

Establishment Inspection Report

Sparboe Farms, Inc.
Hudson, CO 80642-0429

FEI: **3003731382**
EI Start: 05/09/2011
EI End: 05/12/2011

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SUMMARY

(MBB)

This was a directed team inspection of Sparboe Farms, Inc. The focus of this inspection includes review of: 1) The written Salmonella Enteritidis (SE) Prevention Plan 2) A subset of the firm's environmental sampling results and 3) The firm's implementation of pest (rodent and fly) control measures. The inspection was conducted under Amended Assignment - FY11--Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA Concurrence # 2011012601, FACTS No. 1258067.

The firm operates as a wholesale egg laying facility, consisting of (b) (4) laying houses, (b) (4) poultry houses are currently populated with layers.

Each house is identified as

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

The breed of the layers at this facility is (b) (4)

(b) (4)

An inspectional history was not available and the current inspection conducted on 5/9/11 through 5/12/11 was the first FDA egg inspection for the firm.

The inspection was preannounced via telephone on 5/5/11 to Mark D. Friedow, General Manager of Sparboe Farms, Inc. Mr. Friedow is the General Manager and provides oversight for egg farms (production and processing) located in Colorado, Iowa and Minnesota. Mr. Friedow works at the firm's headquarters located in Litchfield, MN. On 5/5/11, Mr. Friedow stated he would not be present during this inspection. The Colorado Department of Agriculture was also informed of this targeted inspection and declined to attend due to a time conflict.

On 5/12/11, a Form FDA-483, Inspectional Observations, was issued for deficiencies related to shared layer house equipment and inadequate environmental sampling equipment, pest monitoring records and screening for stray animals. During the inspection and at inspection closeout, personnel biosecurity measures and 14-16 week environmental testing were discussed with Joy L. Timmons, Production Manager, and (b) (6) DVM, Technical Services Veterinarian. See sections **Inspectional Observations** and **General Discussion Items with Management** for further details. On 5/12/11, Ms. Timmons and (b) (6) stated comments to the inspectional observations would be addressed in the 15 day response letter addressed to the Denver District Director.

The farm is registered according to the Egg Rule. The registration number is 21241125238. The plant (P) number is 1167.

This is a dual jurisdiction firm, monitored by the US Department of Agriculture and Colorado Department of Agriculture. USDA Inspector, Gabriele M. Cordova, was onsite on 5/9/11. Credentials and business cards were provided to Ms. Cordova. At this time, the scope of the targeted egg inspection was discussed with Ms. Cordova.

Post inspectional correspondence (FMD-145) will be addressed to Mr. Vincenzo (NMI) Ruscitti, Processing Plant Manager, located at 6339 Weld County Road 47, PO Box 429, in Hudson, Colorado, 80642.

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ADMINISTRATIVE DATA

Inspected firm: Sparboe Farms, Inc.
Location: 6339 Weld County Road 47
Po Box 429
Hudson, CO 80642-0429
Phone: 303-536-4100
FAX: 303-536-0626
Mailing address: Po Box 429
Hudson, CO 80642-0429

Dates of inspection: 5/9/2011, 5/10/2011, 5/11/2011, 5/12/2011
Days in the facility: 4
Participants: Marie B. Buen-Bigornia, Investigator
Elisa J. Beard, Investigator

(MBB)

This was a team inspection conducted by CSO Elisa J. Beard and myself, CSO Buen-Bigornia. We were present during all days of the inspection.

On 5/9/11, credentials were presented and a Form FDA-482, Notice of Inspection, was issued to Ms. Joy L. Timmons. Ms. Timmons was determined to be the most responsible person at the firm, was present during all days of the inspection and during inspection closeout.

At inspection closeout on 5/12/11, Form FDA-483, Inspectional Observations, was issued to Ms. Timmons. (b) (6) Technical Services DVM, Mr. Vincenzo Ruscitti, Processing Plant Manager, was present at inspection closeout.

A (b) (5) egg inspection questionnaire (as per the assignment) is included as **Attachment 1**.

HISTORY

(MBB)

Headquarters for Sparboe Farms, Inc. is located at PO Box 309, 23577 Minnesota Highway 22, in Litchfield, Minnesota 55355. Sparboe Farms, Inc. was incorporated in the state of Minnesota in 2001. Sparboe Farms, Inc. operates six additional complexes (production and processing) (b) (4)

(b) (4)

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The firm is located on approximately (b) (4) acres. The firm operates an inline operation whereby egg production and processing occurs onsite. Egg production includes all layer house operations. Processing operations include washing, sorting, grading, packaging, refrigeration and shipping.

