

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: **3008776802**
EI Start: 06/29/2011
EI End: 06/29/2011

TABLE OF CONTENTS

Summary 1
Pre-Inspection activities..... 3
Administrative Data 3
History..... 4
Interstate Commerce 4
Jurisdiction..... 5
Individual Responsibility and Persons Interviewed..... 5
Firm's Training Program 6
Manufacturing/Design Operations..... 6
SALMONELLA ENTERITIDIS PREVENTION PLAN 7
Manufacturing Codes..... 9
Complaints 10
Recall Procedures..... 10
Objectionable Conditions and Management's Response 10
Refusals..... 11
General Discussion with Management 11
Additional Information 12
Samples Collected..... 16
Exhibits Collected..... 16
Attachments 17

SUMMARY

(written by LAG)

This targeted inspection of a Shell Egg Producer was conducted pursuant to **FACTS assignment # 1271959, Operation ID # 5351588**, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFGP Assignment # 11-04, ORA Concurrence # 2011012601, dated 02/08/2011, and the KAN-DO FY 11 work plan. The inspection followed the guidance given in the assignment, and 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 (b) (4) Veterinarian, Dr. (b) (4) on 05/10/2011.

Establishment Inspection Report

Sunnyside Farm
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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 reviewed during the inspection include the firm's written SE Prevention Plan, chick receiving records, pest control records, and cleaning and disinfecting records.

This was the first FDA inspection of Sunnyside Farms, Firth, NE. The inspection found the firm has a written SE prevention plan. The firm's bio-security plan is incorporated into their SE Prevention Plan. Investigator McClure and I conducted assessments in 3 Houses. 2 of the 5 Houses on-site were confirmed by firm management to be SE positive.

At the conclusion of the inspection, the firm was issued a **FDA 483, *Inspectional Observations*** for:

- **failing to perform environmental testing in the houses when laying hens were 40-45 weeks of age for House 5 (tested at 48 weeks)**

The following three verbal items were also discussed with management:

- There are no footbaths at the entrances to Houses 3, 4, and 5 since these are now high traffic entrances.
- The grass between Houses 3 and 4 was approximately 3 feet high and needs to be trimmed down.
- Three bird nests were observed outside of the maintenance shed and one was observed outside of House 3.

No samples were collected. No refusals were encountered. At the close of the inspection, management was warned of the firm's responsibility to adhere to the FD&C Act and penalties were explained. Firm management stated they would respond in writing to KAN-DO describing their corrective actions.

Establishment Inspection Report

Sunnyside Farm

Firth, NE 68356

MMM, LAG

FEI:

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EI Start:

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06/29/2011

PRE-INSPECTION ACTIVITIES

The Nebraska State Program Contact, Dr. Hughes (Assistant State Veterinarian / Nebraska Department of Agriculture / Animal Industry Bureau) was contacted on May 10, 2011 to determine if any state quarantine or other issues were in place at this firm. Dr. Hughes stated the firm was not under quarantine and was not aware of the firm reporting any reportable diseases.

The inspection was pre-announced to (b) (4) Veterinarian, (b) (4) DVM on 05/10/2011, who in turn, notified the Farm Manager of the firm, Mr. Earl J. Latshaw.

ADMINISTRATIVE DATA

(written by LAG)

Inspected firm: Sunnyside Farm
Location: 365 S 110th
Firth, NE 68356
Phone: 402-791-2215
FAX: 402-791-2215
Mailing address: 7407 Pella Rd
Firth, NE 68356

Dates of inspection: 6/29/2011
Days in the facility: 1
Participants: Monica M McClure, Investigator
Lori Gioia, Investigator

Upon our arrival at the firm, Investigator McClure and I showed our credentials and an FDA 482, *Notice of Inspection* was issued to Garry J. Heetderks, President. Mr. Heetderks identified himself as the most responsible individual on-site. Credentials were also presented to Jerry L. Tekolste, Treasurer; Rodney (MIUK) Tekolste, Vice President; Earl F. Latshaw, Farm Manager; and Dr. (b) (4) DVM.

An FDA 483, *Inspectional Observations* was issued to Mr. Garry J. Heetderks at the conclusion of the inspection.

This report was written by Investigator McClure and Investigator Gioia.

