

Establishment Inspection Report

Sunbest Papetti Farms
Villisca, IA 50864

FEI: **3008716107**
CST AAH EI Start: 06/13/2011
EI End: 06/13/2011

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SUMMARY
(Written by CST)

The initial targeted inspection of this Shell Egg Producer was conducted pursuant to **FACTS assignment # 1271788, Operation ID # 5350307**, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA Concurrence # 2011012601, dated 02/08/2011, and the KAN-DO FY 11 work plan. The inspection followed the guidance given in the assignment, and requirements of the "New Egg Rule" written in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. The inspection was pre-announced to the firm's Complex Manager, Mr. Gerald R. Fisher on Thursday 06/09/2011.

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The main objectives of the inspection were to:

- Assess compliance with 21 CFR 118 including evaluation of the firm's SE prevention plan, egg laying operation, environmental monitoring and response to positive results, and documentation.
- Conduct inspections of egg laying facilities to determine if the firm is practicing adequate measures to prevent SE contamination of eggs and egg production areas.

Additionally, the inspection was to determine individual responsibility for the firm's SE prevention plan, who owns the layer hens, and who packages the eggs. Documents reviewed during the inspection include the firm's written SE Prevention Plan, Biosecurity Plan, pullet receiving records, pest control records, environmental test result records, egg testing records, refrigeration logs, cleaning and disinfecting procedures, training logs and house maintenance logs.

This was the first FDA inspection of Sunbest Papetti Farms located at 2975 265th Street, Villisca, IA. The inspection found that the firm has a written SE prevention plan to cover its production complexes. The firm's bio-security plan is incorporated into their SE Prevention Plan. We conducted assessments in 2 Layers; 8 and 9. Other layers were not entered due to the presence of SE and/or MS/MG. Please see corresponding sections for more details.

At the conclusion of the inspection, there was no FDA 483, Inspectional Observations issued to the firm, although there were two discussion items regarding administrator responsibility and administrator signature on the firm's SE/Biosecurity Plan. Please refer to the General Discussion with Management section for more details.

No samples were collected. There were no refusals encountered during this inspection.

[REDACTED] (b) (3) (A) Investigator Hoopes provided RFR guidance to management.

At the close of the inspection, management was warned of the firm's responsibility to adhere to the FD&C Act and penalties were explained.

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

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ADMINISTRATIVE DATA

(Written by AAH)

Inspected firm: Sunbest Papetti Farms
Location: 2975 265th St
Villisca, IA 50864
Phone: 712-826-2688
FAX: 712-826-2692
Mailing address: 2975 265th St.
P.O. Box 8
Villisca, IA 50864

Dates of inspection: 6/13/2011
Days in the facility: 1
Participants: Candace S Tucker, Investigator
Andrew A. Hoopes, Investigator

Upon arrival we presented our credentials and issued an FDA 482, Notice of Inspection, to Gerald (Gerry) R. Fisher, Complex Manager. Mr. G. Fisher stated he was the most responsible person at this facility on a day to day basis.

This report was written by Investigators Tucker and Hoopes. The author of each section is directly below the section heading.

HISTORY

(Written by AAH)

The legal name of the firm is Sunbest Papetti Farms. This firm operates as a subsidiary of Sunbest Farms Inc, located at 2265 East Pridemore, Lincoln, AR 72744, which is also their corporate office. It was reported that the above firms are Co-Owned by Dick Latta and Arthur Papetti. This facility began construction in 1994 and began housing birds in 1995.

The firm reported (b) (4) full time employees. Hours of operation are as follows:

Processing: (b) (4)

Production: (b) (4)

(b) (4)

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This is the initial inspection of Sunbest Papetti Farms. The firm has not been involved in any recalls.

