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NOTE TO FOI OFFICER & UNUSED EXHIBITS (CMM)

The firm has requested all information furnished during this inspection be treated as proprietary. The firm's product information, equipment information, supplier information, customer information (name, city and state), and personnel are referred to by name in this report, review carefully before releasing information under FOI.

All Exhibits collected at the firm and not used in this report were shredded.

SUMMARY (CMM)

This comprehensive pre-announced inspection was conducted jointly with the Iowa Department of Agriculture & Land Stewardship (IDALS) per KAN-DO FY 11 work plans, WAID # 1271365, OP ID # 5347712, and the Division of Field Programs and Guidance, Consumer Safety Office memo dated 02/08/2011, Subject: 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 inspection was pre-announced to Mr. Mark D. Friedow, General Manager, Production of Sparboe Farms Inc. on 04/12/2011.

This inspection was originally scheduled for 04/16/11. Per Mr. Friedow's request KAN-DO accepted inspectional date swaps between this facility and the Goodell, IA plant. The swap was requested due to construction of two new poultry houses and the installation of a (b) (4) at this facility.

The inspection was conducted under PAC 03F836. Assignment requisites; FD107 Egg Safety Course materials; Division of Field Programs and Guidance, Consumer Safety Office memo dated 02/08/2011; and the "New Egg Rule" per 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation served as guidance.

This was the first FDA inspection of this hybrid facility (shell egg/ egg breaker production) and the main objectives were to:

- Determine firm's compliance with 21 CFR 118 through evaluation of its physical facilities, records; observed practices; and interviews.
- Conduct on site SE Environmental sampling of a representative number of hen houses – (b) (5).
- Additional objectives were to determine individual responsibility for the firm's SE prevention plan; physical facility versus poultry ownership; and onsite postproduction operations as regards shelled eggs.

During this inspection, the records reviewed and information gathered included but was not limited to the SE Prevention Plan; Chick receiving records & NPIP certification; Pest control records & Monitoring; Production & Operational SOPs; Refrigeration as well as SE Environmental & Egg testing Results. Record review during this inspection was limited; post FDA inspections that resulted in similar FDA 483 observations at multiple facilities owned/operated by the firm, the SE Plan was revised. The revised SE plan was dated 05/16/11, i.e. the initial date of this inspection. Records generated as of the revised SE plan were limited.

This inspection found the firm operating as an in line Shell Egg Facility with an onsite Breaking operation. The facility had 20 poultry houses (one recently completed and one under construction), (b) (4) of which were populated. There was one new house under construction, and one new house whose construction was recently completed. All houses are of the High Rise (b) (4) (b) (4) type. The firm refers to these houses as "(b) (4)" because they are more

(b) (4)

As of the end of this inspection, 05/19/11, the firm has not had any positive SE environmental or egg samples. Our SE Environmental testing was conducted in six houses – 1 South, 4 South, 7 South, 3 North, 6 North, and 9 North. One set (six total samples) of environmental samples consisting of 16 drag swabs each were taken from each of the sampled houses per FDA's protocol for sampling the lower level (manure pit) of High rise poultry houses. These samples correspond to INV665611, INV665612, INV665613, INV653849, INV653850, & INV653851.

This inspection found the firm registered under the b(3) as well as under the Egg Rule per 21 CFR 118.11. The firm did not report any recalls or significant

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complaints.

On 05/19/2011 a FDA 484, Receipt for Samples and a four item FDA 483, Inspectional Observations, was issued to Mr. David L Hasemann, Complex Manager. These observations are:

Observation 1: Your written SE prevention plan lacks appropriate SE prevention measures.

Observation 2: All required records do not include your name and the location of your farm.

Observation 3: All required records do not have the signature or initials of the person performing the operation or creating the record.

Observation 4: You lack adequate review of records created to document your SE Prevention measures.

Firm's management stated they would respond to KAN-DO in writing as regards the FDA 483 observations within 14 days and that a revised SE Plan would be included with the response. Mr. Hasemann, and DVM (b) (6) also stated that the 483 observation would be corrected immediately.

At the close of the inspection, a *New Egg Rule* poster was provided to the firm's management. Management was reminded of its responsibility to adhere to the FD&C Act and informed that failure to do so could result in an action including seizure, injunction, or civil penalties.

ADMINISTRATIVE DATA (BDP)

Upon arrival to Sparboe Farms, Inc. on May 16, 2011, credentials and a FDA 482, Notice of Inspection, were presented to Mr. Mark D. Friedow, General Manager, Production by Investigators Collins M. Mason, Brittany D. Phillips, Kathleen J. Klier, Shaun M. Olson, Kevin E. Klommhaus and Lloyd N.M.I. Krutzfeldt. Mr. Friedow stated he was the most responsible person on site and that he was in charge of all Sparboe Farms Inc. facilities located in Colorado, Iowa, and Minnesota. Mr. Friedow was present only for the first day of the inspection.

An additional FDA 482, Notice of Inspection, was issued to Mr. David L. Hasemann, Complex Manager, on May 17, 2011. Mr. Hasemann is the most responsible person onsite on a day-to-day basis. The second FDA482, Notice of Inspection, was issued when IDALS Investigator Neal N.M.I. Vaughn joined the inspection on May 17, 2011, the only day he was present.

Mr. Hasemann was issued a FDA 484, Receipt for Samples, as well as an FDA483, Inspectional

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Observations, on May 19, 2011.

This EIR is co-authored by all the investigators who partook in this inspection. The Investigator's initials are used to indicate the section of this EIR that she/he/they wrote.

