

Establishment Inspection Report

Sparboe Farms, Inc.
Eagle Grove, IA 50533-8039

CST JLV

FEI:

3006382032

EI Start:

06/27/2011

EI End:

06/27/2011

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SUMMARY

This targeted inspection of a Shell Egg Producer was conducted in accordance with KAN-DO work plans under assignment number 1271548 , Operation ID 5348645, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment number 11 – 04, ORA Concurrence number 2011012601, dated 02/08/2011. 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. A pre – announcement phone call was made to Dawson A. Juhl, Complex Manager on 06/23/2011. Mr. Juhl was unavailable and the pre – announcement was made to Mr. (B) (6) Sparboe Farms SE Plan Administrator.

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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.

Mr. (B) (6) stated the firm had no Salmonella positive environments and no reportable diseases on the farm.

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 which includes the Biosecurity Plan, employee training and logs, fly and rodent monitoring logs, refrigeration logs, pullet receiving records, water testing, cleaning and disinfecting records and Egg Segregation and Re – Introduction SOP. Barn assessments were conducted in barns 3E, 2E, 1W, 4W, and 1E with no objectionable observations noted.

This was the first FDA inspection of Sparboe Farms, Inc. at the Eagle Grove location.

Jeffery L. Verzal, an FDA credentialed Livestock Compliance Investigator from the Iowa Department of Agriculture and Land Stewardship, accompanied me on this inspection and was involved in data collection, review and barn assessments.

No samples were collected, no FDA – 483 List of Observations was issued at the conclusion of this inspection.

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.

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

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ADMINISTRATIVE DATA

Inspected firm: Sparboe Farms, Inc.
Location: 3170 Buchanan Ave
Eagle Grove, IA 50533-8039
Phone:
FAX:
Mailing address: 3170 Buchanan Ave
Eagle Grove, IA 50533-8039
Dates of inspection: 6/27/2011
Days in the facility: 1
Participants: Candace S Tucker, Investigator
Jeffery L. Verzal, Investigator

Upon our arrival at the firm, credentials were presented and an FDA 482, *Notice of Inspection* was issued to Mark D. Friedow General Manager. Mr. Friedow identified himself as the most responsible individual on-site and that he had overall charge of Sparboe Farms Inc. facilities in Colorado, Iowa, and Minnesota.

This report was written solely by Investigator Tucker.

HISTORY

Sparboe Farms Inc is a family owned business that was started by the father (Robert Sparboe) of the current President/CEO, Beth Sparboe Schnell in 1954. The firm began in MN as a distributor of day old chicks to farmers and has now expanded into both the shell egg and egg breaker market servicing retail, wholesale, and foodservice customers in 26 states (<http://sparboe.com/sparboe-farms-overview.html>). The company is incorporated and headquartered in MN but has multiple facilities in Iowa that are both fully and partially owned in that Sparboe owns birds and on site operators own the land/facilities.

A Corporate Organizational Chart has been attached to this report as **exhibit 1**. A complex Organizational Chart has been attached as **exhibit 2**.

The current inspection location was purchased from Embly's Egg Farm in 1993. There were originally four houses until an additional six houses were constructed between 1994 and 2002.

Sparboe Farms, Inc. Eagle Grove location currently has approximately (b) (4) full time employees. Hours of operation are as follows:

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- Office = 7:00 am until 4:00 pm
- Processing = (B) (4)
- Barn = (B) (4)
- Mechanics (B) (4)

With the exception of the office, all departments are scheduled (B) (4)

(B) (3)

FMD 145 SHOULD BE SENT TO/

Sparboe Farms, Inc.
Dawson A. Juhl, Complex Manager
3170 Buchanan Avenue
Eagle Grove, IA. 50533

POST INSPECTIONAL CORRESPONDENCE SHOULD BE ADDRESSED TO

Sparboe Farms, Inc.
Beth Sparboe – Schnell, President & CEO
23577 Minnesota Highway 22
Litchfield, MN. 55355

INTERSTATE COMMERCE/JURISDICTION

The firm is a Shell Egg Producer with greater than (B) (4) 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 under the Egg rule 21 CFR 118.11 (B) (3)

Mr. Friedow stated that about (B) (4) % of the firm's product is sold within the state of Iowa. The top customers are (B) (4) located in (B) (4) and (B) (4) located in (B) (4). Approximately (B) (4) % of the products are distributed in interstate commerce to (B) (4) (B) (4) to (B) (4)

(4)
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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Beth Sparboe Schnell, CEO & President is responsible for the overall management of Sparboe Farms Inc. Ms. Schnell is based at the firm's headquarters in Litchfield MN. We had no communications with Ms. Schnell during this inspection.