INTERSTATE COMMERCE/JURISDICTION

(Written by AAH)

This firm buys (b) (4). The firm generally purchases the pullets from (b) (4), but is currently getting them from (b) (4) located at (b) (4). The pullets are hauled in by (b) (4) located out of (b) (4). The houses on this facility were originally built to house (b) (4) birds. Under UEP standards the firm currently houses (b) (4) birds in each house. The firm reports having an approximately (b) (4)%-(b) (4)% production rate. They are currently producing approximately (b) (4) eggs/(b) (4) for processing and (b) (4) egg/(b) (4) which are being diverted under their SE program. One house in not in production as it was currently re-housed with new birds. Pullet procurement documents were reviewed and followed NPIP guidelines.

The firm is currently using two breaker facilities. All the SE diverted eggs are being sent to (b) (4) and the rejected eggs from grading are being sent to (b) (4). The graded and processed eggs are packaged under (b) (4) brands for (b) (4) located out of Kansas City, MO and (b) (4) (b) (4) brand for (b) (4). Approximately (b) (4)% of the graded eggs are packaged under the (b) (4) brand and the other (b) (4)% are for (b) (4) brand. Approximately (b) (4)%-(b) (4)% of all packaged eggs are shipped outside the state of Iowa. The packaging is done for one customer, (b) (4) located out of (b) (4). Outbound shipping of the processed eggs is arranged and handled by their customer.

FMD 145/OTHER POST INSPECTIONAL CORRESPONDENCES

The FMD 145 should be sent to:

Gerald R. Fisher, Complex Manager
2975 165th St.
P.O. Box 8
Villisca, IA 50864

Other post inspectional correspondences should be sent to:

Dick Latta, Managing Partner/Co-Owner
2265 East Pridemore
P.O. Box 5
Lincoln, AR 72744

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(Written by AAH)

Gerald R. Fisher, Complex Manager: Mr. G. Fisher is the most responsible person at this facility on a day to day basis. Mr. G. Fisher began working for Sunbest in 1995 and became Complex Manager in Sept of 2001. As Complex Manager he is responsible for all operations at this facility including supervising all production, purchasing, and personnel. Mr. G. Fisher stated he has full hire and fire authority. Mr. G. Fisher stated he reports to Dick Latta, Managing Partner/Co-Owner. Mr. Latta is the most responsible person. Mr. Latta is located at the corporate office located at 2265 East Pridemore, Lincoln, AR 72744. An organizational chart was collected and attached as **Exhibit 1**, which explains more of the reporting structure. Mr. Fisher was present throughout the entire inspection and provided much of the information in this report.

Darrin E. Fisher, Production Manager: Mr. D. Fisher oversees the operations of the 10 chicken houses. This includes the care of the birds, organization of the employees, and maintenance. Mr. D. Fisher also oversees the pest control operations which are handled within this facility, which include mainly bait stations (mice) and Fly card (flies). Mr. D. Fisher started working for Sunbest in 1998 and became Production Manager in Sept. 2001. Mr. D. Fisher reports to Mr. G. Fisher. Mr. Fisher was present throughout the entire inspection and provided much of the information in this report.

FIRM'S TRAINING PROGRAM

(Written by CST)

Training for each employee is completed initially, then (b) (4) each (b) (4) and also on an as needed basis in the case of re – training. Employees are trained initially on their specific function and each employee is also trained in areas such as SQF (Safe Quality Food), HAACP, UEP (United Egg Producers) guidelines, egg quality and grading and hygiene and bio-security. Attached to this report as **exhibit 2**, is the June 2010 training log.

MANUFACTURING/DESIGN OPERATIONS

(Written by CST)

Sunbest Papetti Farms produces approximately (b) (4) eggs per (b) (4). This location consists of a USDA monitored shell egg processing plant which is connected to the layer houses by a system of common egg conveyors. The firm's employees operate and maintain 10 layer houses. The company

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assigns (b) (4) employee (b) (4) to complete the (b) (4) required tasks. (b) (4), an employee can be assigned to (b) (4)

There are (b) (4) maintenance personnel employed by the firm. The maintenance department is located in the main building and personnel are called by barn employees as needed for repairs.

Dick Latta and Arthur Papetti are co-owners of Sunbest-Papetti Farms and own the land, houses and birds.

City water is the only water source utilized by the firm. Water is tested (b) (4) in (b) (4) I reviewed test results from July 28, 2010, with no objectionable observations noted.

