

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

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..... 5

Manufacturing/Design Operations..... 6

SALMONELLA ENTERITIDIS PREVENTION PLAN 7

Manufacturing Codes..... 9

Recall Procedures..... 9

Objectionable Conditions and Management's Response 9

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 # 1271953, Operation ID # 5351560** , Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFIG 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 the firm's owner, Mr. Eugene Jurgens on 05/09/2011.

Establishment Inspection Report

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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 Sunny Yolk Egg Ranch, Adams, NE. The firm currently maintains a contract with (b) (4) covering all egg production at this site. The inspection found that 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 Barns.

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

- **failing to fully follow the SE prevention plan.**
- **failure to maintain practices to prevent against cross contamination between houses.**
- **failure to have an SE plan administrator.**
- **failure to have signatures or initials of the person performing the operation on required documents.**

The following three verbal items were also discussed with management:

- Temperatures recorded on the temperature log are above 45°F (50°- 60°F). Curtains were installed and the temperatures recorded thereafter were within range. Bills of lading do not contain the truck temperatures.
- The SE plan states environmental testing is to be performed on manure belts. This needs to be changed to manure pits since there are no manure belts in the houses.
- The (b) (4) review of the animal care which is listed in the plan has not been documented as performed.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

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EI Start:

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EI End:

05/24/2011

No samples were collected. No refusals were encountered. At the close of the inspection, management was reminded 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.

PRE-INSPECTION ACTIVITIES

(written by MMM)

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 firm's owner, Mr. Eugene A. Jurgens on 05/09/2011 and (b) (4) Veterinarian, (b) (4) DVM on 05/10/2011.

ADMINISTRATIVE DATA

(written by LAG)

Inspected firm: Sunny Yolk Egg Ranch LLC
Location: 11762 S. 134th Road
Adams, NE 68301
Phone: 402-988-2140
FAX:
Mailing address: 11762 S. 134th Road
Adams, NE 68301

Dates of inspection: 5/24/2011
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 Eugene A. Jurgens, Owner. Mr. Jurgens identified himself as the most responsible individual on-site.

An FDA 483, *Inspectional Observations* was issued to Mr. Eugene A. Jurgens at the conclusion of the inspection.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

This report was written by Investigator McClure and Investigator Gioia.

HISTORY

(written by LAG)

This was the first FDA inspection of Sunny Yolk Egg Ranch, LLC. Sunny Yolk Egg Ranch, LLC was incorporated in the state of Nebraska in 1997. The corporate headquarters is located at 11762 S. 134th Road, Adams, NE 68301.

The firm began operating in Adams, NE in 1997. The operation consists of 3 houses, 2 of which were built in 1997, and the third in 2004. There are (b) (4) birds in House 1 and 2 (first flocks put in August 1997 for House 1 and September 1997 for House 2), and (b) (4) birds in House 3 (first flock put in January 2005). The ages of the birds are as follows: House 1 is (b) (4) weeks, House 2 is (b) (4) weeks, and House 3 is (b) (4) weeks. Birds are kept for (b) (4) weeks.

The firm currently has (b) (4) full time employees and (b) (4) part time employees, not including the owners, Eugene A. Jurgens and Karen K. Jurgens. Hours of operation are (b) (4). Packing of eggs occurs (b) (4).

All official correspondence and post-inspection correspondence including the FMD-145 should be addressed to: Mr. Eugene A. Jurgens, Owner, Sunny Yolk Egg Ranch, LLC, 11762 S. 134th Road, Adams, NE 68301.

INTERSTATE COMMERCE

(written by LAG)

The firm ships (b) (4)% of its shell eggs within the state of Nebraska according to Mr. Jurgens. The firm ships to (b) (4) in (b) (4) which is a breaker. The other (b) (4) percent may be sold to the table market.

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.

Sunny Yolk Egg Ranch does not provide shipping. According to Dr. (b) (4), (b) (4) (b) (4) utilizes a trucking service, (b) (4) to pick up (b) (4) from Sunny Yolk Egg Ranch and deliver them to (b) (4) in (b) (4).

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

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EI Start:

05/24/2011

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05/24/2011

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. Eugene A. Jurgens, Owner/President is the most responsible person at the firm. His duties include; overseeing egg production and processing operations. Mr. Jurgens was involved in record review and provided some of the information contained in this report. Mr. Jurgens stated the first flocks were put into House 1 in August 1997, House 2 in September 1997, and January 2005 for House 3. The FDA 483, *Inspectional Observations* was issued to Mr. Jurgens.