Mark D. Friedow, General Manager, Production oversees the firm's pullet operations, production and processing operations and general farming operations in CO, IA, and MN. He has been in the egg business for about (B) (6); the last (B) (6) have been with this firm and in his current position. Prior to his current position, Mr. Friedow was a consultant with the agritech division. Mr. Friedow reports to Wayne Carlson, Senior V.P. Supply Chain Management whose office is located at the Litchfield MN., Corporate office. Mr. Friedow currently has (B) (4) direct reports who include complex, production and processing managers, feed department managers and Dr. Hugo (B) (4) the firm's SE Plan administrator. Mr. Friedow was issued the FDA 482, Notice of Inspection. Mr. Friedow's position allows him to make operational changes in the facilities under his management. Mr. Friedow was present during the inspection. Mr. Friedow's office is located in Jefferson, IA.

Dawson A. Juhl, Complex Manager has been with the firm in his current position for (B) (6). Mr. Juhl has the authority to hire and fire, reviews documents; is responsible for the overall operations of the inspected farm and also the pullet farm located at 3190 Hwy 17, Eagle Grove, IA. Mr. Juhl has the authority to make and/or approve purchases; is responsible for the firm's budget and assists as the SE Plan administrator. Mr. Dawson has (B) (4) direct reports who include pullet, production and processing supervisors and the warehouse lead. There are (B) (4) administrative employees who also report to Mr. Juhl. Mr. Juhl was present throughout the entire inspection.

Michael D. Bassler, Production Manager stated his responsibilities include the health and welfare of all poultry as well as barn maintenance; collecting and reviewing completed documents such as pest/fly control, and barn maintenance. Mr. Bassler is responsible for initiating and reviewing the corrective actions as necessary; he is responsible for employee training and environmental and egg sampling. Mr. Bassler reports directly to Mr. Juhl. Mr. Bassler was present throughout the entire inspection.

FIRM'S TRAINING PROGRAM

Training procedures were reviewed and are considered adequate. New employees are trained on required daily duties which include; removing mortality each morning along with reporting (to the plant manager) any increase in mortality; performing general house checks; cleaning techniques and flock inspection which includes training to demonstrate the ability to identify sick birds. The employees are trained to perform neck displacement (dislocation), to properly euthanize hens when necessary such as in the case of a sick bird.

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Part of this new hire training is received from a video produced by the (B) (4) entitled (B) (4), which is viewed by each employee.

Each employee signs and dates a training document when all initial employment training is complete. A copy of the training record for M.P. was collected for review and is attached to this report as **exhibit 3**.

MANUFACTURING/DESIGN OPERATIONS

Sparboe Farms Inc. Eagle Grove, Iowa, is an in-line and off-line facility. The in-line operation consists of layer houses connected with a common egg belt to the processing and packing facility on site. The firm has 10 multi-level layer houses. Multi-level house style means the eggs are laid on the upper level and the manure drops directly from the cages/tiers to the lower level. Barns are configured as follows: Barns 1 – 5W(est) contain (B) (4) rows and (B) (4) tiers; barns 1 – 4 E(ast) contain (B) (4) rows, (B) (4) tiers, and barn 5E(ast) contains (B) (4) rows, (B) (4) tiers. Cages hold (B) (4) to (B) (4) birds depending on cage size. During the inspection, there were a total of (B) (4) total birds on the farm. A (B) (4) flock summary report documenting production and feed information along with mortality has been attached to this report as **exhibit 4**.