Shell eggs that do meet the table egg requirements (size and color) are distributed to a breaking facility called (b) (4)

The firm also processes and packages shell eggs received (b) (4) (b) (4) Sparboe Farms, Inc. has contracted (b) (4) to produce shell eggs for Sparboe Farms, Inc. located in Hudson, Colorado. Sparboe Farms, Inc. located in Hudson, Colorado does not process or package shell eggs for any other shell egg producer.

An inspectional history was not available and the current inspection conducted on 5/9/11 through 5/12/11 was the first FDA inspection for the firm.

Business hours are from 7:00 AM to 4:30 PM. Monday through Friday. Layer house operations hours are from (b) (4) (b) (4) Processing plant operations are from (b) (4) (b) (4) The firm has (b) (4) full time employees, which includes egg production and processing plant employees.

Day old chicks are purchased from two major chick suppliers: (b) (4) (b) (4) At times the firm has purchased chicks from (b) (4) (b) (4)

On 5/10/11, (b) (6) DVM, Technical Services Veterinarian, provided a list of pullet farms which the firm contracts to raise day old chicks:

(b) (4)

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INTERSTATE COMMERCE/JURISDICTION
(MBB)

The firm operates as a wholesale egg producer. Approximately (b) (4) dozen eggs are produced onsite annually; of this amount, approximately (b) (4) dozen eggs are received from (b) (4) (b) (4) for processing, packaging and shipment. (b) (4) (b) (4) The firm refers to processing and packing shell eggs produced at another facility as side loading.

Shell eggs that do meet the table egg requirements (size and color) are distributed to a breaking facility called Sparboe Foods located in New Hampton, IA. Approximately (b) (4) of the shell eggs produced onsite are sent to the egg breaking facility.

Approximately (b) (4) of shell eggs are distributed out of state to (b) (4) Out of state customers include food service firms such as (b) (4) (b) (4)

The firm's top three customers are (b) (4) Shell eggs distributed to (b) (4) are delivered to (b) (4) and are then distributed to (b) (4) retail stores. Shell eggs for (b) (4) are delivered to (b) (4) (b) (4) distribution centers.

Day old chicks are purchased from (b) (4) major chick suppliers: (b) (4) (b) (4) At times the firm has purchased chicks from (b) (4) See **Exhibit 1** for further details. (b) (4) (b) (4) At this time, the pullets are delivered to the firm and placed into the layer houses for egg production.

On 5/10/11, (b) (6) DVM, Technical Services Veterinarian, provided a list of pullet farms which the firm contracts to raise day old chicks:

(b) (4)

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Egg trays and flats are purchased from (b) (4) Shipping boxes are purchased from (b) (4)

Composted chicken manure is distributed to (b) (4) (b) (4)

Post production layers are distributed to (b) (4) (b) (4)

Promotional methods include an (b) (4) (b) (4)

The firm owns (b) (4) refrigerated trucks that deliver throughout the Colorado Front Range.

The firm is classified under establishment size code (b) (4)

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
(MBB)

Mr. Mark D. Friedow, General Production Manager

Mr. Friedow's office is located at Sparboe Farms, Inc. headquarters, located at 1140 Timber Drive in Litchfield, Minnesota. Mr. Friedow is present onsite on a (b) (4) basis and provides oversight for production and processing for the Colorado, Iowa and Minnesota location. This information was provided by Mr. Vincenzo (NMI) Ruscitti, Processing Plant Manager on 5/9/11. Mr. Friedow was not present during the inspection.

Ms. Joy L. Timmons, Production Manager

Ms. Timmons has worked at this egg laying facility for approximately (b) (6) (b) (6) Ms. Timmons has been the Production Manager since (b) (6) and is responsible for all production (layer house) operations. Daily responsibilities include monitoring flock welfare, pest control (fly and rodent), environmental testing, equipment maintenance and product and employee safety. Ms. Timmons reports directly to Mr. Mark D. Friedow, General Production Manager, and supervises (b) (4) production workers. Ms. Timmons was present during all inspection days and provided a majority of the information contained in this report. Ms. Timmons is designated as the onsite Salmonella Enteritidis (SE) Prevention Plan Administrator and is responsible for the plan's implementation onsite. Ms. Timmons received environmental sampling training from (b) (6) DVM, Technical Service Veterinarian,

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sometime before July 9, 2010; Ms. Timmons could not provide a definite date of when this training occurred.