Inspected firm: Sparboe Farms, Inc.
Location: 3159 Buchanan Ave
Eagle Grove, IA 50533
Phone: 515-603-3050
FAX: 515-603-3057
Mailing address: 3159 Buchanan Ave
Eagle Grove, IA 50533
Dates of inspection: 05/16/2011 – 05/19/2011
Days in the facility: 4 days
Participants: Investigators: Collins M. Mason, Kathleen J. Klier, Brittany D. Phillips, Shaun M. Olson, Kevin E. Klommmhaus, Lloyd N.M.I¹. Krutzfeldt, Neal N.M.I. Vaughn

HISTORY

(KJK)

GENERAL:

Sparboe Farms Inc is a family owned business started by the father of the current CEO, Beth Sparboe Schnell, in 1954. The firm started off 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 corporate office for Sparboe Farms, Inc. is located at 23577 Minnesota Highway, PO Box 309, Litchfield, MN 55355. The firm is incorporated in the state of Minnesota; however, it is also registered as a domestic corporation in Iowa and Colorado.

The firm operations consist of twenty layer houses (two new and unpopulated, one of which is still under construction), a USDA FSIS monitored breaker facility, and a USDA monitored postproduction shell eggs processing plant (in-line production system). The firm refers to this complex/location as the "Vincent Layer Farms". According to Mr. Hasemann, (b) (4) of the twenty Vincent Layer Farms were built from August 2002 until December 2004. Construction of the two remaining layers begun in the summer of 2010; construction of these two layers is still ongoing. According to Mr. Hasemann, this complex began operating on May 2, 2003. Like

¹ N.M.I: No middle initial

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previously stated, there are twenty houses on the premises; however only (b) (4) are currently populated with layers.

This complex has (b) (4) full-time employees. According to Mr. Friedow, farm and processing operations occur from (b) (4) through (b) (4); office operations occur from 7:00 AM – 4:30 PM Monday through Friday; and shell egg shipping activities occur from (b) (4) through (b) (4).

The firm is registered per the Egg Rule as well as per the (b) (3). During the current inspection, we became aware the firm had (b) (3) under the address of 3159 Buchanan Avenue, Eagle Grove, IA 50533; one registration was filed (b) (3). Mr. Hasemann stated Mike Schmidt, QA Manager, is responsible for filing registrations for Sparboe facilities and may have registered again. Mr. Hasemann was provided with the FDA's website (www.fda.gov) for guidance on cancelling the newer registration.

INSPECTIONAL:

No previous inspections had been conducted at this facility.

FMD 145/OTHER POST INSPECTIONAL CORRESPONDENCES (KJK)

FMD 145:

Mr. David L. Hasemann
Complex Manager
3159 Buchanan Avenue
Eagle Grove, IA 50533

Other Post Inspectional Correspondences should be sent to:

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

INTERSTATE COMMERCE (SMO)

According to Mr. Friedow, the firm purchases pullets from (b) (4)

these pullets originate from other locations including (b) (4); (b) (4); and the state of (b) (4)

Mr. Friedow stated that approximately (b) (4)% of the firm's outbound shelled eggs and liquid eggs product is shipped interstate and that the firm's primary shelled egg customer is (b) (4). The firm ships its shelled eggs out to (b) (4). The latter firm then ships the eggs out to (b) (4). Mr. Friedow indicated that all (b) (4) (in the continental U.S.), (b) (4) (b) (4) in (b) (4), (b) (4) in (b) (4), and (b) (4) in (b) (4) and (b) (4) receive shelled eggs from the inspected firm.

The (b) (4) facilities which receive the firm's shelled eggs are located in (b) (4) (b) (4) (b) (4) (b) (4)

The firm's liquid egg product is transported to (b) (4) where the it is processed and pasteurized. According to Mr. Hasemann, (b) (4) arrange all outbound shelled and liquid egg product shipments; and the previously mentioned products are shipped in (b) (4) owned semi-trucks.

After approximately (b) (4) weeks, each barn is depopulated. When a barn is depopulated, the chickens removed from the barn are shipped to (b) (4) in (b) (4) to be rendered and processed into products for human consumption. These products are shipped to (b) (4) and (b) (4). According to Mr. Hasemann, outbound chicken shipment is coordinated by Sparboe Farms, Inc.'s Pullet Department located in Latimer, IA.

JURISDICTION (SMO)

The firm operates as a grower of shell eggs and egg products, which are sold to the (b) (4) (b) (4). The shell eggs are packaged into flats holding (b) (4) eggs per flat. These flats are then placed into cases, which hold approximately (b) (4) flats per case. According to Mr. Friedow, the firm's shell egg operations accounts for approximately (b) (4)% of the inspected firm's business.

The firm also has an egg breaking operation, which produces liquid egg product using cracked (non-leaking) eggs, and eggs not meeting specification. The liquid egg product is shipped to

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(b) (4) in (b) (4) for processing, and pasteurization. Mr. Friedow stated the firm's egg breaking operations accounts for approximately (b) (4)% of the inspected firm's business.

INDIVIDUAL RESPONSIBILITY AND PERSON'S INTERVIEWED

(BDP & SMO)

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 communication with Ms. Schnell during this inspection.

Wayne Carlson, Senior V.P. Supply Chain Management oversees production related operations for Sparboe Farms Inc. Mr. Carlson is based at the firm's headquarters in Litchfield MN. We had no communication with Mr. Carlson during this inspection.