The layer house 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 processing area.
- The USDA conducts pre-operation inspections of equipment for sanitation per USDA checklist.
- The eggs go through (B) (4) presoak procedures.
- The eggs are washed using a (B) (4) washer system.
- The eggs are rinsed with (B) (4) water mixture.
- Posts rinsing the eggs are analyzed through visual candling booths for checks (i.e. cracks), blood, meat spots, and dirt.
- The eggs are routed via lanes for placement into filler flats (egg cartons) carton, enclosed, boxed into cases for shipping, and taped.
- The taped cases are manually loaded onto pallets and placed into the cooler. (A review of the temperature logs from the past year showed no deviations.
- Shell eggs remain in the cooler until they are shipped to the customer.
- Shell eggs have a 30 day shelf life.

The off-line operations are treated the same as the in-line except the eggs are received from outside facilities and are shipped unprocessed until they arrive at Sparboe. Processing procedures are

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similar.

Eggs are packed in cartons containing (B) (4) or (B) (4) eggs or are (B) (4). All pallets contain (B) (4) cases per pallet with (B) (4) dozen eggs per case.

There are (B) (4) total employees who are responsible for egg production and maintenance. (B) (4) employees work as mechanics; (B) (4) employee works utility and is responsible for tasks such as mowing and fly monitoring. The remaining employees are responsible for daily barn tasks including the flocks within, and (B) (4) employee floats between these positions covering days off.

Electricity, water and barn temperatures are monitored to alarm (after hours) if any of the aforementioned systems fail. The alarm calls Mr. (B) (4) first. If there is no response the system continues by dialing Mr. (B) (4), Mr. (B) (4) and Mr. (B) (4) and continues this sequence until there is a response. Mr. Bassler and Mr. Juhl can also monitor the barns through their (B) (4) and (B) (4). A printout of the housing system software that documents amounts of feed and water used, barn temperatures and ventilation information for Monday, June 27, 2011 at 07:27:25 has been attached to this report as **exhibit 5**.

A facility diagram has been attached to this report as **exhibit 6**, and a diagram of the processing/office building has been attached as **exhibit 7**.

SALMONELLA ENTERITIDIS PREVENTION PLAN

Sparboe Farms, Inc. Salmonella Prevention Program is attached to this report as **Exhibit 8**.

The plan covers the following items:

- Basics
 1. Executive Summary
 2. General Principles
 3. Definitions
 4. Laboratory Designation
 5. Administration and Record Keeping
 6. Registration
 7. Enforcement and Compliance

- Salmonella Program
 1. Salmonella Prevention
 2. Layer Sampling Procedures; Collection
 3. Samples for Salmonella Testing

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- Procedures for a SE Environmental Positive
 1. Biosecurity Procedures
 2. Vaccination for SE Environmental Positive
 3. Pullets
 4. Layers
 5. egg samples for Salmonella testing
 6. Flock Isolation
 7. Cleaning and Disinfection Procedures
 8. Disinfectants

 - Other Procedures for SE Prevention
 1. pest Control Procedures
 2. Rodent Control
 3. Fly Control
 4. Drinking Water and Water Systems
 5. Egg Refrigeration

Review of the SE Plan was conducted simultaneously with that of other records to ensure the Plans requirements were followed and the Plan followed the regulations set forth in 21 CFR 118.

Pullet Procurement and testing was reviewed with no observations noted; cleaning/disinfecting records after barn depopulation were reviewed from May of 2010 to June 3, 2011 and appeared adequate; water testing performed by (B) (4) was reviewed from January 2007 until January 2011 with no observed deviations. (B) (4) (B) (4) for (B) (4) located at (B) (4) (B) (4) has been attached to this report as **exhibit 9**. Barn maintenance was reviewed for the month of May, 2011. The document was complete, signatures were in place and the required tasks followed job description training. Cooler logs were reviewed from January 2011 until present with no observations noted. Fly monitoring documents were reviewed from March 2011 until June 2011 and all were complete, contained the required signatures and corrective actions were in place as required. Rodent monitoring was observed from July 2010 until June 8, 2011 along with Rodent Index Averages. Documents were complete, contained the required signatures and corrective actions were in place as required.

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PEST CONTROL

The firm contracts with (B) (4) to manage the farms' pest control. (B) (4) visits the farm (B) (4)

A description of the firm's pest control procedures begins on page 24 of the Sparboe Farms, Inc. SE Plan. The section describes items such as rodent control during flock change; details of tasks completed (B) (4) per barn; and corrective actions including thresholds.