(b) (6) **DVM, Technical Service Veterinarian**

(b) (6) has been working for at the firm's headquarters located in Litchfield, Minnesota for (b) (6) years as the Technical Service Veterinarian. (b) (6) is responsible for the overall health of the flocks, the development and implementation of the firm's Salmonella Enteritidis (SE) Prevention Plan; specifically, portions related to cleaning and disinfection and food safety. (b) (6) does not supervise any employees, but provides technical guidance to all of the firm's owned and contracted brooder, pullet and production facilities. (b) (6) visits the firm approximately (b) (4) each year. (b) (6) reports directly to Mr. Mark D. Friedow, General Production Manager. (b) (6) is the administrator for all Salmonella Enteritidis (SE) Prevention Plans for all Sparboe Farms Inc. located in the USA. (b) (6) was present during all inspection days and provided a majority of the information contained in this report. (b) (6) received environmental sampling training through various meetings and conferences held within the egg industry prior to July 9, 2010.

Mr. Vincenzo (NMI) Ruscitti, Processing Plant Manager

Mr. Ruscitti has worked at this egg laying facility for approximately (b) (6). (b) (6) Mr. Ruscitti has been the Processing Plant Manager since (b) (6) and is responsible for all processing operations; processing includes sorting, washing, grading, packaging, cold storage and shipment. Mr. Ruscitti reports directly to Mr. Mark D. Friedow.

FIRM'S TRAINING PROGRAM

(MBB)

The firm provides on the job training to all production and processing employees. Training is specific to the job performed. Ms. Timmons, Production Manager, provides training to all production (barn employee) workers and Mr. Ruscitti, Processing Plant Manager, provides training to all processing employees. Training occurs at time of hire with (b) (4) refresher courses, on an as needed basis. (b) (4) Upon completion of training, employees are required to sign training records. See **Exhibit 3** for further details. Employees also receive training in biosecurity and biosecurity measures. See **Exhibit 4** for further details.

The firm is audited annually by the USDA. Also, the firm conducts third party and internal audits. The Process Verified Programs (PVP) is a USDA audit that focuses on traceability of shell eggs. The Safe Quality Food (Level 3) is a third party audit that focuses on food processing safety (production, processing, storage and transport). (b) (4) internal audits focus on a combination of the PVP and SQF audits.

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MANUFACTURING/DESIGN OPERATIONS

(MBB)

The firm operates as a wholesale shell egg producer. Approximately (b) (4) layers are present onsite and (b) (4) dozen shell eggs are produced onsite annually. The egg laying operation consists of (b) (4) layer houses (b) (4) each identified as (b) (4).
(b) (4)
(b) (4) See **Exhibit 2** for the location of each layer house.

Layer Houses

Layer houses are identified with the firm's location and poultry house number. For example,

(b) (4)

The interior (b) (4) and the exterior of the following high rise manure pit houses were to be inspected: (b) (4)

(b) (4)

On 5/9/11, (b) (4) were inspected. No issues were noted regarding the interior and exterior of layer house (b) (4). No issues were noted with the interior walkthrough of (b) (4). However, a hole was observed in the bird netting of layer house (b) (4). See **Inspectional Observation 3** for further details.

The barn of house (b) (4) was inspected and no issues were noted. However, the pit contained manure approximately 2 to 6 feet in height and was impassable for inspection. On 5/9/11, Mr. Ruscitti, Processing Plant Manager, stated the same manure collection would be observed in the remaining layer houses (b) (4) as manure is only removed (b) (4). (b) (4) Since the remaining high rise houses with manure pits were impassable, 2 different houses were inspected. (b) (4) were chosen to fulfill the prescribed number of layer houses as per the assignment. No issues were noted with the interior and exterior walkthrough of (b) (4).

(b) (4)
(b) (4) The breed of the layers at this facility is (b) (4). The strains are

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The current occupancy, age and strain of the flock inspected are listed below in **Table 1**. Flock Information. Post molt environmental testing data for layers of (b) (4) were reviewed. However an interior and exterior walkthrough of the house (b) (4) was not performed. Flock information for layers houses inside (b) (4) is included in **Table 1** below.

(b) (4)



Table 1. Flock Information. MBB 5/26/11.