Feed is purchased from (b) (4), located in (b) (4). Sunbest-Papetti Farms own the trucks used to haul the purchased feed. These trucks are dedicated to the Sunbest-Papetti farm only.

The firm cleans out the manure pits (b) (4). The firm recently built a manure stock pile hut for the SE positive manure to hold during the summer when they need to clean an SE positive house. The firm sells their manure to approximately (b) (4) customers and they try to stay within a (b) (4) mile radius of their firm. (b) (4) people work on manure pits. (b) (4) runs the skid loader while the other (b) (4) drive manure spreader.

Dead birds are placed in trash cans inside each house and are emptied into the dumpster on (b) (4), (b) (4), and (b) (4) just before (b) (4) picks up. This is to deter rummaging and to be neighborly.

MANUFACTURING CODES

(Written by AAH)

The firm puts a label on the boxes of eggs which includes the (b) (4). The label also includes the packaging date in Julian form, the expiration date, which is 30 days past the packaging date, and the (b) (4). The (b) (4) which of the (b) (4) (b) (4)

SALMONELLA ENTERITIDIS/BIOSECURITY PLAN

(Written by CST)

The firm provided a copy of their SE/Biosecurity Plan, version 5, created 4-5-2011. The document has been attached to this report as **exhibit 4**. The plan covers the following:

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- Traffic Control
- Equipment and Vehicles
- Animals
- Farm Sanitation
- Pest Control
- Enhanced Biosecurity Practices
- Poultry Disease rapid response plan
- Company Quarantine Requirements
- Contract Grower and Family Restriction
- Procedure for Feed Deliveries
- Procedure for Manure Disposal
- Procedure for Mortality Disposal
- Refrigeration of eggs

The plan was written by a group of employees of the firm. Mr. Gerald Fisher, Mr. Darrin Fisher and Mr. Manuel Zavala (Plant manager and SQF practitioner) co-wrote the plan. The plan was sent for review to (b) (7)(C) who is an employee of (b) (4) one of the firm's customers.

The plan and documents required by the plan were reviewed to assess compliance with the final egg rule, 21 CFR 118, and the firm's written plan. No objectionable observations were noted during this review in that pest/fly control documents were completed and contained all required information. Rodent Indexes were calculated and corrective actions were in place for indexes above 2. Fly cards are collected (b) (4) counted and recorded. Documents recording bait dates and the bait used were reviewed with no objectionable observations. Environmental sampling and testing is completed according to the rule, egg diversion and testing were compliant with 21 CFR 118. Cleaning and disinfecting of SE positive houses after depopulation also maintained compliance.

The firm uses a pest consultant (b) (4) located at (b) (4) (b) (4). The firm follows guidance provided by the consultant.

Eggs are refrigerated at the (b) (4). The cooler temperature is checked (b) (4) by process personnel and recorded. Each (b) (4) processing is complete, an inventory of cooler contents is completed and the amount of each grade (Jumbo, Ex-Large, Large etc) in cases is recorded. Temperatures of shipping vehicles are checked prior to loading eggs onto the vehicle.

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SALMONELLA ENTERITIDIS POSITIVE ENVIRONMENTAL SAMPLES

(Written by CST)

The firm uses (b) (4) for all of their environmental/egg testing. The firm received positive environmental samples from barn number 9 in September 2010. When the positive environmental was received, the firm sent another sample to (b) (4) located at (b) (4) (b) (4). The second sample was used as a (b) (4) sample.

As environmental testing continued, other houses became environmentally positive for SE. The firm began to divert immediately following the environmental positive sent to (b) (4). This positive environmental was discovered around the time the firm begins to clean out barn manure pits. As barns were tested and the firm received positive environmental results in other barns, the firm began an investigation. Although the firm has no investigation conclusion as to the root cause of barn nine becoming environmentally positive, the investigation did conclude the skid loader utilized to remove manure from the manure pits is the probable root cause for the additional houses testing environmentally positive. A review of the firm's positive test result dates and dates of diversion along with egg testing found the firm to be in compliance with the New Egg Rule, 21 CFR 118.