Establishment Inspection ReportSunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
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(written by LAG)

This was the first FDA inspection of Sunnyside Farms. Sunnyside Farms was incorporated in the state of Nebraska in 1998. The corporate headquarters is located at 7407 Pella Road, Firth, NE 68358.

The firm began operating in Firth, NE in 1998. Mr. Heetderks stated there used to be six owners when the firm began operations in 1998, but he, along with Mr. Jerry L. Tekolste and Mr. Rodney (MIUK) Tekolste have been the owners for some time now. The operation consists of 5 houses, 2 of which were built in 1998, one in 2001, one in 2004, and the last in 2008. There are (b) (4) birds in House 1 and 2, 131,510 birds in House 3, (b) (4) birds in House 4, and (b) (4) birds in House 5. The ages of the birds are as follows: House 1 is 49 weeks, House 2 is 48 weeks, House 3 is 66 weeks, House 4 is 56 weeks, and House 5 is 21 weeks. Birds are kept for (b) (4) weeks. The environmental testing which was conducted on (b) (4) came back positive for *Salmonella enteritidis* for Houses 1 and 2.

The firm currently has (b) (4) full time employees. Hours of operation are (b) (4) (b) (4). Packing of eggs occurs (b) (4) when the farm is in full production.

All official correspondence and post-inspection correspondence including the FMD-145 should be addressed to: Mr. Garry J. Heetderks, President, Sunnyside Farms, 7407 Pella Road, Firth, NE 68358.

INTERSTATE COMMERCE

(written by LAG)

The firm ships (b) (4)% of its shell eggs within the state of Nebraska according to Mr. Heetderks. The firm ships to (b) (4) (b) (4) in (b) (4) which is a breaker. The other (b) (4) percent may be sold to the table market. Mr. Latshaw stated the last time eggs were sent to the table market was around Easter of this year.

Investigators McClure and Gioia reviewed National Poultry Improvement Plan (NPIP) Reports from (b) (4) in (b) (4) and (b) (4) in (b) (4), confirming chicks are procured from at least (b) (4) interstate firms.

Establishment Inspection Report

Sunnyside Farm

Firth, NE 68356

MMM, LAG

FEI:

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JURISDICTION

(written by MMM)

The firm is a Shell Egg Producer with greater than 3000 laying hens that produces shell eggs for the table market and is subject to requirements in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. The firm is registered with the FDA.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(written by LAG)

Mr. Garry J. Heetderks, Owner/President is the most responsible person at the firm. His duties include communicating with (b) (4) and coordinating all contract matters. Mr. Heetderks has been part owner since inception. The FDA 483, *Inspectional Observations* was issued to Mr. Heetderks. Mr. Heetderks was present during the entire inspection and provided some information contained in this report.

Mr. Jerry L. Tekolste, Owner/Treasurer is responsible for the financial portion of the business including billing. Mr. Tekolste has been part owner since inception. Mr. Tekolste was present during the entire inspection and provided some information contained in this report.

Mr. Earl F. Latshaw, Farm Manager is responsible for managing all employees, overseeing the care of all of the laying hens, and overseeing all day-to-day farm operations with the exception of the financial portion. Mr. Latshaw has been with the company as Farm Manager since 2000. All employees at the firm report to him. Mr. Latshaw reports to Mr. Heetderks, Mr. J. Tekolste, and Mr. Rodney Tekolste, Owner/Vice President. Mr. Latshaw was present during the entire inspection and provided most of the information contained in this report.

Dr. (b) (4) DVM for (b) (4) is responsible for providing support to Mr. (b) (4), Manager of Contract Farms including; walking and inspecting the houses, checking for mortality, review of production, corrections as needed, suggestions for baiting for pest control, and general consulting. Dr. (b) (4) has been with (b) (4) for approximately (b) (6) and has been working with Sunnyside Farms since it began production in (b) (6). Dr. (b) (4) reports to (b) (4), Vice President of Live Production for (b) (4). Dr. (b) (4) was present during the entire inspection and provided some information contained in this report.

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

FIRM'S TRAINING PROGRAM

(written by LAG)

Training records were reviewed during this inspection and no objections noted. Mr. Latshaw stated annual training is provided to all employees regarding the firms' Biosecurity plan and UEP code of conduct. Mr. Latshaw stated (b) (4) provided the training materials which include a training video and Power Point presentations. Mr. Latshaw provides the employees with the (b) (4) and (b) (4) trainings; documented on the (b) (4) Compliance Checklist, provided as **Exhibit 2**.