A rodent index average was reviewed from 10/5 – 12/29/2010 and is attached to this report as **exhibit 10**. Management stated Dr. (B) (6) creates these graphs to demonstrate corrective actions were effective.

There are a total of (B) traps located in the (B) (4) and (B) (4) of each barn and (B) traps located (B) (4) of each barn. During each (B) (4) visit, service personnel of (B) (4) walk the (B) (4) and (B) (4) of each barn, count and document (on Rodent Index documents) the number of rodents caught in each trap in each barn. A visual check of rodent and fly activity is performed simultaneously on (B) (4) of each barn. When completed, a summary of findings is written on Service Reports, which are provided to the farm's manager for review, along with documented corrective actions as in **exhibit 11**, showing house 3E(ast) had added (B) (4) on 3/9/11 and (B) (4) (B) (4) had been moved (toward activity) on 6/2/11 (as shown with squares penciled in).

FLY CONTROL

Insect control begins on page 24 of the SE Plan. The section includes (B) (4) fly monitoring; thresholds and corrective actions if the threshold (B) is exceeded. Fly monitoring Program documents were reviewed from 03/05 – 06/2011 and were completed, contained instructions to properly perform the fly count, corrective actions if necessary and were reviewed. A fly monitoring program document from 03/12/2011 showing a corrective action taken in barn 4W for a threshold of 412 has been attached to this report as **exhibit 12**.

The firm's Fly Control Procedures for Sparboe Farms Eagle Layer Site has been attached to this report as **exhibit 13**. This procedure follows manure cleanout and is performed in a clean pit.

A fly control spreadsheet containing information which describes the type of fly control and the date used has been attached to this report as **exhibit 14**.

MANUFACTURING CODES

The Sparboe Farms Inc., Eagle Grove, Iowa poultry establishment number is P-1002 and the

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(B) (4)

(B) (4)

Example (B) is the (B) (4)
(4)
(B) is the (B) (4)
(4)

COMPLAINTS

The firm maintains complaint files, which are handled first by the Customer Service Department. The firm utilizes a software system that creates an excel spreadsheet of complaints allowing the firm to trend and track complaints. Complaints are tracked and trended (B) (4).

If the Customer Service department cannot resolve a complaint, it is forwarded to Mike Schmidt who is next responsible for the complaint resolution. In an unusual situation, Mr. Schmidt will contact Mr. Friedow and Mr. (B) (6).

The complaint procedure the firm utilizes is included in the Safe Quality Food Registry.

Usual complaints include check (cracked) eggs, blood egg (internal blood spot) which is responsible for approximately one out of every six complaints.

RECALL PROCEDURES

The firm's recall policy was reviewed and appears adequate. The policy classifies recalls based on results of a Health Hazard and Risk Evaluation which is completed by the Quality Assurance Manager. The policy defines each recall team member and describes his/her responsibilities.

This policy determines employee responsibilities for the recall team, lists documents required for a product trace back, recall contact information, recall organizational chart, Federal agencies for reporting purposes, and a blank copy of the form used to input customer correspondence.

REFUSALS

There were no refusals encountered during the inspection.

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GENERAL DISCUSSION WITH MANAGEMENT

Those present for the inspection close were Mark D. Friedow, Dawson A. Juhl and Michael D. Bassler. Findings of barn assessments were reported by Investigator Verzal. He reported barns were assessed by bird age from youngest to oldest as follows: 3E, 2E, 1W, 4W and 1E. The assessment found a fan in barn 3E missing a louver which management stated they would fix.

No FDA – 483 List of Observations was issued and no items were discussed.

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

ADDITIONAL INFORMATION

Attachment A: (B) (5) [Redacted]

(B) (5) [Large Redacted Area]