The firm does not have perimeter fencing surrounding the property. However, each poultry house contains lockable doors to limit access. The firm has one gated main entrance and office. Completing and signing a visitor log in sheet (with questionnaire) documents a visitor's history of visits to other egg laying facilities (day of visit and down time from visit), microbiological laboratories, the recent handling of birds and reptiles and any biosecurity preventative measures taken prior to the visit. See **Exhibit 5** for further details.

(b) (4)



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Collected manure is distributed to (b) (4)
(b) (4)

The layer house equipment is not dedicated to each layer house. See **Inspectional Observation 1** for further details. Examples of shared layer house equipment include brooms, brushes, screwdrivers and the skid loader. Employees do not change clothes upon entering a new layer house. See **General Discussion Item 1** for further details.

(b) (4)

Layers

Day old chicks are purchased from (b) (4) major chick suppliers: (b) (4)

(b) (4)

At times the firm has purchased chicks

from (b) (4)

(b) (4)

(b) (4)

The firm uses well water for production and processing. Well water is chlorinated and is provided to the layers as drinking water.

At approximately (b) (4) the pullets are placed into clean laying houses. Laying houses are cleaned and disinfected at time of depopulation.

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(b) (4)

Egg that do not meet quality standards of a table egg (size and color) are delivered to an egg breaking and treatment facility. The name of the egg breaking and treatment facility is (b) (4)
(b) (4)

The average age of a post production flock is approximately (b) (4) of age. All post production layers are distributed to (b) (4)
(b) (4)

When post production layers are removed from a layer houses, the layer house is cleaned and disinfected. Cleaning and disinfection is monitored and documented. All remaining manure from the previous flock is removed and the house is thoroughly cleaned (scraped, washed down and sanitized) prior to housing a new flock of pullets. On 5/10/11, the cleaning and disinfection logs for layer houses (b) (4) were reviewed. No issues were noted. See **Exhibit 11** for further details.

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Environmental Testing

On 5/10/11 through 5/12/11 records related to flock numbers (b) (4) were reviewed. Flock records include National Poultry Improvement Plan (NPIP) certifications of chicks grown in Salmonella Enteritidis (SE) monitored conditions, layer house cleaning and disinfecting logs and if applicable, environmental testing results (b) (4)

(b) (4)

The frequency of environmental testing is based upon age of the flock. Older flocks have missing environmental testing data due to the implementation date of the Egg Rule. See **Table 2** located below for further details.

(b) (4)

Table 2. Reviewed Environmental Testing Results. MBB 5/26/11.

On 5/11/11, (b) (6) stated the firm does not own pullet housing onsite; further, the firm contracts pullet farms to raise purchased chicks into pullets. Contract pullet farms are located in (b) (4). Further, pullet testing (~~14-16 weeks~~) is performed at the pullet farm. All environmental results generated at these pullet farms are provided to (b) (6) at headquarters (MN). The results are then transmitted to Ms. Timmons, Production Manager (CO). On 5/10/11, (b) (6) DVM, stated the contract pullet farms have been performing environmental testing approximately ~~two weeks earlier (12 weeks)~~ and not at ~~14-16 weeks~~. See **General Discussion Item 2B** for further details.

Upon further record review after inspection closeout, the firm owns (b) (4) pullet houses located onsite. See **Exhibit 31** for further details. Onsite pullet testing was not performed at ~~14-16 weeks~~ for layers

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currently housed in (b) (4) testing occurred at ~~12 weeks~~ of age. Environmental sampling results for pullet houses identified (b) (4) all document environmental testing at (b) (4) of age.

On 5/10/11, ~~14-16 week~~ environmental testing records for layers now located in house (b) (4) were reviewed. The contract pullet houses identified as (b) (4) performed environmental testing at ~~14 to 16~~ (b) (4) **Exhibit 14** states the age of the flock during testing as ~~12-8 weeks~~, however, according to NPIP certification papers, pullets at age of testing were approximately ~~14-15 weeks~~ of age.

Environmental testing is performed at ~~40-45 weeks~~ of age. Environmental sampling for house/flock (b) (4) and were reviewed. No issues were noted. See **Exhibit 22** and **23** for further details.

Environmental testing is performed at ~~4-6 weeks~~ after the end of any molting process. The firm has defined post molt sampling when (b) (4)

(b) (4)
were also reviewed and no issues were noted.