Mark D. Friedow, General Manager, Production, oversees the firm's pullets and layer facilities in CO, IA, and MN. He has been with the company for the past (b) (6) and has been in his current position for the last (b) (6). Mr. Friedow reports to Wayne Carlson, Senior V.P. Supply Chain Management and has approximately (b) (4) direct reports. Mr. Friedow was present only on the first day of the inspection. Credentials and a Notice of Inspection, FDA 482 were presented to Mr. Friedow on day 1 of this inspection.

(b) (6), **Nutritionist**, formulates the poultry diet throughout Sparboe Farms Inc. Mr. (b) (6) reports to Mr. Friedow and does not have any direct reports. He has been at the firm for (b) (6), all of which has been spent in his current position. We had no communication with Mr. (b) (6) during this inspection.

(b) (6), **DVM, Veterinarian**, is responsible for all food safety issues and bird health. Dr. (b) (6) is also listed as the Author – Administrator of the Salmonella Prevention Program. Dr. (b) (6) has been working with the company for over (b) (6) and reports to Mr. Mark Friedow, General Manager, Production. Dr. (b) (6) does not have any direct reports. Dr. (b) (6) was present for the entire inspection and provided information contained within this report.

David L. Hasemann, Complex Manager, oversees the Vincent layer and pullet sites and is the site SE Plan program administrator. He is responsible for the whole layer facility which includes breaking and egg production. Mr. Hasemann has been the complex manager at this location for approximately (b) (6) and reports to Mr. Mark Friedow, General Manager, Production. Mr. Hasemann has (b) (4) direct reports. Mr. Hasemann was present for the entire inspection and

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provided information contained within this report. Mr. Hasemann was issued a FDA484, Receipt for Samples and well as the FDA483, Inspectional Observations at the close of the inspection. A Notice of Inspection, FDA 482, was presented to Mr. Friedow when IDALS investigator Neil Vaughn joined the inspection team.

(b) (6) **Production Lead**, is in charge of lived production in the barns. He oversees people in the barns and verifies that all things are getting done such as making sure birds are fed. Mr. (b) (6) has been with the company in his current position for (b) (6) and reports to Mr. David Hasemann, Complex Manager. Mr. (b) (6) has (b) (4) direct reports. He was present for the entire inspection.

Daren Dugan, Processing Manager, in additional to his titled duties is the deputy SE Plan program administrator of the inspected facility. We had no communication with Mr. Dugan during this inspection.

An Organizational chart for the firm is included as Exhibit 9.

FIRM'S TRAINING PROGRAM (KJK)

Mr. Hasemann is responsible for local trainings at this complex. Upon initial employment, employees are required to read the "(b) (4)", watch the Animal Welfare and Biosecurity videos, and undergo Proper Bird Handling and Barn Employee Training procedures. According to Mr. Hasemann, (b) (4) refresher training is conducted on an individual basis. He stated these refresher trainings are typically completed before the (b) (4) audit ((b) (4) - (b) (4)). Training attendance records were reviewed during this inspection.

Dr. (b) (6), has been a veterinarian for approximately (b) (6). He stated he had participated in the (b) (6) in (b) (6) (b) (6) meeting with (b) (6) in (b) (6); (b) (6) in (b) (6) (b) (6); and the (b) (6)

MANUFACTURING/DESIGN OPERATIONS (SMO)

GENERAL OPERATIONS

This firm is an in-line production facility. The facility has 20 High Rise layer houses, (b) (4) of which are operational. Multi-level house style means the eggs are laid on the first level and the manure drops directly from the cages/tiers to the second floor or lower level. The dimensions of the layer houses are (b) (4) feet long, with (b) (4) rows of cages, (b) (4) tiers high. Each cage is (b) (4) square inches with approximately (b) (4) hens per cage.

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.
- FSIS investigators inspect the Breaker operation

POULTRY HOUSES

The High Rise layer houses at this facility are referred to as “(b) (4)”. This modification to the typical High Rise facility according to Dr. (b) (6) was more efficient. (b) (4)

(b) (4)

(b) (4) According to Dr. (b) (6) egg production is higher, and management of manure (as regards sales) and poultry production cycles is better in the (b) (4) type High Rise layer house.

CLEANING

During the egg production process, eggs are conveyed on a belt from each individual barn onto a common egg belt where they are co-mingled with eggs from the other barns, eventually arriving at the facility’s egg processing plant. Upon reaching the plant, the eggs are washed by (b) (4) egg washers with oscillating brushes in (b) (4) F water with a pH of approximately (b) (4) using a USDA approved detergent. After leaving the washers, the eggs are sanitized with (b) (4) at a concentration of (b) (4) ppm, dried, and a food grade (b) (4) is applied to the outer shell.

The eggs then go through a candling procedure where all eggs found with leaks, or blood/meat

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spots are removed. Dirty eggs are routed back through the washing process, and eggs with non-leaking cracks are sent to the breaker.

All eggs sent to the breaker are rewashed, visibly inspected for the presence of dirt and leaks. These eggs are also re-sanitized in a (b) (4) solution (concentration of (b) (4) ppm), rinsed with potable water, and then broken into individual cups so that the contents can be visually inspected for acceptance.

The firm provided us with their General Egg Flow Description document which summarizes the cleaning procedures performed on the eggs throughout the entire production process. This document is specific to the inspected location and was updated on 05/17/2011. A copy of the firm's General Egg Flow Description document is attached as **Exhibit 7**.