Mrs. Karen K. Jurgens, Owner/Treasurer is also responsible for overseeing egg production along with record keeping. Mrs. Jurgens 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 20 years and has been working with Mr. and Mrs. Jurgens at their farm since it began production in 1997. Dr. (b) (4) reports to (b) (4) Vice President of Live Production for (b) (4)

(b) (4), **General Manager Contract Egg Production/Spent Hen Sales for (b) (4)** is responsible for looking after contract egg producers and reviewing operations at these farms. He has been with (b) (4) for 47 years and has been associated with Sunny Yolk Egg Ranch, LLC since its inception.

FIRM'S TRAINING PROGRAM

(written by LAG)

Training records were reviewed during this inspection and no objections noted. Mrs. Jurgens stated she provides annual training to all employees. Training includes biosecurity practices such as not keeping pet birds at home, showing up to work with clean clothes, and ensuring no stray animals enter the laying houses.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

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FEI:

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EI Start:

05/24/2011

EI End:

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MANUFACTURING/DESIGN OPERATIONS

(written by LAG)

Sunny Yolk Egg Ranch LLC, in Adams, NE, receives (b) (4) % of their pullets from (b) (4) (b) (4) located in (b) (4). The firm requires these pullets to be SE clean and keeps NPIP documentation within their SE Plan notebook; see **Exhibit 2, pp 1-3**.

Sunny Yolk Egg Ranch, LLC in Adams, NE produces approximately (b) (4) eggs per (b) (4). This location consists of a shell egg processing room connected to hen houses by a system of common egg conveyors. Mr. and Mrs. Jurgens own the land and the houses and the hens are owned by (b) (4) (b) (4). The firm utilizes (b) (4) separate on-site water wells as their water source (b) (4) (b) (4) 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 two of the firm's high rise houses have direct drop manure pits from the cages and the third utilizes 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 and the third house has (b) (4) hens. Houses have (b) (4) tiers of hens on each row and (b) (4) rows per house. The dimensions of Houses 1 and 2 are (b) (4) feet wide by (b) (4) feet long, and House 3 is (b) (4) feet wide by (b) (4) feet long.

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

Farm Packing/ Refrigeration/ Shipping Operations

(written by MMM)

Eggs are hand packed and placed on a pallet; the pallet is identified with a yellow tag containing the following information: Date Produced; Producer; Flock #; House #; and Age of birds. All pallets of eggs are stored within an on-site cooler until shipped.

Firm management monitors the cooler's temperature. The cooler temperature is checked (b) (4) and recorded on the form entitled, (b) (4). A review of this log was conducted and a representative portion of the logs are attached to this report as **Exhibit 3; pp 1-3** (08/01/2010-09/30/2010 & 05/01-24/2011). This review found several days where the cooler temperature was recorded above 45°F; See the **Objectionable Conditions and Managements Response** section of this report for further details. We questioned Mr. and Mrs.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

Jurgens about this at which they stated an (b) (4) had been installed in September 2010 to help maintain a lower temperature on the side of the cooler where the eggs are stored. Logs reviewed after mid-September showed the temperatures were maintained at 45°F or below. Additionally, shelled eggs are being shipped out of the cooler at least (b) (4) in (b) (4).

SALMONELLA ENTERITIDIS PREVENTION PLAN

(written by MMM)

The firm provided a copy of their Sunny Yolk Egg Ranch Salmonella Enteritidis Plan; see **Exhibit 1, pp 1-27**. Investigator Gioia and I reviewed documents to assess compliance with the final egg rule, 21 CFR 118.

The plan covers the following items:

- Record Location
- Biosecurity
- Pest Management
- Pullet Testing
- Testing Methodology
- Refrigeration
- Cleaning and Disinfecting Between Flocks
- Egg Diversion
- Egg Treatment
- Record Keeping

At the start of our inspection, Mr. Jurgens reported that the firm had no current SE positive houses and they had never had an SE positive result detected in environmental monitoring. He stated that the firm conducts environmental sampling and testing for SE at the 45 week flock age (the firm's SE plan states, "***Egg belts and manure belts are swabbed at 45 weeks***"), See **Exhibit 1, pg 14**. 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's McClure and Gioia reviewed Layer testing results and found environmental sampling had been conducted on Flock (b) (4) weeks of age, See **Exhibit 4**. Hens are removed from the houses at approximately (b) (4) weeks, the farm does not molt birds.