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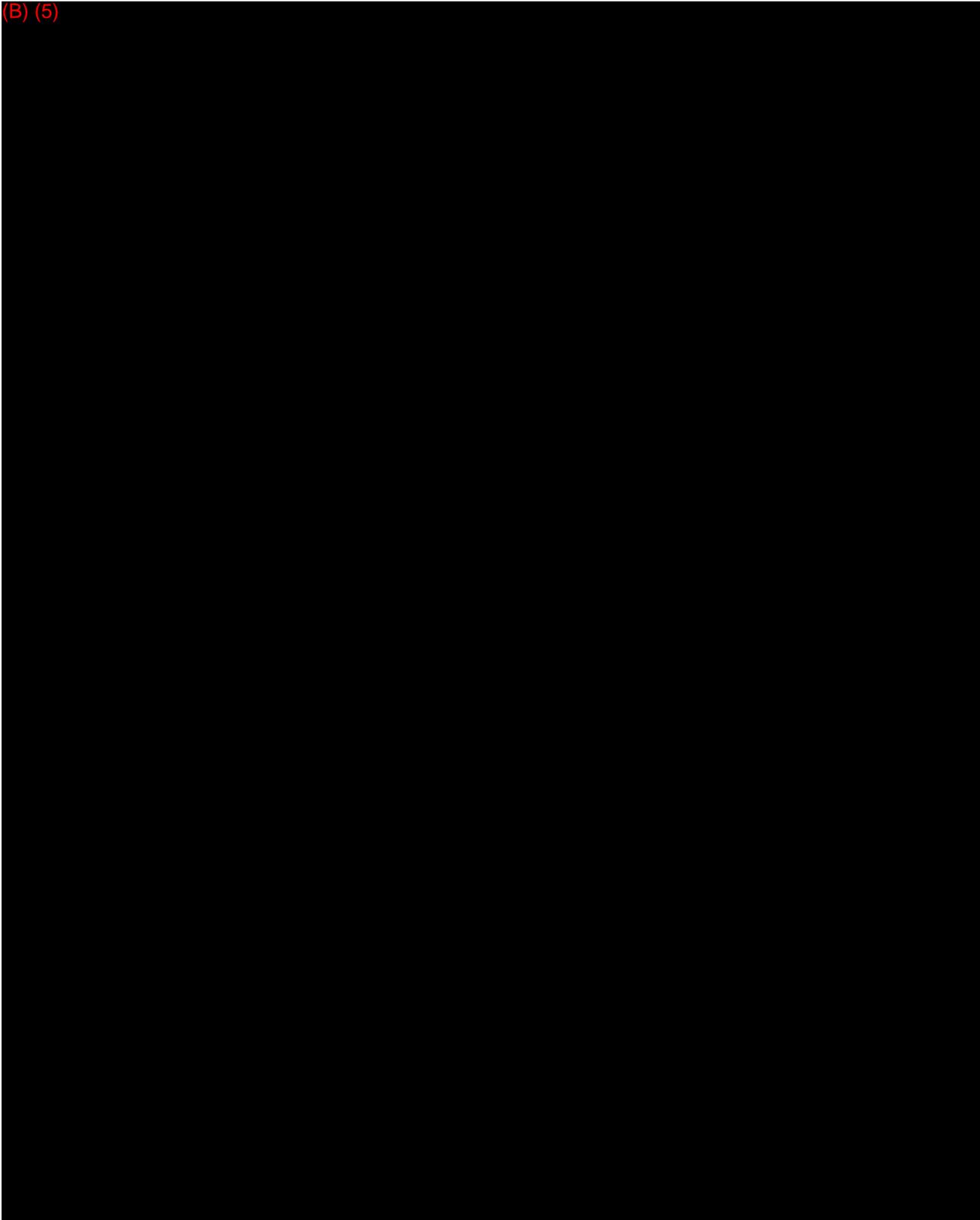
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(B) (5)