According to Dr. (b) (6), prior to the current inspection the firm did not keep cleaning records. He stated that these records would be kept from the week beginning 05/23/2011 onwards. A copy of the firm's (b) (4) dated 05/10/2011 is included as **Exhibit 15**. According to Dr. (b) (6), the firm cleans out each barn between flocks. Each flock occupies a barn for approximately (b) (4) weeks.

According to Mr. Hasemann, his firm performs cleanout procedures using either (b) (4) cleaning or (b) (4) cleaning methods. Mr. Hasemann stated his firm uses a (b) (4) to perform (b) (4) cleaning. He stated the (b) (4) is disinfected after each use and prior to use in another barn. Mr. Hasemann stated his firm performs (b) (4) cleaning procedures by hand through the use of single use brushes.

Each barn at the inspected location contains a machine known as a (b) (4) which (b) (4) (b) (4) of the barn where the chickens are housed, (b) (4) (b) (4) of the barn, which is known as the manure pit. According to Dr. (b) (6), each barn's (b) (4) is run (b) (4). Dr. (b) (6) stated the firm cleans out the lower level i.e. manure pits (b) (4) during the (b) (4)

SALMONELLA ENTERITIDIS PREVENTION PLAN

(CMM)

The firm's Salmonella Enteritidis Prevention plan consists of one document labeled Salmonella Prevention Program – Sparboe Farms, Inc. Vincent Facility (SOP.OPS.PRD 7 Revised (b) (4)) [**Exhibit 1**]. The SE Plan Administrator for all of Sparboe Farms Inc. is Dr. (b) (6) (b) (6), DVM. Dr. (b) (6) has assigned David Hasemann, Complex Manager and Daren Dugan,

Processing Manager as the onsite administrators of this plan.

SALMONELLA PREVENTION PROGRAM

Topics covered by Sparboe Farms Inc. Salmonella Prevention Program (SOP.OPS.PRD 7 Revised (b) (4), **Exhibit 1**, include:

- Definitions
- Laboratory Designation For Samples
- Administration And Record Keeping
- Registration
- Enforcement And Compliance
- Salmonella Prevention
- Layer Sampling Procedures
- Environmental Sampling Procedures
- Biosecurity Procedures
- Barn Isolation
- Cleaning & Disinfection
- Pest Control Procedures
- Vaccination Procedures
- Transportation

Our review of this document was conducted simultaneously with that of other records and was complemented by management interview in order to ascertain the alignment of operational practices with operational requirements per the firm's SE Prevention Plan. The records for all (b) (4) active layer houses were reviewed but those of the houses SE environmentally sampled houses; 1 South, 4 South, 7 South, 3 North, 6 North, and 9 North; were more closely evaluated. **Exhibit 5** provides summary flock age by house number.

Review of the firm's records showed that all SE testing was conducted in accordance with the time frame specified in the Final Egg Rule. Chicks are also sourced per the Egg Rule requirement, a sample NPIP certificate is attached as **Exhibit 6**. All tests are conducted by the laboratory of (b) (4) in accordance with an approved FDA procedure. Samples are transported same day or shipped (b) (4) (b) (4) to that lab.

One issue that arose during this inspection was developing appropriate methodology to evaluate

a relatively new SE Prevention Plan. According to Dr. (b) (6), the parent firm, Sparboe Companies Inc. had incorporated FDA observations from recent inspections of its facilities into the current revision of its SE Plan. The SE Prevention Plan for the currently inspected firm was effective as of the beginning of this inspection i.e. 05/16/11. The firm had not generated sufficient 21 CFR 118 related records to allow for a comprehensive evaluation of this plan nor had its employees been provided the opportunity to put this revised plan into practice.

Nonetheless, we had immediate concerns after we read the revised SE Prevention Plan. SE Preventative cross contamination practices is conditional to SE positive flock, the plan is not adequately reviewed, and it contains multiple errors and inaccuracies (some related to the Egg Rule). (See **Objectionable conditions and Management Response**, Observations 1 & 4). Prior to closing the inspection, we made a request to the management for documents generated under the currently revised SE Prevention Plan of 05/16/11. Our review of these documents resulted in observations 2, 3 and 4-2 (see applicable observations in section on **Objectionable conditions and Management Response**). Some of the documents that we reviewed did not list the name and location of the firm; did not have the signature or initials of the person performing the operation or creating the record; and were not reviewed by the SE Prevention Plan site Administrators or their designees. See section titled Objectionable Conditions and Management's Response for further information.

ENVIRONMENTAL SAMPLING & EGG TESTING RESULTS

(CMM)

As of the end of this inspection, the firm has not had any positive environmental samples or egg tests.

PEST CONTROL

(CMM)

RODENTS:

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

A summary of the firm's pest control contract is listed as **Exhibit 4**. The diagram of the layer house upper level extermination plan is listed as **Exhibit 8**. A review of the records from 07/04/10 to 05/16/11 did not show any deficiencies. The last rodent activity at the facility was recorded on 11/15/10 and the highest rodent index listed in the reviewed records was (b) (4).

(b) (4)

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the (b) (4) and have to follow the same biosecurity measures observed by the firm's workers see **Exhibit 4, pg 1**. Their service protocol includes a walk of the interior and exterior 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 (b) (4) on both levels of each barn. When completed, a summary of findings is written on Service Reports which are provided to the Complex manager for review. The Service Reports document findings and explain any additional measures performed. The only additional measures performed at this firm were for fly control.

Assigned inspectors conducted assessments in six houses --1 South, 4 South, 7 South, 3 North, 6 North, and 9 North. No rodent activity was observed in any of the six houses assessed.