MANUFACTURING/DESIGN OPERATIONS

(written by LAG)

Sunnyside Farms (SSF) in Firth, NE produces approximately (b) (4) eggs per (b) (4) when all houses are in full production. This location consists of a shell egg processing room connected to hen houses by a system of common egg conveyors. Sunnyside Farms own the land and the houses and the hens are owned by (b) (4). The firm utilizes (b) (4) separate on-site water wells as their water source and all of the firm's poultry feed requirements are supplied by (b) (4) in (b) (4). (b) (4) The (b) (4) and (b) (4) used for a protein source are supplied by (b) (4) in (b) (4). The wells were last tested in 2009 and Mr. Heetderks stated testing would be performed (b) (4) in the future.

The firm receives pullets from (b) (4) and (b) (4) (b) (4) located in (b) (4). According to firm management, pullets are required to be SE clean; NPIP certificates were reviewed during the inspection and copies were provided by Mr. Latshaw; see **Exhibit 3, pp 1-13**.

The firm's 3 high rise houses have direct drop manure pits from the cages and the last two belted houses utilize manure scrapers. All hen houses are wood frame structures with concrete foundations, metal roofs, and metal siding. Each of the first 2 houses has a total of (b) (4) hens per house, the third house has (b) (4) hens, the fourth house has (b) (4) hens and the fifth house has (b) (4) hens. Houses 1, 2, and 3 have (b) (4) tiers of hens on each row and (b) (4) rows per house and there are either (b) (4) or (b) (4) birds per cage. House 4 has (b) (4) rows and (b) (4) tiers with (b) (4) or (b) (4) birds per cage and House 5 has (b) (4) rows and (b) (4) tiers with (b) (4) birds per cage. The dimensions of Houses 1, 2, and 3 are approximately (b) (4) feet wide by (b) (4) feet long, and Houses 4 and 5 are approximately (b) (4) feet wide by (b) (4) feet long with (b) (4) feet being cages and the last (b) (4) feet is used to store manure. See **Exhibit 4, pp 1-3** for cage information and house layouts provided by firm management.

The firms operation is as follows:

- The caged hens on the tiers lay eggs which roll to an escalator belt.
- The escalator belt transports the eggs to the main conveyor belt.

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

- The main conveyor belt continually moves throughout each house and transports the eggs into the processing area.

Farm Packing/ Refrigeration/ Shipping Operations

(written by MMM)

Eggs are hand packed and placed on a pallet; the pallet is identified with a colored tag containing the following information: Date Produced; Producer; Flock #; UEP #; and House #. All pallets of eggs are stored in on-site coolers until shipped.

SSF employees monitor the cooler's temperature. A cooler temperature check is conducted (b) (4) in the morning, and the temperature is recorded on the form entitled, "Sunny Side Farm (b) (4) Cooler Temperatures". A review of this log was conducted and a representative portion of the logs are attached to this report as **Exhibit 5; pp 1-2** (09/01-30/2010 & 06/01-29/2011). This review found several days where the cooler temperature was recorded above 45°F. We questioned firm management about this at which they stated three new cooling units had been installed in September 2010 to help maintain a lower temperature. Logs reviewed after mid-September showed the temperatures were more consistently maintained at 45°F or below. According to June 2011 (b) (4) Cooler Temperature log, temperatures in the cooler ranged from 44°F - 57°F; a (b) (4) was (b) (4) as a corrective action. Eggs are picked up at least (b) (4) (b) (4) and (b) (4). Refrigerated trucks are always used to haul eggs from firm to (b) (4) in (b) (4) (b) (4). Additionally, shelled eggs are being shipped out of the cooler at least (b) (4) (b) (4) order.

SALMONELLA ENTERITIDIS PREVENTION PLAN

(written by MMM)

The firm provided a copy of their Sunny Side Farms SE Prevention Plan; see **Exhibit 1, pp 1-75**. Investigator Gioia and I reviewed documents to assess compliance with the final egg rule, 21 CFR 118.