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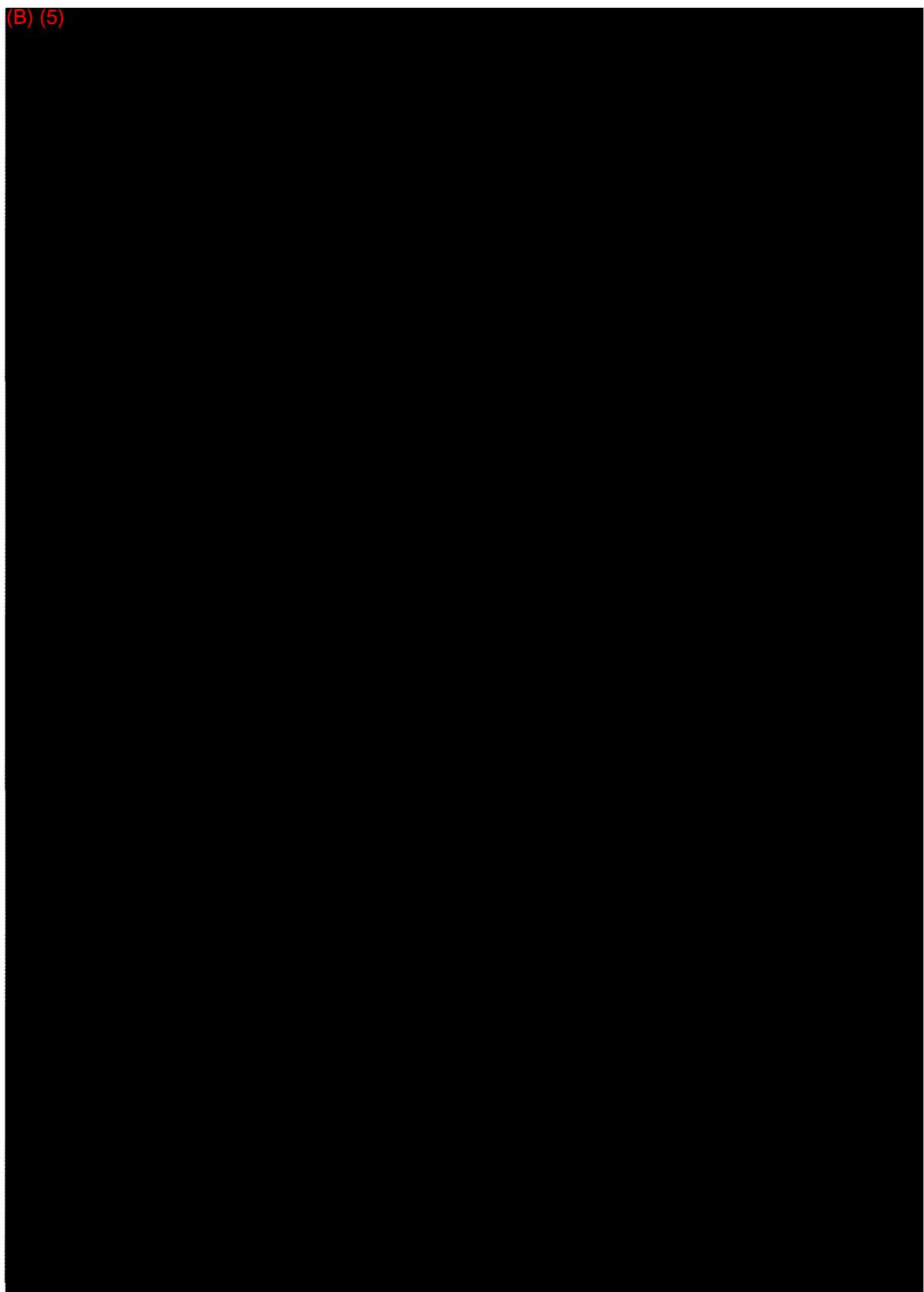
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(B) (5)