MANUFACTURING CODES
(MBB)

Manufacturing codes are stamped onto the shipping containers. The manufacturing code contains the (b) (4) of packaging and a sell by date. The manufacturing code appears as:

P-1167
DOP 130 SELL BY: JUN-08-11

(b) (4)

SELL BY: JUN-08-11 = Self explanatory

COMPLAINTS
(MBB)

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On 5/10/11, Mr. Vincenzo Ruscitti, Processing Plant Manager, stated the firm has not received any complaints of injury or illness from the consumption of finished product.

RECALL PROCEDURES

(MBB)

On 5/10/11, recall procedures were provided by Mr. Vincenzo Ruscitti, Processing Plant Manager. A mock recall is conducted (b) (4) See **Exhibit 25** for further details.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

You do not maintain practices that will protect against cross contamination when equipment is moved among poultry houses.

Specifically,

A) On 5/11/11, by your own admission, equipment used in all layer house operations is shared among the laying houses. Further, the shared equipment is not cleaned and disinfected. Equipment includes (but not limited to) brooms, screwdrivers and the skid loader (used for manure removal).

B) On 5/10/11, upon review of SOP.OPS.PRD 8 Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility (5/10/2011), the plan fails to address cross contamination from equipment movement between layer houses.

Reference: 21 CFR 118.4(b)(2)

Supporting Evidence and Relevance:

Shared equipment used for layer house operations can potentially cause cross contamination, in the event Salmonella Enteritidis is present. Layer house operations include maintenance and manure removal.

Discussion with Management:

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On 5/12/11, (b) (6) DVM, and Ms. Joy L. Timmons, Production Manager, stated that a statement for correction could not be provided at this time. Further research and discussion is required at the corporate level and will be addressed in the 15 day response letter to the Denver District Director.

OBSERVATION 2

You did not maintain records documenting compliance with rodent and other pest control measures.

Specifically on 5/9/11, by your own admission, fly monitoring documentation has not been performed as of 5/9/11.

Reference: 21 CFR 118.10(a)(3)(ii)

Supporting Evidence and Relevance:

On 5/10/11, Ms. Joy L. Timmons, Production Manager, stated fly monitoring has been in place for three years. However, documentation related to fly monitoring has not been performed as of 5/9/11.

Discussion with Management:

On 5/12/11, Ms. Timmons, Production Manger, stated documentation of fly monitoring began on 5/10/11. Ms. Timmons provided one monitoring log for review (**Exhibit 26**).

OBSERVATION 3

Stray animals are not prevented from entering poultry houses.

Specifically on 5/9/11, a hole was observed in the bird netting located along the northwest corner eave of layer house (b) (4). The hole measured approximately 48 inches in length and 24 inches in width.

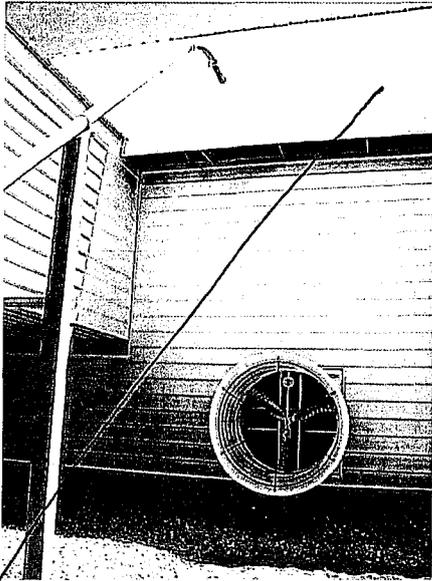
Reference: 21 CFR 118.4(b)(4)

Supporting Evidence and Relevance:

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Digital Photo 003. Photo of the northwest corner eave of layer house 04S. MBB 5/9/11.



Digital Photo 002. Close up photo of the bird netting containing the hole. MBB. 5/9/11.

Discussion with Management:

On 5/12/11, Ms. Timmons stated the hole was immediately repaired on 5/9/11. Ms. Timmons provided a digital photo of the correction. See **Exhibit 27** for further details.

OBSERVATION 4

For testing to detect SE in environmental samples, you did not have the sample testing conducted by the method entitled "Environmental Sampling and Detection of Salmonella in Poultry Houses." most current edition, or an equivalent method in accuracy, precision and sensitivity in detecting SE.

Specifically on 5/10/11, by your own admission, hydra-sponges were used to perform environmental testing (~~40-45-week and 4-6 post-molt~~) prior to 5/9/11. The use of hydra-sponges are not recognized as an equivalent method.