The plan covers the following items:

- SE Plan Administration, Plan Administrators: Garry Heetderks and Earl Latshaw; see **Exhibit 1, page 5**
- Record Location
- Biosecurity
- Pest Management
- Pullet Testing
- Testing Methodology

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

- Refrigeration
- Cleaning and Disinfecting Between Flocks
- Egg Diversion
- Egg Treatment
- Record Keeping

SSF's SE Plan states the firm conducts environmental sampling and testing for SE at 40 to 45 weeks, see **Exhibit 1, pg 38**. Additionally, Dr. (b) (4) DVM with (b) (4) stated the firm always conducts environmental testing at the end of each flock's lay cycle; Investigator Gioia and I reviewed Layer testing results and found environmental sampling had been conducted multiple times on flocks ranging in age from 70-73 weeks of age, See **Exhibit 6, p 1**. Hens are removed from the houses at approximately (b) (4) weeks, the farm does not currently molt birds.

We reviewed the testing methodology and sampling procedure; see **Exhibit 1, pp 39-41**, under "Pullet Test SOP" and "Layer House SE Test SOP". The firm's SE Prevention Plan details pullet testing and environmental monitoring schedules for SE. The plan also details the firm's response in the event of positive SE results in pullets or the environment. The sampling plan for pullet and layer houses appeared to be in accordance with sampling guidance. The firm sends their SE environmental samples to (b) (4) in (b) (4). Mr. Latshaw is responsible for insuring sample collection for SE monitoring at appropriate time points, documentation of results, and reporting results to appropriate company personnel. Mr. Latshaw provided a copy of the report of SE monitoring sample result from 11-May-10 to 13-Jun-11; a review of the report found that two results were reported as positive for SE; Flocks (b) (4) & (b) (4) on (b) (4); see **Exhibit 6, pp 1-4**.

Cleaning and Disinfecting

According to the firm's SE Plan, hen houses are cleaned and disinfected when a positive SE environmental test results. Please refer to **Exhibit 1, pp 51-55**. The plan outlines dry cleaning and disinfection procedures between flocks. The plan includes wet cleaning procedures for SE positive houses. Additionally, procedures for segregating/diverting eggs are included in the plan for flocks determined to be SE positive; see **Exhibit 1, pp 49**.

Personnel Movement

Prior to the positive SE houses, employees did not practice biosecurity measures when traveling from one house to another. All employees enter through the back of the egg packing room where each employee maintains a private locker and separate pair of clean shoes. Employees walk through "(b) (4)", a (b) (4) footbath located at the entrance to the egg packing room before entering Houses #1-5; separate entrances to the houses were not utilized by employees. Dr. (b) (4) provided the firm with updated correction procedures specific to Houses 1 & 2 on 6/29/11; to be implemented immediately. See **Exhibit 1, pp 49-50** for the following personnel updates:

- Separate shoe covers, clothes cover and hand covering

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

- Personnel going to other houses will go outside and enter through ground floor doors instead of entering through houses 1 & 2
- Dead birds should not be taken to other houses
- Maintenance people will be expected to have separate clothes, hand coverings and shoes for houses 1 & 2 and wipe tools with disinfectant
- Footbaths will be placed at the doors of each house, See **General Discussion with Management** section of this report regarding this new SOP

Pest Control

(written by LAG)

Sunnyside Farms manages their pest control program internally. The firm's SE Prevention Plan, see **Exhibit 1, pp 29-33**, includes plans for rodent and fly monitoring and corrective actions. The plan also outlines the firm's procedure for rodent baiting and trap placement in each house.

During assessments of the hen houses one live rodent was observed on the layer level of House 3. There was no idle equipment or material for harborage in the yards around houses. The grass between Houses 2 and 3 was approximately three feet high. See **General Discussion with Management**. A review of the firm's Mouse Numbers sheets and Pest Control Log found that inspection of traps and bait stations appeared to be conducted (b) (4) as required by the firm's SE Prevention Plan.

The firm's plan for fly control outlined in the SE Prevention Plan, includes the methodology and logs, see **Exhibit 1, p 75** for example of Pest Control Log. Methodology includes monitoring houses daily, and if any flies are observed, the houses are baited. The firm decided recently to change their methodology to now walk up and down one aisle in the house with fly paper, count the flies and record on the log. The firm also uses natural means of fly control, namely a species of (b) (4), which help keep the fly population down. Mr. Heetderks and Mr. J. Tekolste stated manure is removed from the houses about (b) (4)

Refrigeration

Please refer to **Exhibit 1, pp 44-47** for the firm's refrigeration procedures for SE control.