The firm's corrective action was a review of the SE Plan, adding a more intense cleaning and disinfection of the skid loader between houses and re – training the skid loader operator of the importance of cleaning and disinfecting the equipment. Employees follow the written plan in that barn employees move from positive barn to positive barn if necessary, but do not move from positive to a negative barn. This rule applies to all employees including barn workers, maintenance and manure pit workers.

Barn 9 has been depopulated, cleaned and disinfected, re – tested environmentally and repopulated after receiving a negative environmental test result. Other positive barns are 1, 3, 4, 7 and 10. **Barn 1** has been converted back to table egg production after receiving the final negative egg test on 03/04/2011, **barn 3** egg production continues to be diverted and has received one negative egg test on 06/10/2011, **barn 4** egg production continues to be diverted and has received three negative egg tests with the last negative received on 06/03/2011. **Barn 7** has been converted back to table egg production after 4 negative egg tests with the last one received on 04/15/2011 and **barn 10** has also been converted back to table egg production with the receipt of the fourth negative egg test on 01/10/2011.

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MYCOPLASMA SYNOVIAE

(Written by CST)

I called Dr. Schmidt (State Veterinarian for the state of Iowa) during a previous inspection to clear up some confusion about the reportable diseases and reporting responsibility. Dr. Schmidt does get monthly reports concerning MS and MG from laboratories in the state and determines the need to follow up positives from those reports. Dr. Schmidt also stated he has access to the test result database at the Veterinary Diagnostic Laboratory, so he is able to look up any results of concern. He also stated he did not want each and every form containing positive MS and/or MG results to come to his office as the viruses are so wide spread. Dr. Schmidt stated 60 to 75% of layer flocks have either had these virus isolated from samples, or have antibodies to the viruses. Dr. Schmidt further explained the viruses cause no harm to humans. I asked Dr. Schmidt for guidance regarding these two viruses as it pertains to assessing houses on site when one or more houses are positive for MS or MG. Dr. Schmidt stated assessments could be accomplished by moving from negative to positive house regardless of age of birds, then wait 72 hours between farms.

COMPLAINTS

(Written by CST)

The firm maintains a complaint file. Complaints were reviewed and contained appropriate investigations and corrective actions.

RECALL PROCEDURES

(Written by CST)

The firm has a recall procedure and conducts mock recalls (b) (4). A copy of a mock recall conducted on 06/02/2011 has been attached to this report as **exhibit 3**.

GENERAL DISCUSSION WITH MANAGEMENT

(Written by CST)

Those present for the closing discussion were Mr. Gerald and Mr. Darrin Fisher. There was discussion that the copy of the SE plan we received upon request was not signed. Mr. Gerald Fisher stated he would sign all plans printed for review. It was also discussed although Mr. Gerald Fisher had verified the plan; it was not documented who is responsible for the contents as plan administrator. Mr. Fisher immediately added his name as the plan administrator.

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

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ADDITIONAL INFORMATION

(Written by CST)

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

(b) (5)

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VOLUNTARY CORRECTIONS

(Written by CST)

Mr. Gerald Fisher signed his name to the plan appointing responsibility to himself as plan administrator.

EXHIBITS COLLECTED

- Exhibit 1: A copy of the firm's Organizational Chart, 1 page.
- Exhibit 2: A copy of the June 2010 employee training log, 1 page.
- Exhibit 3: A copy of the firm's mock recall performed on 06/02/2011, 3 pages.
- Exhibit 4: A copy of the firm's SE/Biosecurity Plan, version 5, dated 4-5-2011, 20 pages.

ATTACHMENTS

- A copy of the FDA – 482 Notice of Inspection, issued to Gerald R. Fisher on 06/13/2011.
- A copy of the assignment identified as 1271788

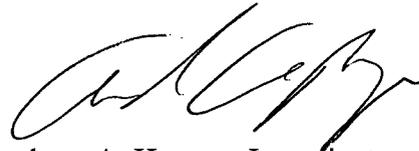
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Candace S Tucker, Investigator



Andrew A. Hoopes, Investigator