We reviewed the testing methodology and sampling procedure; see **Exhibit 1, pp 13-16**, 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

Establishment Inspection Report

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Adams, NE 68301

MMM, LAG

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EI Start: 05/24/2011

EI End: 05/24/2011

environmental samples to (b) (4) in (b) (4) Mr. and Mrs. Jurgens are responsible for insuring sample collection for SE monitoring at appropriate time points, documentation of results, and reporting results to appropriate company personnel. Mrs. Jurgens provided a copy of the SE monitoring sample results from 28-Jun-10 through 16-Mar-11; a review of the report found that all reported results were negative for SE, See **Exhibit 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, page 20-23**. The plan outlines dry cleaning and disinfection procedures between flocks. The plan includes wet cleaning procedures for SE positive houses. Additionally, procedures for segregating and treatment of eggs are included in the plan for flocks determined to be SE positive; see **Exhibit 1, pp 24-26**.

According to Mr. Jurgens, the firm conducts pit cleanings (b) (4) He stated, under SE negative conditions, houses are dry cleaned; manure and food is removed and water lines are cleared in between flocks.

Personnel Movement

Employees do not practice biosecurity measures when traveling from one house to another. All employees enter through the egg packing room and walk through "(b) (4)"; a (b) (4) (b) (4) footbath located at the entrance to the egg packing room before entering Houses 1 - 3; separate entrances to the houses are not utilized by employees.

Dr. (b) (4) reported if one of the houses was found SE positive, the whole farm would be considered SE positive and all eggs from the farm would be processed using a 5 log treatment. This policy is not written into the farm's SE plan; see the **Objectionable Conditions and Managements Response** section of this report for additional information.

Pest Control

(written by LAG)

Sunny Yolk Egg Ranch, LLC manages their pest control program internally. The firm's SE Prevention Plan, see **Exhibit 1, pp 9-12**, 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 no live rodents were observed on layer levels of houses. There was no idle equipment or material for harborage in the yards around houses and grass was maintained. 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.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

The firm's plan for fly control outlined in the SE Prevention Plan, includes the methodology and logs. Methodology includes monitoring houses (b) (4) and if any flies are observed, the houses are baited with (b) (4). Mrs. Jurgens also stated when she walks the houses, she rates the fly activity on a scale of (b) (4) and logs this number on her "Fly Numbers" sheet. The firm also uses natural means of fly control, namely (b) (4) and (b) (4)s, which help keep the fly population down. Mr. Jurgens stated manure is removed from each house every (b) (4).

Please refer to **Exhibit 5, pp 1-8** for copies of the firm's "Mouse Number" logs (dated 7-18-10 – 5-15-11), "Fly Number" logs (dated 7-18-10 – 5-20-11), and corresponding "SE Compliance Summary" sheets provided by Mrs. Jurgens for review.

Refrigeration

Please refer to **Exhibit 1, pp 17-19** for the firm's refrigeration procedures for SE control.

MANUFACTURING CODES

(written by LAG)

Mrs. Jurgens stated the farm does not issue P numbers since the eggs are processed by (b) (4) (b) (4) in (b) (4) (b) (4) cases of eggs are placed on each pallet and the pallets are identified with a tag, see **Exhibit 6**. The tag includes the date produced, the producer, the flock number, the house number, and the age of the birds.

RECALL PROCEDURES

(written by MMM)

Mr. and Mrs. Jurgens stated there have been no recalls for eggs from their firm.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

(written by MMM)

The following observations were provided to management at the conclusion of the inspection:

Observation 1:

Your written SE prevention plan is not fully implemented and followed.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

Specifically, your plan states foot baths are to be placed in high traffic areas and between sections. We observed dry footbaths at the entrance to the office and the entrance to the processing plant only.

Supporting Evidence and Relevance:

As per the Egg Rule {21 CFR 118.4}, firm's are required to implement an SE plan and follow it in addition to 118 regulations. Please refer to **Exhibit 1 pages 6** for foot bath directives.

Discussion with Management:

Mrs. Jurgens replied they would change the language in the plan or add footbaths between houses.

