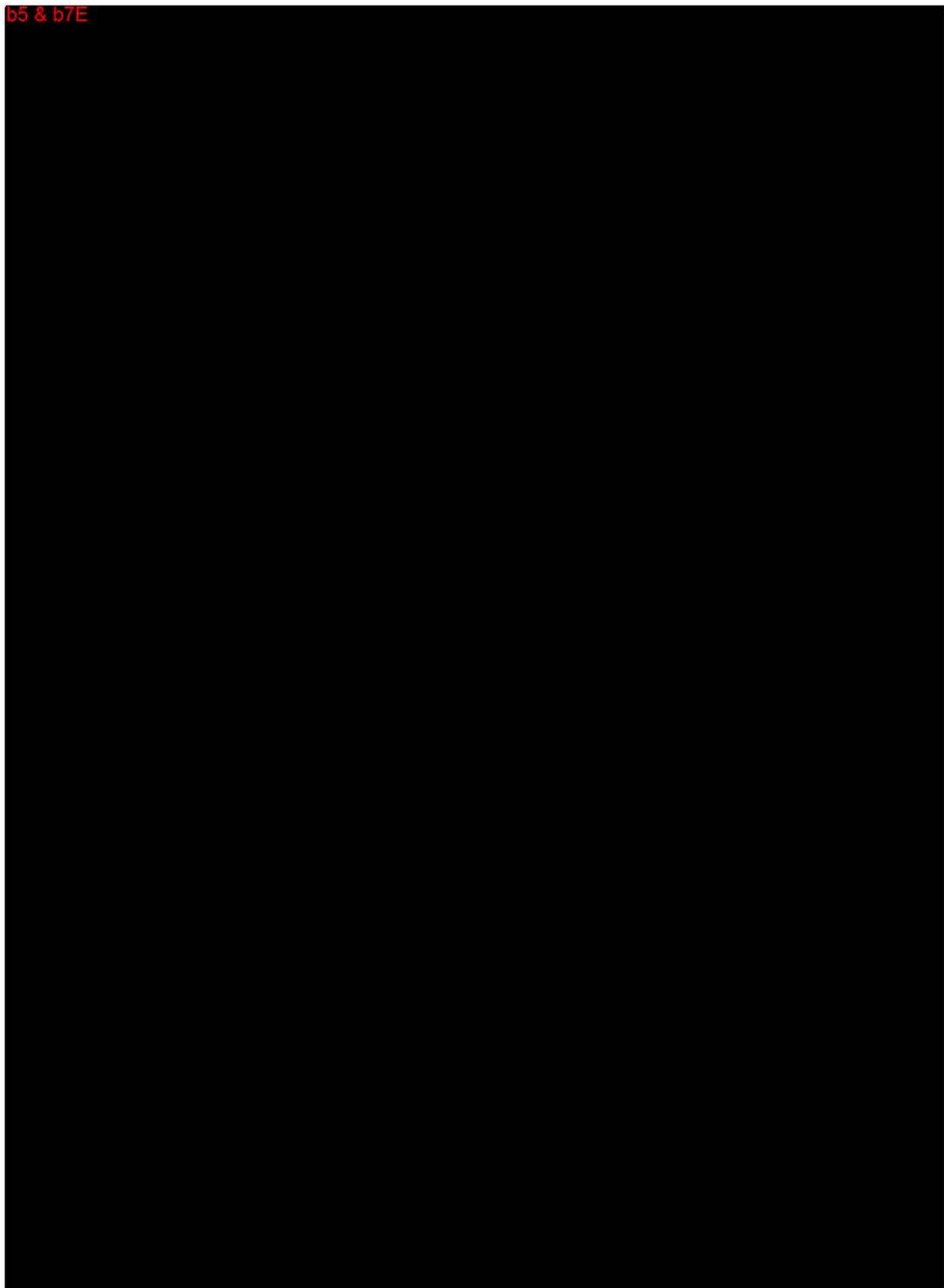
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b5 & B7E

SAMPLES COLLECTED

No samples were collected during the current inspection.

POST INSPECTIONAL INFORMATION

A post inspectional conversation with Dr. Schmidt found he has access to the test result database at the **b4** so he is able to look up any results of concern. He also stated he did not want each and every form containing positive MS and/or MG results to come to his office as the viruses are so wide spread. Dr. Schmidt stated 60 to 75% of layer flocks have either had these virus isolated from samples, or have antibodies to the viruses. Dr. Schmidt further explained the viruses cause no harm to humans. I asked Dr. Schmidt for guidance regarding these two viruses as it pertains to assessing houses on site when one or more houses are positive for MS or MG. Dr. Schmidt stated assessments could be accomplished by moving from negative to positive house regardless of age of birds, then wait 72 hours between farms.

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Although the firm stated they were registered **b(3)** post inspectional database searches found the firm was not registered. A call to Danny L. Snyder on 06/22/2011 resulted in Mr. Snyder stating he would contact Mr. Vanden Hoek, Quality Manager and register the firm immediately.

EXHIBITS COLLECTED

Exhibit 1: A copy of the incorporation registration for Hawkeye Pride Egg Farms, LLP, printed from the state of Iowa Corporation database, 1 page.

Exhibit 2: A copy of the firm's organizational chart (Chain of Command), 1 page.

Exhibit 3: A copy of Form B, which demonstrates the **b4** located between houses, 1 page.

Exhibit 4: A copy of Form C, which is a completed rodent monitoring log, 1 page.

Exhibit 5: A copy of Form D, which is a completed fly monitoring log, 1 page.

Exhibit 6: A copy of the firm's Customer Care (complaint) procedure, 1 page.

Exhibit 7: A copy of the firm's Recall procedure, 1 page.

Exhibit 8: A copy of the firm's SE (Salmonella Enteritidis)/Biosecurity Plan, 18 pages.

Exhibit 9: A copy of the MG/MS test results from Hy-Line International, 1 page.

ATTACHMENTS

A copy of the FDA – 482 issued to Danny L. Snyder on 06/06/2011.

A copy of the assignment identified as 1271374, Operation ID, 5347758.

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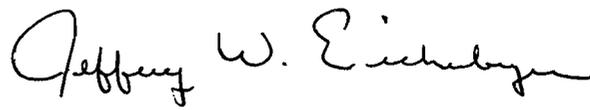
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Candace S Tucker, Investigator



Jeffrey W. Eichenberger, Investigator