MANUFACTURING CODES

(written by LAG)

Mr. Latshaw stated the farm does not issue P numbers since the eggs are processed by (b) (4) (b) (4) in (b) (4) (b) (4) eggs are placed on each pallet and the pallets are

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

identified with a tag, see **Exhibit 7, p 1**. The tag includes the date produced, the producer, the flock number, the house number, and the UEP number. The eggs produced in Houses 1 and 2 have been marked with another tag (See **Exhibit 7, p 2**) which denotes the eggs must be treated to achieve a 5 log reduction since these houses were recently tested and the results were positive for SE.

COMPLAINTS

(written by MMM)

The firm's complaint handling procedures were not reviewed as a part of this inspection.

RECALL PROCEDURES

Mr. Latshaw and Dr. (b) (4) stated there have been no recalls for any Sunnyside Farms eggs.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

The following observation was provided to management at the conclusion of the inspection:

Environmental testing for SE was not done in a poultry house when laying hens were 40-45 weeks of age.

Specifically, Flock (b) (4) in House 5 were tested for SE at 48 weeks of age.

Supporting Evidence and Relevance:

As per the Egg Rule {21 CFR 118.5(a)}, environmental testing for SE in a poultry house is required to be done when laying hens in the house are 40-45 weeks of age. Additionally, please refer to **Exhibit 1 pages 38** for the firm's SE testing procedures which states, "***manure belts are swabbed at 40 to 45 weeks***".

Discussion with Management:

No comments were provided by firm management during the closeout discussion.

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

FEI: 3008776802
EI Start: 06/29/2011
EI End: 06/29/2011

REFUSALS

There were no refusals for this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Prior to the inspection, on 6/27/11, Dr. (b) (4) notified me the firm currently had 2 SE positive houses (Houses 1 & 2). Positive results were confirmed on 6/24/11; samples had been taken from the houses for the 45 week environmental monitoring on 6/18/11. Dr. (b) (4) stated the firm began diverting eggs from Houses 1 & 2 on 6/24/11. During the inspection, firm management reported Houses 1 & 2 had tested borderline SE positive in September 2010 when the previous flocks ((b) (4) & (b) (4)) were 72 weeks of age; the firm re-tested, tests came back negative. Mr. Latshaw stated additional cleaning and disinfection ((b) (4)) was completed prior to introducing current flocks ((b) (4) & (b) (4)) to the houses, including all fans and shutters. All of the manure was removed from the houses and extra bait was put out in the basements. According to Mr. Latshaw, no documentation was completed to verify the reported cleaning and disinfection processes. Dr. (b) (4) stated the firm intends to spray a (b) (4) onto the birds in Houses 1 & 2; no timeframe was given.

The final discussion with management was held at the firm's office on 06/29/11. Firm representatives included: Garry J. Heetderks, Owner/President, Jerry L. Tekolste, Owner/Treasurer, Earl F. Latshaw, Farm Manager and (b) (4) DVM for (b) (4) FDA representatives included Investigators McClure and Gioia. A one item FDA 483, *Inspectional Observations* was issued to and discussed with Mr. Heetderks, Owner/President.

In addition to the FDA 483, the following three verbal observations were discussed with firm management:

- Footbaths were not present at the entrances to Houses 3, 4, and 5. Since Houses 1 and 2 are SE positive, entry into the other three houses is made through the exterior doors of the houses (3-5). Per the firm's updated SE procedures for positive houses, dated 6/28/2011, footbaths will be placed at the doors of each house, please refer to **Exhibit 1, p 49**.
- During the house assessments, three bird nests were observed on the exterior of the maintenance shed and one was observed outside of House 3.
- The grass in the area between Houses 2 and 3 was observed to be approximately three feet high. This tall grass could potentially be a harborage area for rodents and other pests.

Investigator McClure warned management of their responsibilities to comply with the Food Drug and Cosmetic Act. Penalties for noncompliance and the 15 day response opportunity were discussed.