Observation 2:

You do not maintain practices to protect against cross contamination when employees and equipment are moved between poultry houses.

Specifically, your SE prevention plan does not address biosecurity if a house was SE positive. No documentaion is maintained for the foot powder; frequency for changing and criteria dictating powder change.

Supporting Evidence and Relevance:

As per the Egg Rule {21 CFR 118.4}, firm's are required to maintain practices that will protect against cross contamination when persons and equipment is moved among poultry houses. We verified employees walk through Houses 1 - 3; no preventative measures were in place to prevent cross contamination from one layer to the other. The firm's SE Plan does not contain SOP's in the case that one of the layers tested SE positive.

Discussion with Management:

Prior to the closeout, Dr. (b) (4) reported all flocks are vaccinated against SE. Firm Management replied with "ok" after reading observation 2.

Observation 3:

Your written SE plan does not bear a date or carry the signature of the person(s) who administer the plan.

Supporting Evidence and Relevance:

As per the Egg Rule {21 CFR 118.10(b)(3)}, the written SE prevention plan must be dated and carry the signature of the person who administers the plan. The SE Plan provided to us does not bare a date or a signature of the administrator of the plan.

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

Discussion with Management:

Mrs. Jurgens replied, "ok" after reading observation 3.

Observation 4:

All required records do not have the signature or initials of the person performing the operation or creating the record.

Specifically, your "Fly Number" sheets dated 7-18-10 – 5-20-11 do not contain initials of the person recording fly count results.

Supporting Evidence and Relevance:

As per the Egg Rule {21 CFR 118.10(b)(3)}, records shall be maintained with the signature or initials of the person performing the operation or creating the record. The Pest Monitoring Log mentioned above does not contain signatures or initials; see **Exhibit 5, pages 4-5**.

Discussion with Management:

Mrs. Jurgens reported she would add a column to the form for employees to write initials in.

REFUSALS

There were no refusals for this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

(written by LAG and MMM)

The final discussion with management was held in the office of the firm on 5/23/11. Firm representatives included: Eugene A. Jurgens, Owner; Karen K. Jurgens, Owner; (b) (4) DVM for (b) (4); and (b) (4), General Manager Contract Egg Production/Spent Hen Sales for (b) (4). FDA representatives included Investigators McClure and Gioia. A four item FDA 483, *Inspectional Observations* was issued to and discussed with Mr. Jurgens, Owner.

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

- Cooler Temperatures were found to be above 45°F 30 out of 31 days in August 2010 and 21 days out of 30 days in September 2010. It appears the temperatures reduced to 45°F consistently after the (b) (4) was installed on September 19, 2010; see **Exhibit 3, pp 1-3**. Additionally, a letter dated July 9, 2010 within the SE Plan states drivers are required to

Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

3008776472

EI Start:

05/24/2011

EI End:

05/24/2011

record the temperature setting on the Bill of Lading and the farm is required to check their copy of the Bill of Lading to assure the temperature setting was reported, see Exhibit X, pp x. Upon review of BOL dated 5-9-11, no temperature was recorded; see **Exhibit 7, pg 1**. Firm management provided a copy of the new BOL they intend to start using where a line has been added designated for (b) (4) see **Exhibit 7, pg 2**.

- The SE prevention plan states they will swab manure belts and not pits, see **Exhibit 1, pg 14**. Neither house has manure belts. Mrs. Jurgens stated she would change the word "belts" to "pits".
- The SE prevention plan states there will be a (b) (4) review of the animal care. Blank review sheets were observed in the plan, but none had been completed. Please refer to **Exhibit 1, pp 3**.

Management was provided with an Egg Rule Poster. 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.

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, DFIG Assignment # 11-04, ORA Concurrence # 2011012601, dated 02/03/2011, Amended 02/08/2011:

Attachment A: Inspection/Data Collection Tool for Targeted Inspections

(b) (5)

Establishment Inspection Report

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EI End:

05/24/2011

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Establishment Inspection Report

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05/24/2011

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Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