INSECTS

Insect control practices are listed on page 24 of the firm's SE Prevention Plan. Our review of the operations showed that the firm's practices as regards insect control were sufficient. The records and recordkeeping was however deficient. See **Objectionable Conditions and Management's Response, Observations 2, 3, & 4-2** for further information.

Assigned inspectors conducted assessments in six houses --1 South, 4 South, 7 South, 3 North, 6 North, and 9 North. No insect activity, especially flies in the lower level i.e. manure pit was insignificant in all six houses assessed.

MANUFACTURING CODES

(KJK)

The firm manufactures shell eggs under USDA certification grading which are packaged in (b) (4) dozen cases which are identified with the (b) (4) (b) (4) and sell by date. (b) (4) % of packed shell eggs contain this information on the case via an (b) (4) (b) (4) However (b) (4) % are (b) (4)

Example: (b) (4) (b) (4)
(b) (4) (b) (4)
15 JUN 2011 [Sell by date, which varies by state]

COMPLAINTS

(KJK)

According to Mr. Friedow, egg complaints are handled by the Consumer Service Department

and complaints are tracked within the firm's system. Mike Schmidt, QA Manager (located in Litchfield, MN), is responsible for responding to the complaints and notifies Mr. Friedow if the Customer Service Department is unable to resolve them.

Mr. Friedow stated that 80% of the complaints received are due to either checked eggs (cracks); egg shell having a blood stain/spot; and/or the complainant observes a "meat spot" in the egg. Mr. Friedow stated Sparboe Farms, Inc. receives approximately 20 complaints a month nationwide. He later stated the majority of the complaints received are due to freight issues.

RECALL PROCEDURES
(SMO)

Mr. Friedow stated his firm kept recall procedures onsite. I reviewed the recall procedure which is entitled as Revision 7, and is dated 05/13/2010.

The firm's recall procedure objectives are: (b) (4)
(b) (4)

If the firm finds a product recall to be necessary, the firm will first classify the recall according to the severity of the defect. (b) (4)
(b) (4)
(b) (4)

When a product recall is initiated, the process is as follows: (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

The firm's aforementioned recall strategy calls for the assembly of a (b) (4) which is comprised of the following:

(b) (4) | (b) (4)

| | |
|---------|---------|
| (b) (4) | (b) (4) |

According to Dr. (b) (6) the firm has not had to initiate a product recall at the inspected location.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE
(CMM)

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

OBSERVATION 1

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

Your Salmonella Prevention Program, SOP.OPS.PRD 8 Revised on (b) (4) does not include cross contamination practices when persons or equipment move between poultry houses without "Flock Isolation".

Reference: 21 CFR 118.4.b.

Supporting Evidence and Relevance:

Per the Egg Rule {21 CFR 118.4}, firm's are required to have and implement a written SE Plan. One of the minimum requirements of that SE Prevention plan is that firms maintain practices which guard against SE cross contamination as their personnel move between poultry houses. Firms are not exempted from compliance with this requirement based on the SE status of the houses or their facility. This requirement is important because under the Egg Rule, SE testing occurs on a definite timeline and not daily. Without daily testing, a firm cannot provide 100% assurance that its houses/facility is truly SE negative. As a result, cross contamination controls provide an additional safe guard against SE contamination.

As an additional safeguard measure to be rendered effective, cross contamination practices must be in place prior to a house/facility becoming SE positive. That way these practices can limit the spread of SE that would result from the time lapse (if any) between a house actually becoming SE positive and when a firm officially becomes aware of the house's positive SE status.

The SE Prevention Plan informs on farm practices at the firm. According to Mr. Hasemann, firm employees moved between barns as needed to get the job done. In this regards, the absence of defined cross contamination practices between poultry houses without "Flock Isolation" signifies that the firm does not have any adequate SE Prevention practices in place.

Discussion with Management: Dr. (b) (6) the firm's SE Plan Administrator stated that the SE Plan would be revised and corrected to reflect the concerns expressed within this observation. He stated that the firm's management would respond in writing to KAN-DO within 14 days and that the response would include a copy of the Revised SE Prevention Plan.

Related Exhibits:

Exhibit 1: Firm's SE Prevention Plan revised 05/16/11. Note that the index pg 2 and the subtitles throughout the document does not address cross contamination.

Related Observations: Observation 4

OBSERVATION 2

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

Specifically,

Your documents titled "(b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" fails to identify your firm by name and location.

Reference: 21 CFR 118.10b.1

Supporting Evidence and Relevance:

Per the Egg Rule records must contain the name and location of the farm. During this inspection we reviewed (b) (4) generated records for the Fly Control Log, the Cooler Monitoring Log, and the (b) (4) Fly Chart from 07/04/10 to 05/18/11. None of the records reviewed, including records generated post implementation of the firm's SE Prevention Plan revised 05/16/11, listed the firm's name and location.

Discussion with Management:

Mr. Hasemann, Complex Manager responded that the corrections to the documents would be made immediately as it was an easy fix. He stated that the corrections would be acknowledged in the firm's formal response to KAN-DO within 14 days.

Related Exhibits: See Exhibits 1, 2, & 5.

Exhibit 1: Salmonella Prevention Plan revised 05/16/11 does not specify any records requirement.

Exhibit 3: Fly Control Log does not list name and location of the farm.

Exhibit 4: Cooler monitoring Log does not list name and location of the farm.

Exhibit 11: (b) (4) Fly Chart does not list name and location of the farm.

Related Observations:

Observations 3 & 4.