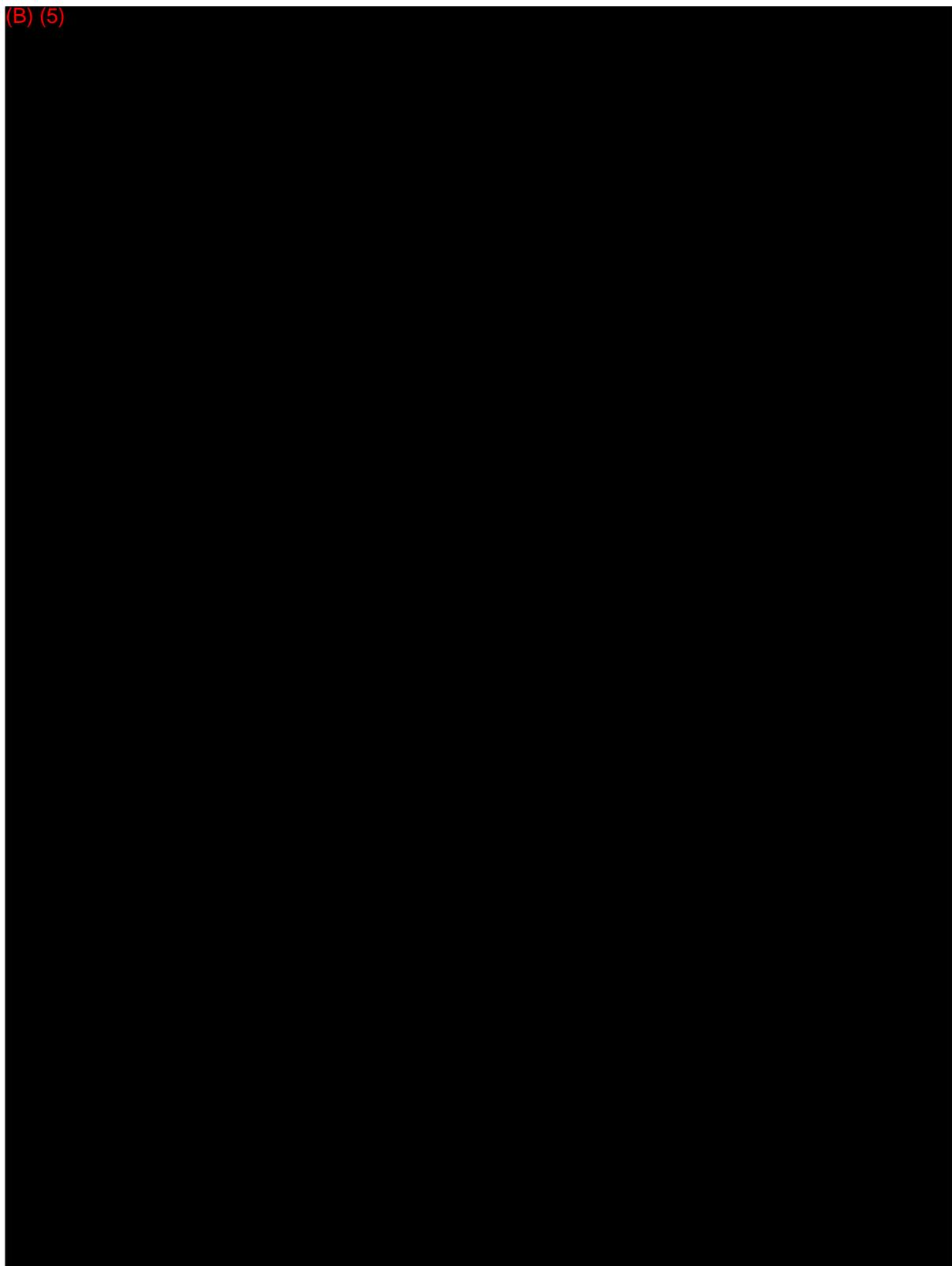
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(B) (5)



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SAMPLES COLLECTED

No samples were collected during the inspection

EXHIBITS COLLECTED

Exhibit 1: A copy of the firm's Corporate Organizational Chart, 1 page.

Exhibit 2: A copy of the Complex Organizational Chart, 1 page.

Exhibit 3: A copy of training procedure and signature for training employee M.P., 4 pages.

Exhibit 4: A copy of the (B) (4) Flock Summary Report for the week ending 6/18/2011, 1 page.

Exhibit 5: A copy of the (B) (4) 1 page.

Exhibit 6: A copy of the facility layout, 1 page.

Exhibit 7: A copy of the process/office building diagram, 1 page.

Exhibit 8: A copy of the firm's SE Plan, 26 pages.

Exhibit 9: A copy of (B) (4) 1 page.

Exhibit 10: A copy of a Rodent Averages graph for 10 – 12/2010, 1 page.

Exhibit 11: A copy of corrective action (increase (B) (4) conducted in barn 3E, 1 page.

Exhibit 12: A copy of a Fly Monitoring Program document dated 3/12/11, 1 page.

Exhibit 13: A copy of the firm's Fly Control Procedures for Sparboe Farms Eagle Layer Site, 1 page.

Exhibit 14: A copy of the firm's Fly Control, product used and date done spreadsheet, 1 page.

ATTACHMENTS

A copy of the completed FDA – 482 issued to Mark D. Friedow on 06/27/2011

A copy of the assignment identified as 1271548

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Candace S Tucker, Investigator



Jeffery L. Verzal, Livestock Compliance
Investigator