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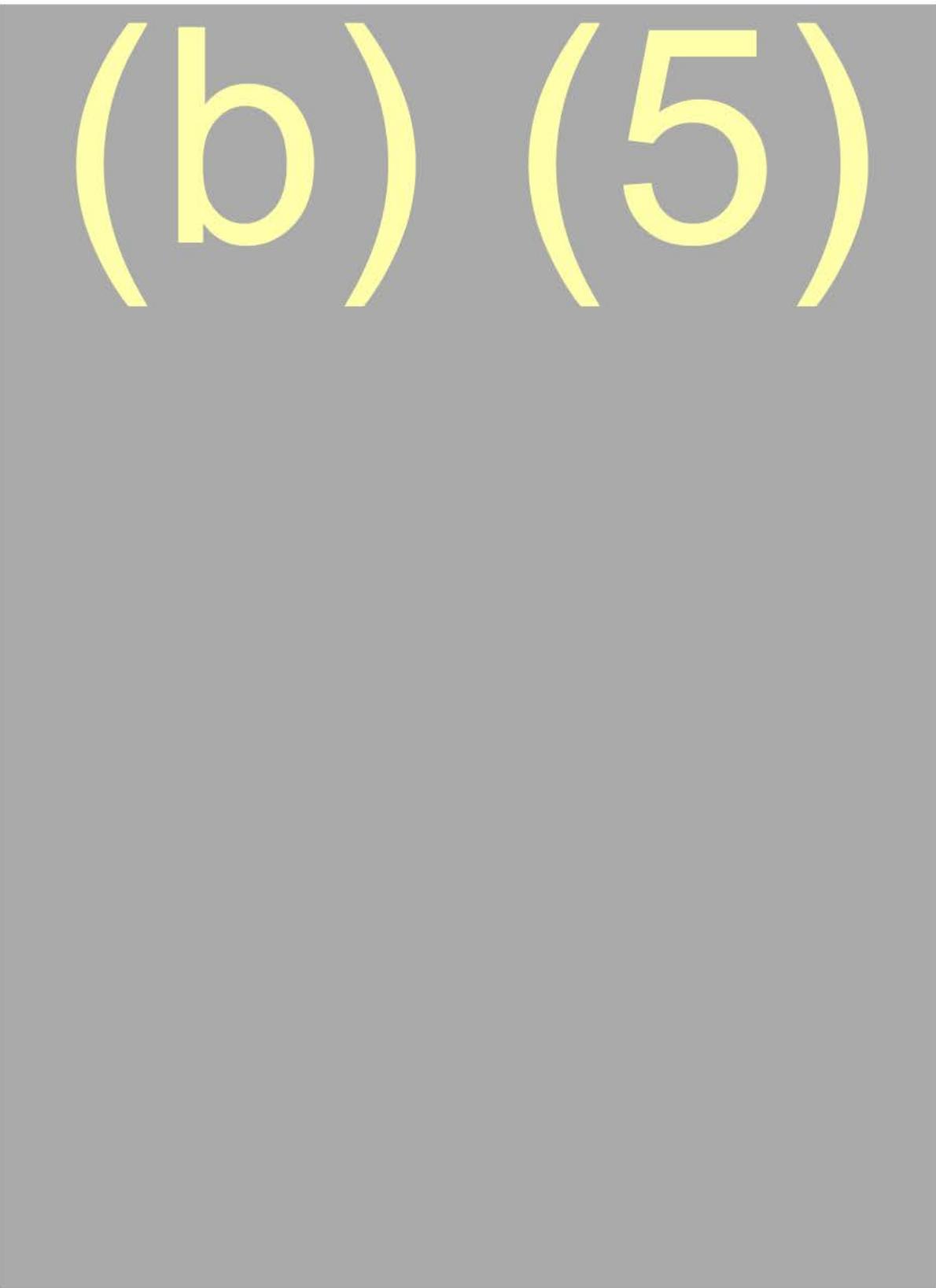
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05/24/2011

EI End:

05/24/2011



Establishment Inspection Report

Sunny Yolk Egg Ranch LLC

Adams, NE 68301

MMM, LAG

FEI:

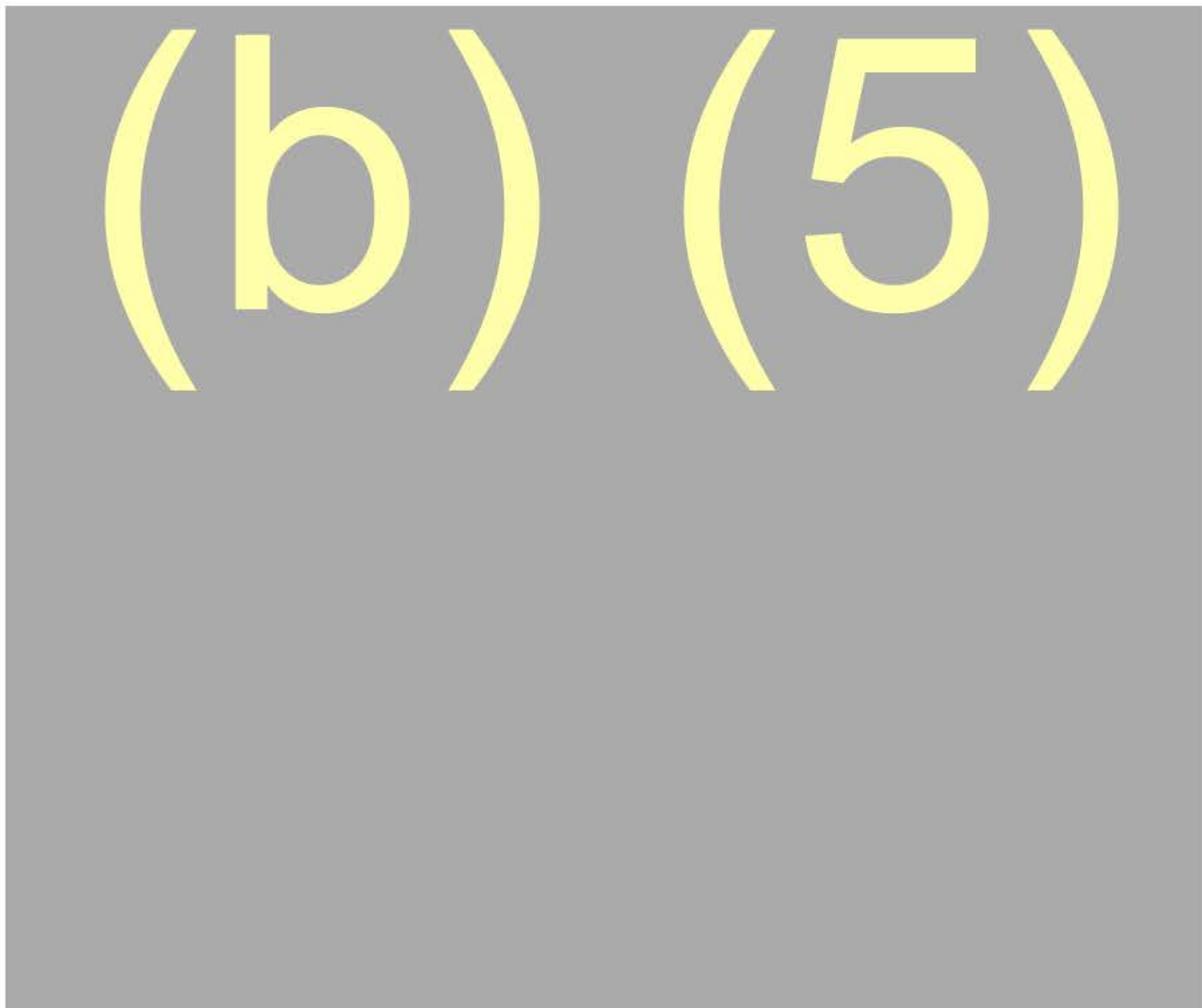
3008776472

EI Start:

05/24/2011

EI End:

05/24/2011



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, created 9/13/2010; pp 1-27
2. NPIP Certificates, pp 1-3
3. Cooler Refrigeration Logs, pp 1-3
4. SE test results
5. Rodent/Fly Monitoring Logs; pp 1-8

Establishment Inspection Report

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EI Start:

05/24/2011

EI End:

05/24/2011

6. Pallet Tag

7. Bill of Lading, pp 1-2

ATTACHMENTS

- Copy of FDA Form 482, *Notice of Inspection*, issued to Eugene A. Jurgens, Owner, Sunny Yolk Egg Ranch LLC, Adams, NE, dated 05/24/2011
- Copy of FDA Form 483, *Inspectional Observations*, issued to Eugene A. Jurgens, Owner, Sunny Yolk Egg Ranch LLC, Adams, NE, dated 05/24/2011



Monica M McClure, Investigator



Lori Gioia, Investigator