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SUMMARY

Targeted initial inspection of this shell egg producer was initiated per FY' 11 Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA Concurrence #2011012601 (FACTS assignment #1258067) and conducted in accordance with Division of Field Programs and Guidance memo dated February 3, 2011.

This inspection included a review of the firm's Salmonella Enteritidis (SE) Prevention Plan, a review of some of the firm's environmental testing results, and an evaluation of the firm's implementation of its rodent/pest control measures. It also included a walk-through of 4 layer houses and completion of Attachment A from assignment memo.

A close-out meeting was held with management on 04/12/2011. Minor sanitation issues were discussed. A Form FDA 483, Inspectional Observations, was not issued.

Establishment Inspection Report

CAL-MAINE FOODS, INC.

Lake Wales, FL 33898

FEI:

3008827877

EI Start:

04/12/2011

EI End:

04/12/2011

The firm is registered with the FDA's Shell Egg Producer Registration.

No samples were collected and there were no refusals.

ADMINISTRATIVE DATA

Inspected firm: CAL-MAINE FOODS, INC.
Location: 1803 TINDELL CAMP ROAD
Lake Wales, FL 33898
Phone: 863-439-0002
FAX: 863-439-0012
Mailing address: PO Box 9021
Winter Haven, FL 33883

Dates of inspection: 4/12/2011
Days in the facility: 1
Participants: Jason D. Tenney, Investigator
Lisa A. Warner, Investigator

I, Investigator Jason D. Tenney, acted as lead for this inspection and wrote this entire inspectional report. I was accompanied by Investigator Lisa A. Warner.

On 04/12/2011, we presented our credentials and issued a Form FDA 482, Notice of Inspection, to Mr. Thomas J. Ford, General Manager, who stated that he was the most responsible person at the firm.

On 04/12/2011, we held a close-out meeting with Mr. Ford, Ms. Tammy D. Willis, Compliance and Safety Manager, Ms. Emily M. Latowski, Compliance Manager, Mr. Kevin M. Davis, Operations Manager, Mr. Christopher K. Myers, Operations Manager, and Mr. William J. Stevens, Complex Manager (b) (4) farm). Minor sanitation issues were discussed. An FDA 483 was not issued.

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HISTORY

This was the first FDA inspection of Cal-Maine Foods, Inc. in Lake Wales, FL. Cal-Maine Foods, Inc. owns several egg laying farms throughout the United States and its home office is located in Jackson, MS. This farm was purchased by Cal-Maine Foods in 2005 and is incorporated in Mississippi. It was rebuilt in 2004 after being devastated by Hurricane Charlie. Hours of operation are (b) (4) days/year with office hours of 7:00am – 4:00pm, Monday through Friday.

Post Inspectional Correspondence should be addressed to:

Mr. Thomas J. Ford

Cal-Maine Foods, Inc.

PO Box 9021

Winter Haven, FL 33883

The firm is registered with the FDA.

INTERSTATE COMMERCE

According to Mr. Kevin M. Davis, Operations Manager, most pullets (young hen, less than (b) (4) weeks old, that has not yet begun to lay eggs) are received from contract farms within Florida including (b) (4) and (b) (4). However, the firm may receive pullets from company owned farms in (b) (4) and (b) (4).

All shell eggs for the table market are sold within the state of Florida. This accounts for approximately (b) (4) of all eggs produced. Major customers include (b) (4) and (b) (4). Approximately (b) (4) of all eggs produced are sold to (b) (4) an egg breaker facility in (b) (4).

JURISDICTION

Cal-Maine Foods, Inc. manufactures, and distributes (b) (4) wholesale, shell eggs for the table market, which are regulated by the FDA under authority of the Public Health Service Act.

Mr. Davis reported an approximate average annual sales volume of (b) (4).

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Thomas J. Ford, General Manager, affirmed that he is the most responsible individual at the firm and has the authority to prevent, detect, and correct violations of current regulations. Mr. Ford reports to Mr. Christopher K. Myers, Operations Manager (Southeast Region), and Mr. Myers reports to Mr. Bob Scott, V.P. of Operations.

We were accompanied by Mr. Ford, Mr. Myers, Mr. Robin M. Neuhofer, Production Manager (b) (4), Ms. Tammy D. Willis, Compliance and Safety Manager, Mr. William J. Stevens, Complex Manager (b) (4), and Ms. Emily M. Latowski, Compliance Manager, at various times throughout the inspection.

Mr. Davis identified and provided a copy of Cal-Maine Foods, Inc., Lake Wales organizational chart (**Exhibit #1**). Also attached is Cal-Maine Foods, Inc. Southeast Region organizational chart provided at a previous Cal-Maine Foods, Inc. inspection.