Reference: 21 CFR 118.8(a)

Supporting Evidence and Relevance:

As per the method entitled, "Environmental Sampling and Detection of Salmonella in Poultry Houses", dry drag swabs are to be used for environmental sampling.

Discussion with Management:

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On 5/12/11, (b) (6) DVM, stated dry drag swabs will be purchased as of 5/12/11. Once the dry drag swabs are received, (b) (6) would provide training to Ms. Timmons for proper use. (b) (6) (b) (6) could not provide any further comments and stated additional details related to equipment ordering and training would be addressed in the 15 day response letter to the Denver District Director.

OBSERVATION 5

All required records do not include the location of your farm.

Specifically on 5/10/11, records related to rodent and refrigeration monitoring did not contain the firm's location.

Reference: 21 CFR 118.10(b)(1)

Supporting Evidence and Relevance:

The Daily Refrigeration Monitoring Logs (**Exhibit 10**) and Rodent Monitoring Logs (**Exhibit 28**) do not contain the firm's physical location.

Discussion with Management:

On 5/12/11, Ms. Timmons, Production Manager, stated all future rodent monitoring logs would contain the firm's physical address. On 5/12/11, Mr. Ruscitti, Processing Plant Manager, stated that refrigeration logs would need to be addressed at the corporate level and that further details would be addressed in a 15 day response letter to the Denver District Director.

REFUSALS

(MBB)

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

(MBB)

1) Salmonella Enteritidis (SE) prevention measures and layer house employee clothing

On 5/10/11, Ms. Timmons, Production Manager, stated that employees are not required to change into new clothes prior to entering into a new layer house. On 5/12/11, I explained to Ms. Timmons

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and (b) (6) DVM, cross contamination could occur between layer houses in the event that Salmonella Enteritidis was present.

On 5/12/11, Ms. Timmons described the following practices currently in place to prevent cross contamination:

Personnel clothing and shoes

Wearing personal clothing and shoes to work is prohibited. Employees are required to don clean coveralls (provided by the firm) each work day. Used coveralls remain at the firm for laundering. Shoes are also provided to each employee and remain at the firm at the end of the workday. Layer house employees who work inside high rise manure pit houses have dedicated irrigation boots. The irrigation boots are only used to walk through the manure pits. Further, the irrigation boots are dedicated to each layer house manure pit.

Employee Traffic

- One boot dip station is present at the entrance of each layer house and employees are required to dip boots prior to entering into the house. Boot dip stations are changed on an as needed basis. Disinfectants used such as iodine will change from the color of dark brown to colorless; this color change is an indicator for the disinfectant to be replaced.
- Production employees are not allowed to walk through the processing area.

2) Environmental testing at ~~14-16 weeks~~

A) Document entitled, SOP.OPS. PRD 8 Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility was reviewed from 5/10/11 through 5/12/11. The program stated if the environmental test for pullets at ~~12 weeks~~ of age is positive, retest same environment ASAP and before the pullets are to be moved out of premises. Pullet environmental testing is required at ~~14-16 weeks~~ of age. See **Exhibit 6, page 19** for further details:

B) On 5/11/11, (b) (6) stated he provides technical guidance for all contract brooder and pullet farmers; further, he advised contract brooder and pullet farms to conduct environmental testing when pullets were ~~12 weeks~~ of age. (b) (4) layer houses inspected contained pullets environmentally tested at approximately ~~12 weeks~~ of age. I explained to (b) (6) pullet testing is required at ~~14-16 weeks~~.

1) On 5/10/11, ~~14-16 week~~ environmental testing records for layers in house (b) (4) were reviewed. The contract pullet houses identified as (b) (4) (b) (4) Both contract pullet farms performed environmental testing at ~~91 and 92 days, approximately 13 weeks~~ of age.

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2) On 5/10/11, 14-16 week environmental testing records for layers now located in house (b) (4) were reviewed. The contract pullet houses identified as (b) (4) performed environmental testing at 10-13 weeks.

On 5/12/11, (b) (6) DVM, agreed that pullet testing occur at 14-16 weeks and not 12 weeks. (b) (6) DVM, could not provide a detailed statement of correction and stated he would provide further details of correction in the 15 day response letter addressed to the Denver District Director.