OBSERVATION 3

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

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or creating the record.

Specifically,

Your documents titled "(b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" fails to include the signature or initials of the person performing the operation.

Reference: 21 CFR 118.10b.3

Supporting Evidence and Relevance:

Per the Egg Rule all required records must contain the signature or initials of the person performing the operation or creating the record. During this inspection we reviewed (b) (4) generated records for the Fly Control Log, the Cooler Monitoring Log, and the (b) (4) Fly Chart from 07/04/10 to 05/18/11. None of the Fly Control Log and the (b) (4) Fly Chart records reviewed, including records generated post implementation of the firm's SE Prevention Plan revised 05/16/11, contain the signature or initials of the person performing the operation or creating the record. The Cooler Monitoring Log is a (b) (4) record. The records we reviewed from 02/14/11 to 05/19/11 did not contain the signature or initials of the person performing the operation or creating the record. The period 05/16/11 through 05/19/11 are post implementation of the firm's SE Prevention Plan revised 05/16/11.

Discussion with Management:

See observation 2.

Related Exhibits:

Exhibit 1: Salmonella Prevention Plan revised 05/16/11 does not specify any record management requirement.

Exhibit 3, Fly Control Log; does not meet the requirement.

Exhibit 4: Cooler Monitoring Log does not meet the requirement.

Exhibit 11: (b) (4) Fly Chart does not meet the requirement

Related Observation:

Observation 2 & 4.

OBSERVATION 4

You lack adequate review of records created to document your SE Prevention measures.

Specifically,

1. Your Salmonella Prevention Program, SOP.OPS.PRD 8 Revised on 5.16.2011 lacks adequate review as evidenced by the following:
 - A. Page 9, I. D. 5) c) states "Based on the FDA Final Rule, we have up to 10 days to send egg samples for testing." This is inaccurate.
 - B. Page 18, III B. 1) a) states "Initiate egg testing within 10 days of receiving notification of the positive environmental test." This statement is not in compliance with current FDA regulations.
 - C. Page 16, II D. 4) c) states "(b) (4)"
"(b) (4)" " whereas Page 17, II D. 6) g) i.
- vi. specifies a different procedure for egg belt sampling.
 - D. Sections "D. Pest Control Procedures"; "G. Refrigeration"; and "H. Transportation" are subtitles under "IV. Programs and Procedures on a SE Environmental Positive." indicating that these sections shall only be followed if there is a SE positive environmental sample. However these items are required regardless of the SE status of the barn.
 - E. Page 24, IV. D. 3) c) states "Threshold per barn is (b) (4) fly counts or higher." This statement as written does not indicate a threshold.
2. Your documents titled "(b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" have not been reviewed. Additionally your document titled "(b) (4) FLY Counts" and the document that you identified as your "Fly Control log" as prepared do not include space for review.

Reference: 21 CFR 118.9.

Supporting Evidence and Relevance:

Per the Egg Rule adequate document preparation and review are implicit to the SE Prevention Plan. Inaccuracies in that plan results in deficiencies in practices. Likewise an important part of the SE Plan is the revision of required documents by competent personnel. This ensures that the operational practices adhere to the SE Prevention plan and thus mitigate the spread of SE.

The Egg rule does not state that firms have ten days to send egg samples for testing nor is there an FDA regulation that requires firm to begin egg testing within 10 days of receiving notification

of the positive environmental test. 210 CFR 118 requires states “Begin egg testing (described in §118.6), unless you divert eggs to treatment as defined in §118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10-calendar days of receiving notification of the positive environmental test.” The statements from the firm’s SE Prevention Plan revised 05/16/11 and listed in observations 4.1.A & 4.1.B are not accurate interpretations of any of the regulations covered within the current version of 21 CFR 118 regulations as of this inspection.

The firm’s current environmental sampling procedure lists two non-equivalent methodologies for sampling of egg belts. As a result, it is confusing and does not provide clear instructions for the firm’s personnel to complete this required task. In the SE Prevention Plan Page 16, II D. 4) c) requires personnel to sample the two middle egg belts. The firm has (b) (4) type house with (b) (4) cage tiers, and hence (b) (4) sets of egg belts. Egg belts (b) (4); i.e. (b) (4) sets of egg belts not (b) (4) sets; would constitute the (b) (4) egg belts. This procedure does not specify. Additionally, sampling of “(b) (4) egg belts” is not compatible with the procedure outlined in the SE Prevention Plan Page 17, II D. 6) g) i. - vi. The latter procedure requires the hand swabbing every (b) (4) feet “.. (b) (4) (b) (4) ..” – Pg 17, II D. 6) g) iii.

SE Plan general requirements irrespective of the SE status of the house are presented within the SE Prevention Plan revised 05/16/11 only under the title "IV. Programs and Procedures on a SE Environmental Positive." The Refrigeration and Transportation within the Egg Rule are not conditional incidental to poultry houses SE status.

The rule required that egg producers with more than 50,000 laying hens to comply with the regulations listed in 21 CFR 118 by July 9, 2010. This firm has over (b) (4) chickens. As a result, it should have been in compliance for approximately 10 months. Non-review of records generated by the firm 10 months post Egg rule required compliance date points to operational deficiencies. Adequate review of requisite records per the Egg rule is necessary to control and prevent the spread of SE.

Discussion with Management:

Dr. (b) (6) stated that the observations as regards the SE Plan were errors and that he would have the SE Plan corrected. Complex Manager, Mr. Hasemann stated that he would ensure that all SE Prevention Plan required records generated at the firm are reviewed. See observations 1 & 2.