FIRM'S TRAINING PROGRAM

Mr. Davis attended a training seminar on FDA's Final Egg Rule in June 2010. The seminar was conducted by Dr. Ryn McDonald, Director of Food Safety and Administrator of SE Prevention Plans for all Cal-Maine owned farms. He has been with the company for 5 years.

MANUFACTURING/DESIGN OPERATIONS

b5 & b7e

This firm has no inspectional history. It has had no previous evidence of public health concern nor has it had an order of diversion.

The farm has (b) (4) houses. A "Google maps" satellite photo of the farm which shows the lay-out of the houses was identified and provided by Ms. Willis (**Exhibit #2**). Each house has an average of (b) (4) hens ((b) (4)). At the time of our inspection, all houses were full and, according to Mr. Davis, there were approximately (b) (4) hens at the farm. Approximately (b) (4) dozen eggs are produced (b) (4) and (b) (4) of all eggs produced are sold to an egg breaker facility ((b) (4)).

Mr. Davis reported that the firm has no current SE positive houses and that they have never had SE positive results detected in environmental monitoring. He stated that the firm conducts environmental testing at the 40-45 week flock age specified in the egg rule and after induced molting. The firm participates in SQF and GFSI certification.

b5 & b7/e

The farm is registered according to the Egg Rule. Its 'P' number, which is the number given to the firm by the USDA, is 1809. All birds are owned by Cal-Maine Foods, Inc. and all eggs are packed by Cal-Maine Foods, Inc., Lake Wales, FL.

We reviewed the firm's SE Prevention Plan and noted that it covers all areas as required by 21 CFR 118.4.

All pullets are received when they are ^{(b) (4)} weeks of age, after negative SE environmental testing at the pullet farm is confirmed. According to Mr. Davis, all birds at this firm have been vaccinated to prevent SE.

The firm uses ^{b4} for rodent monitoring inside and outside all houses. We reviewed the firm's Rodent Pest Logs, Rodent Indexing forms, corrective actions sheets, and Visual Rodent evaluation forms for December 2010 through March 2011 and noted no deficiencies. All stations observed were functional and accessible. We did not observe any rodents during our inspection.

The firm monitors for flies with ^{(b) (4)}. The ^{b4} in designated areas of each house. ^{b4}

^{b4} We reviewed the firm's fly monitoring logs for December 2010 through March 2011 and noted no deficiencies. We did not observe an over-abundance of flies during our inspection.

According to Mr. Davis, environmental sampling is conducted when hens are between 40-45 weeks of age and 4-6 weeks after induced molting. We reviewed the firm's sampling records for all houses and noted no discrepancies. The firm has had no positive sampling results.

On 04/12/2011, we inspected layer houses 1-4. We observed minor sanitation issues including an approximate 2" gap on the left side of the exit door at the front of house 1 and an approximate 2" diameter hole at the bottom left corner at the back of the pit in house 3. These were verbally discussed with management at the close-out meeting.

MANUFACTURING CODES

Manufacturing codes are stamped onto egg cartons and may consist of a Use By or Best By date. All include the Julian Date and "P1809", which is the firm's USDA number.

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COMPLAINTS

The firm maintains a written complaint procedure and, according to Mr. Davis, has never had a food safety related complaint.

RECALL PROCEDURES

The firm maintains a written recall procedure and, according to Mr. Davis, has never had to recall any eggs. Mock recalls are conducted (b) (4) with the last mock recall having been completed on 02/02/2011.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

On 04/12/2011, a close-out meeting was held with Mr. Thomas J. Ford, General Manager. Also present at the meeting were Mr. Kevin M. Davis, Operations Manager, Mr. Christopher K. Myers (Southeast Region), Mr. William J. Stevens, Complex Manager (b) (4), Ms. Emily M. Latwoski, Compliance Manager, and Ms. Tammy D. Willis, Compliance and Safety Manager. We discussed holes found in houses 1 and 3. Mr. Davis said the firm was in the process of wrapping plastic tarp around the pits of all houses and they have not completed house 3 yet. He also said they were going to look into better sealing the door in house 1. A Form FDA 483, Inspectional Observations, was not issued.

REFUSALS

There were no refusals.

ADDITIONAL INFORMATION

Per assignment, I pre-announced this inspection.

SAMPLES COLLECTED

No samples were collected.

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EXHIBITS COLLECTED


- Copy of Cal-Maine, Lake Wales organizational chart (1 page)
- Google maps satellite view of firm (1 page)

ATTACHMENTS

- Form FDA 482, Notice of Inspection, dated 04/12/2011
- Copy of Cal-Maine Foods, Inc. Southeast Operations organizational chart (1 page)
- FACTS assignment # 1258067 sheet (3 pages)



Jason D. Tenney, Investigator



Lisa A. Warner, Investigator