3) Rodent Monitoring Records

(EJB)

On 05/10/11, I reviewed Rodent Monitoring records dated 07/24/10 to 05/7/11. On Rodent Monitoring record dated 9/25/10, house (b) (4) noted 45 rodents and had a (b) (4) I asked Ms. Timmons what actions were taken due the exceeded (b) (4) She explained that she evaluated barn (b) (4) for any rodent entries and communicated with (b) (4) However, there were no corrective actions documented. During the close-out discussion on 05/12/11, Ms. Timmons generated two Corrective Action Logs for pest control (rodent and fly) performed by production employees and contracted pest control representatives. See (**Exhibit 29**) for further details.

ADDITIONAL INFORMATION

1) Salmonella Enteritidis (SE) Prevention Plan Review

The firm's Salmonella Enteritidis (SE) Prevention Plan is also referred to as SOP.OPS.PRD 8 Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility dated 5/10/11 and will be referred to as Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility throughout the remainder of this report. A copy of the program was provided the same day requested and is stored electronically. See **Exhibit 6** for further details.

The author and administrator of the plan is (b) (6) DVM. The onsite administrator is Ms. Joy L. Timmons, Production Manager. See EIR sections Individual Responsibility and Persons Interviewed and Firm's Training Program for Ms. Timmons and (b) (6) qualifications as plan co-administrators.

The Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility covers the following aspects: 1) Administration of the Salmonella Enteritidis Prevention Plan 2) Record keeping for the Salmonella Enteritidis Prevention Plan 3) Records on pullets (NPIP) and environmental sampling results 4) Salmonella vaccination program and procedures 5) Salmonella prevention program including pullets and layers 6) Salmonella sampling and testing 7) Cleaning and disinfection procedures on empty barns 8) Pest control program and procedures 9) Egg storage and refrigeration

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~~procedures 10) Egg shell transportation procedures and 11) Egg diversion and re-introduction procedures~~

The Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility was reviewed from 5/10/11 through 5/12/11. The program stated environmental test for pullets at ~~12 weeks~~ of age; see **General Discussion with Management 2A** for further details. No other issues were noted.

2) Pest Control

(EJB)

Rodent Control

According to the firm's Salmonella Prevention Program, monitoring of rodents is based on a Rodent Index (RI) indicator, the firm will conduct measures such as remove all feed from the feed system; remove all eggs after flock has been eliminated, and communicate with pest control representative when increased activity occurs, (see **Exhibit 6, page 24**).

The firm contracts with (b) (4) (b) (4) monitors all interior rodent traps (b) (4) (b) (4) and exterior traps are monitored (b) (4) service reports were reviewed from 07/2/10 to 5/7/11, no issues were noted. Ms. Timmons provide a copy of (b) (4) Scope of Service, see **Exhibit 30**.

The firm also conducts in-house pest/rodent control to manage the farms' pest control. According to Ms. Timmons, every (b) (4) barn employees are required to walk each barn, check traps, remove and count rodents, and document number of rodents for each barn (on Rodent Index documents). The rodents are saved until Ms. Timmons verifies the number of rodents and then the rodents are discarded. Ms. Timmons states that the Rodent Index (RI) should be lower than (b) (4) She explained the RI is determined by (b) (4) (b) (4) If the RI is greater than (b) (4) Ms. Timmons will conduct an investigation by looking for rodent entry way, seal any holes found, and will communicate with (b) (4) to determine a solution. Procedures for a RI value greater than (b) (4) are included as **Exhibit 32**.

During the inspection Rodent Monitoring records dated 07/24/10 to 05/7/11 were reviewed. On 9/25/10, in house (b) (4) rodents were documented with a (b) (4) No corrective actions were documented. See **General Discussion Item 3** for further details.

Fly Control

According to the firm's Salmonella Prevention Program, the firm will conduct fly control (b) (4) or more frequently based on the threshold (see **Exhibit 1, page 24**). On 5/10/11, Ms. Timmons stated that she does monitor for flies but there are no fly monitoring documentation at this time. See **Objectionable Conditions and Management Response, Observation 2**.

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Prior to 5/9/11, spec papers were placed in the front of each barn and a visual check was performed.

(b) (4)

(b) (4) Further, fly jars were placed outside of each house, along the base of the exterior wall. Fly jars are used in the summer months as a monitoring device.

(b) (4)

3) Water Testing: Records Review

Water testing records with dates ranging from 7/21/10 to 4/11/11 were reviewed. No issues were noted.