Related Exhibits:

Exhibit 1: Salmonella Prevention Plan revised 05/16/11 contains the listed inaccuracies and errors on the listed page numbers.

Exhibit 3: Fly Control Log not prepared per requirement of egg rule.

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Exhibit 4: Cooler monitoring Log not prepared per requirement of egg rule.

Exhibit 11 (b) (4) Fly Chart not prepared per requirement of egg rule.

Related Observation:

Observations 1, 2, & 3.

REFUSALS

(CMM)

There were no refusals during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

(KJK)

The close out meeting with FDA Investigators (Collins M. Mason, Brittany D. Phillips, Shaun M. Olson, Kevin E. Klommhaus, Lloyd N.M.I. Krutzfeldt, and I) was held on 05/19/2011. Misters David L. Hasemann, Complex Manager; (b) (6), Veterinarian; and (b) (6) (b) (6), Production Lead, were in attendance.

A four item FDA 483, *Inspectional Observations*, was issued to Mr. Hasemann. **Please refer to the Objectionable Conditions and Management's Response section** for further details regarding these items. The following items were verbally discussed with management:

- The firm's "Salmonella Prevention Program" references an "Egg Segregation and Re-Introduction SOP", **Exhibit 2**, which discusses egg segregation, sampling and egg re-introduction procedures when SE + environmental samples and egg samples occur. This SOP states if the firm has a positive egg result, the firm will continue to pack eggs on plastic, label pallet with a red tag and send to New Hampton. Dr. (b) (6) stated the red tag associated with the pallet would be blank and accompanying documents would not indicate in writing the status of the eggs. I informed management the positive SE eggs would need to be labeled according to the regulation. After reading 21 CFR 118.6 (f) aloud, Dr. (b) (6) stated he would incorporate this statement on the pallet and all accompanying documents.
- The firm provided us with the original "Salmonella Prevention Program" (SOP.OPS.PRD.8, Revised on 5.16.2011) when we requested a copy on May 16, 2011. On May 19, 2011, Dr. (b) (6) stated the firm prints out a new plan and the administrators sign it as needed. CSO

Brittany D. Phillips informed the firm there should only be one original document per revision.

- On May 17, 2011, Kevin E. Klommhaus, Lloyd N.M.I. Krutzfeldt, and I observed the following in house identified as 9 North:
 - About 300 ft from the front of the house, a brown looking substance was found on the lower metal railing of Row 1 (right side).
 - About 150-200 ft from the front of the house, a brown looking substance was found on the lower and middle metal railings of Row 7 (right side). **Please refer to Exhibit 13, photograph 1-2.**
 - While observing the brown looking substance within Row 7 of house 9 North, Mr. (b) (6) stated, "It's manure". I informed Mr. Hasemann that this issue could potentially lead to a cross contamination issue. In all instances, the brown substances are very close to the caged hens. **Please refer to the "VOLUNTARY CORRECTIONS" section within this report for further detail on this matter.**

- On May 18, 2011, Lloyd N.M.I. Krutzfeldt, observed the exterior wood joist (associated with the eave inlet of house 6 North) allowed for a three inch gap due to its current state. This was located on the North side of the house in between fan 5 and 6. **Please refer to Exhibit 13, photograph 3-4.** On May 19, 2011, Mr. Hasemann stated the exterior wood joist had been fixed; however this correction was not verified by the FDA.

- During this inspection, we noticed the firm's "Salmonella Prevention Program" (SOP.OPS.PRD.8, Revised on 5.16.2011) contained their Egg Production Farm number. The importance and safety of this number was conveyed to management and Dr. (b) (6) stated he would eliminate the number from the program document.

Management was provided with an Egg Rule Poster. At the close of the inspection, management was warned of their responsibilities to adhere to the Food, Drug and Cosmetic Act and the consequences for failing to adhere were discussed. Management stated they would respond in writing to KAN-DO describing their corrective actions within 15 business days.

SAMPLES COLLECTED (SMO)

The following environmental samples were taken during the EI of Sparboe Farm's, Inc. Vincent Layer location on 05/17/2011 and 05/18/2011 as per FACTS Assignment ID 1271365. Please refer to **Exhibit 8** for the layout of the barns (all barns are identical.)

Environmental samples were collected using the following methods:

Drag Swab – Pre-made drag swabs, 2 per bag, were moistened with (b) (5) Evaporated Milk inside of a sterile whirlpak bag. Using aseptic technique and sterile gloves, the pre-moistened swab was removed from the bag and used to drag along the lower level of the houses i.e. the manure pits. Post dragging each swab was immediately placed aseptically in an individual whirlpak bag after its string was cut. Approximately 2-3 tablespoons of evaporated milk was poured into the whirlpak bags and the bags were closed.

Environmental samples were collected as follows:

Sample INV665612 collected from house 9 North on 0517/11 consisted of 16 sub-samples.
Sample INV665613 collected from house 3 North on 0517/11 consisted of 16 sub-samples.
Sample INV665611 collected from house 7 South on 0518/11 consisted of 16 sub-samples.
Sample INV653849 collected from house 4 South on 0518/11 consisted of 16 sub-samples.
Sample INV653850 collected from house 1 South on 0518/11 consisted of 16 sub-samples.
Sample INV653851 collected from house 6 North on 0518/11 consisted of 16 sub-samples.