Establishment Inspection Report

Sunnyside Farm
Firth, NE 68356

MMM, LAG

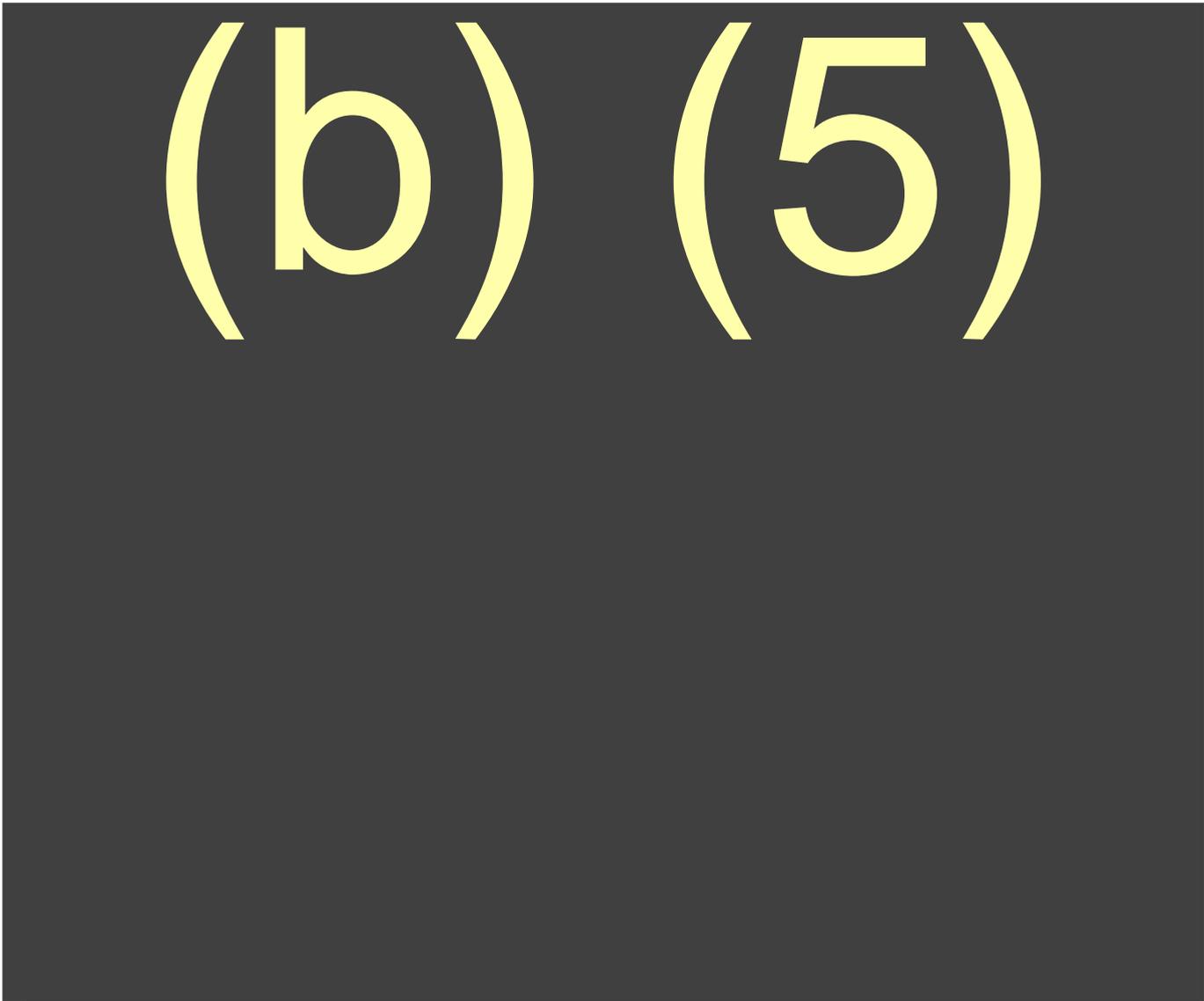
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ADDITIONAL INFORMATION

(written by LAG)

The following checklist is inserted in this EIR as directed in **FACTS assignment # 1271948**, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA Concurrence # 2011012601, dated 02/03/2011, Amended 02/08/2011:

Attachment A: Inspection/Data Collection Tool for *Targeted Inspections*



Establishment Inspection Report

Sunnyside Farm

Firth, NE 68356

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EI Start:

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EI End:

06/29/2011

(b) (5)

Establishment Inspection Report

Sunnyside Farm

Firth, NE 68356

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EI Start:

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EI End:

06/29/2011

(b) (5)

Establishment Inspection Report

Sunnyside Farm

Firth, NE 68356

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06/29/2011

EI End:

06/29/2011

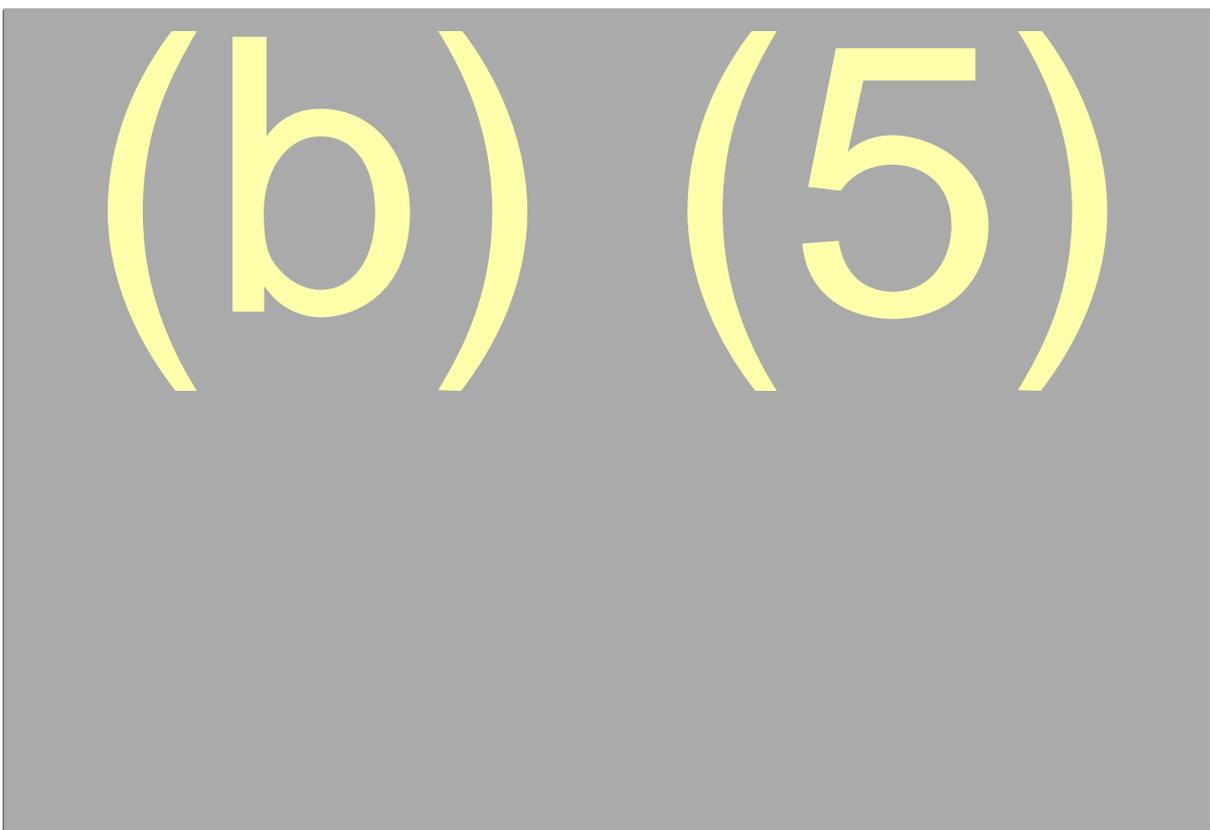
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Establishment Inspection Report

Sunnyside Farm
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MMM, LAG

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Recommendation for comprehensive inspection: (b) (5)

SAMPLES COLLECTED

The assignment did not call for samples and none were collected during the inspection.

EXHIBITS COLLECTED

1. Salmonella Enteritidis Plan, pp 1-75
2. (b) (4) Compliance Checklist
3. NPIP Certificates, pp 1-13
4. Cage/House Information pp 1-3
5. Cooler Refrigeration Logs, pp 1-2
6. SE test results, pp 1-4
7. Product Tags, pp 1-2

Establishment Inspection Report

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ATTACHMENTS

- Copy of FDA Form 482, *Notice of Inspection*, issued to Garry J. Heetderks, President, Sunnyside Farms, Firth, NE, dated 6/29/11
- Copy of FDA Form 483, *Inspectional Observations*, issued to Garry J. Heetderks, President, Sunnyside Farms, Firth, NE, dated 6/29/11


Monica M McClure, Investigator


Lori Gioia, Investigator