4) Upon further review of ~~14-16 week~~ environmental pullet testing records (after inspection closeout) it was discovered a pullet farm exists in Colorado. On 6/6/11, Ms. Timmons, Production Manager, stated that there are no pullet houses located onsite; however, the firm owns a pullet farm located on Weld County Road 16 in Hudson, Colorado. The pullet farm is referred to as Hudson Pullets and contains (b) (4) pullet houses. Ms. Timmons stated biosecurity and environmental testing requirements listed in The Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility also apply to Hudson Pullets.

SAMPLES COLLECTED

(MBB)

No environmental samples were collected during this inspection.

EXHIBITS COLLECTED

Exhibit 1- UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE NATIONAL POULTRY IMPROVEMENT PLANT REPORT OF SALES OF HATCHING EGGS, CHICKS, AND POULTS DATE OF SHIPMENT 10-18-10, 1 page.

Exhibit 2- Sparboe Farms production Exterior Bait Stations Tim cats Amended 5-7-2011, 1 page

Exhibit 3- Sparboe Farms Process Verified Barn Employee Training Date 9/23/08 Revision 4, 4 pages

Exhibit 4- SPARBOE FARMS BIO-SECURITY HUDSON FACILITY, 2 pages

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Exhibit 5- SPARBOE COMPANIES BIOSECURITY PROCEDURES Visitor Sign-in Sheet
Revision #5 January 2, 2011, 1 page

Exhibit 6- SOP.OPS.PRD 8 Salmonella Prevention Program- Sparboe Farms, Inc. Hudson Facility
Revised on 5/10/2011, 26 pages

Exhibit 7- SPARBOE FARMS Egg Segregation and Re-Introduction SOP Contract Production Farm
04.08.11- Revision 1, 3 pages

Exhibit 8- WELD Co COLORADO Analysis Report Number: ENSG110401-039 Date Analyzed
4/12/2011, 1 page

Exhibit 9- Sparboe Farms Attachment 8 Daily Control Point Log Date 05-06-11, 1 page

Exhibit 10- Sparboe Farms Attachment 11 Daily Refrigeration Monitoring Log Plant Hudson Month
April Year 2011, 1 page

Exhibit 11- Sparboe Farms Attachment 14 Monitoring of Cleaning and Disinfecting Date: 2/3/11
House/Flock: (b) (4) 1 page

Exhibit 12- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 13- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 14- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 15- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 16- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 17- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 18- Veterinary Diagnostic Laboratory (b) (4)
(b) (4)

Exhibit 19- (b) (4) Avian Diagnostics Final Report (b) (4)
(b) (4)

Exhibit 20- (b) (4) Avian Diagnostics Final Report (b) (4)
(b) (4)

Exhibit 21- (b) (4) Avian Diagnostics Final Report (b) (4)
(b) (4)

Exhibit 22- (b) (4) Avian Diagnostic Final Report (b) (4)
(b) (4)

Exhibit 23- (b) (4) Avian Diagnostic Final Report (b) (4)
(b) (4)

Exhibit 24- (b) (4) VETERINARY DIAGNOSTIC LABORATORIES
Laboratory Report Case (b) (4)

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Exhibit 25- Sparboe Companies Recall Policy, 8 pages

Exhibit 26- Fly Monitoring Sparboe Hudson Date: 5/11/2011 Prepared by: (b) (6) 5/11/2011, 1 page

Exhibit 27- Sparboe Farms Inc. (b) (4) Corrected 5/9/11 4:00PM (b) (6) 1 page

Exhibit 28- Rodent Monitoring Sparboe Hudson Date 2/5/2011 Prepared By: (b) (6) 2/12/11, 1 page

Exhibit 29- Sparboe Farms 6339 Weld County Rd 47 Hudson, Colorado 80642 Corrective Action Log, 2 pages

Exhibit 30- (b) (4) COMMERCIAL SERVICES Scope of Service, 1 page

Exhibit 31- FDA Salmonella Testing Schedule, 1 page

Exhibit 32- Hudson Salmonella Prevention Program May 5th, 2011. Rodent Control If higher than RI (b) (4) 1 page

Exhibit 33- Hudson Salmonella Prevention Program May 11th, 2011. Fly Control If higher than (b) (4) 1 page

Exhibit 34- FDA 525, Sample Package Identification, containing 1 CDR with digital photos, 1 page

ATTACHMENTS

Form FDA-482, Notice of Inspection, dated 5/9/11

Form FDA-483, Inspectional Observations, dated 5/12/11

Attachment 1- Attachment B: (b) (5)



Marie B. Buen-Bigornia, Investigator



Elisa J. Beard, Investigator