Subsample schedule is as follows:

| <u>Sub #</u> | <u>House Location</u> | <u>Sub #</u> | <u>House Location</u> |
|--------------|-----------------------|--------------|-----------------------|
| Sub 1 | Manure Row 1 left. | Sub 9 | Manure Row 5 left. |
| Sub 2 | Manure Row 1 right. | Sub 10 | Manure Row 5 right |
| Sub 3 | Manure Row 2 left. | Sub 11 | Manure Row 6 left. |
| Sub 4 | Manure Row 2 right. | Sub 12 | Manure Row 6 right |
| Sub 5 | Manure Row 3 left. | Sub 13 | Manure Row 7 left. |
| Sub 6 | Manure Row 3 right. | Sub 14 | Manure Row 7 right |
| Sub 7 | Manure Row 4 left. | Sub 15 | Manure Row 8 left. |
| Sub 8 | Manure Row 4 right | Sub 16 | Manure Row 8 right |

VOLUNTARY CORRECTIONS
(CMM)

There were two voluntary corrections made by the firm during the current EI. Both corrections are entered in FACTS under inspectional achievements for this inspection.

- On May 17, 2011, investigators Klier, Klomnhaus, & Krutzfeldt observed a brown looking substance identified by the firm's Production lead to be manure in multiple locations of the upper level of house 9 North. On May 19, 2011, investigator Krutzfeldt verified that the substance had been cleaned.
- On May 18, 2011, Investigator Krutzfeldt, observed the exterior wood joist (associated with the eave inlet of house 6 North) had a gap that allowed for the entry of non-native animals into the house. **Please refer to Exhibit 13, photograph 3-4.** On May 19, 2011, Mr. Hasemann stated the exterior wood joist had been fixed; this correction was verified by investigator Krutzfeldt.

ADDITIONAL INFORMATION
(KJK, KEK, LK, NV, written by KJK)

FIRM'S REQUEST TO TAKE INVESTIGATORS PHOTOS

Firm's management made a request to take photos of inspectors during the current inspection. Dr. (b) (6) stated that the firm had adopted FDA sampling procedures and the photos would be used for training, familiarization, and to better help the firm replicate lower level (manure pit) sampling procedures as practiced by the inspection team. Firm's request was forwarded to KAN-DO through DSM RP supervisor and approved. Per investigators request (as directed by KAN-DO) a copy of all photos taken by the firm was provided via email on 05/18/11. The master copy of these photos is attached as **Exhibit 12.**

ATTACHMENT B: INSPECTION/DATA COLLECTION TOOL FOR COMPREHENSIVE INSPECTIONS

Note: The following checklist is inserted in this EIR as directed in **FACTS assignment # 1258067**, 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:

(b) (5)

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(b) (5)

Recommendation for comprehensive inspection:

(b) (5)

IA Department of Inspection and Appeals was contacted to determine if any state quarantine or other issues were in place at this firm.

ATTACHMENTS

(CMM)

FDA 482, Notice of Inspection, issued to Mr. Mark D. Friedow, General Manager, Production dated 05/17/2011. 3 pages

FDA 482, Notice of Inspection, issued to Mr. David L. Hasemann, Complex Manager, dated 05/18/2011 (IDALS Investigator Neal Vaughn joined and withdrew from the inspection that day). 3 pages

FDA 483, Inspectional Observations, issued to Mr. David L. Hasemann, Complex Manager dated 05/19/2011. 2 pages

FDA 484, Receipt for Samples, issued to Mr. David L. Hasemann, Complex Manager dated 05/19/2011. 1 page

EXHIBITS COLLECTED

(CMM)

| | | |
|-----------|--|----------|
| Exhibit 1 | Salmonella Prevention Program revised 5.16.2011 | 25 pages |
| Exhibit 2 | Egg Segregation and Re-Introduction SOP | 5 pages |
| Exhibit 3 | Fly Control Log | 11 pages |
| Exhibit 4 | Biosecurity Policy with Exterminator | 4 pages |
| Exhibit 5 | Poultry Flock ages by House | 2 pages |
| Exhibit 6 | Sample NPIP certificate for pullets | 1 page |
| Exhibit 7 | Manufacturing design Operations summary | 1 page |
| Exhibit 8 | Poultry house upper level house extermination plan | 1 page |
| Exhibit 9 | Organizational Chart | 1 page |

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|------------|---|---------|
| Exhibit 10 | Cooler Monitoring log | 1 page |
| Exhibit 11 | (b) (4) Fly Chart | 1 page |
| Exhibit 12 | Master CD of Photos taken by the firm | 1 page |
| Exhibit 13 | Photo Exhibit | 4 pages |
| Exhibit 14 | Master CD of Photos taken during the Inspection | 1 page |
| Exhibit 15 | Barn Cleaning Checklist | 1 page |

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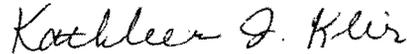
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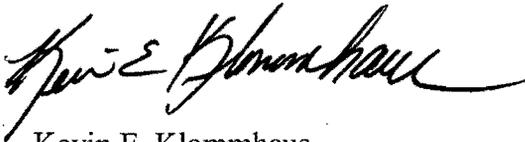
EI End: 05/19/2011



Collins M. Mason



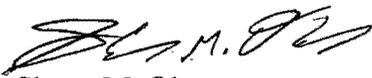
Kathleen J. Klier



Kevin E. Klomhaus



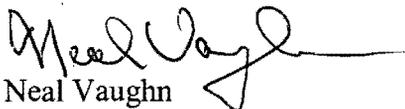
Lloyd Krutzfeldt



Shaun M. Olson



Brittany D. Phillips



Neal Vaughn