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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. It 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 6 layer houses and completion of Attachment A from assignment memo.

The inspection revealed the firm produces eggs for the table market and is implementing an SE Prevention Plan. A Form FDA 483, Inspectional Observations, was issued to Mr. Joshua R. Moore,

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General Manager, regarding failure to prevent stray animals from entering layer houses. He agreed with the observation and promised corrections and a response.

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: 707 NW HILLANDALE GLN  
LAKE CITY, FL 32055  
Phone: 386-397-2641  
FAX: 386-397-2338  
Mailing address: 247 NW Hillandale Glen  
Lake City, FL 32055

Dates of inspection: 4/5/2011, 4/6/2011  
Days in the facility: 2  
Participants: Jason D. Tenney, Investigator  
Lindsay R. Mundy, Investigator

I, Investigator Jason D. Tenney, acted as lead for this inspection and wrote this entire inspectional report. I was accompanied by Investigator Lindsay R. Mundy.

On 04/05/2011, we presented our credentials and issued a Form FDA 482, Notice of Inspection, to Mr. Joshua R. Moore, General Manager, who stated that he was the most responsible person at the firm. We also presented our credentials to Mr. Kenneth E. Carver, Operations Manager.

On 04/06/2011, we issued a Form FDA 483, Inspectional Observations, to Mr. Moore. He agreed with the observation and promised correction.

**HISTORY**

This was the first FDA inspection of Cal-Maine Foods, Inc. in Lake City, FL. Mr. Moore explained that Cal-Maine Foods, Inc. owns several egg laying farms throughout the United States and its home office is located in Jackson, MS. The Lake City farm is incorporated in Mississippi and was built sometime in the 1970s. Hours of operation are (b) (4) days/year with

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office hours of 8:00am – 5:00pm, Monday through Friday. The Lake City farm has approximately (b) (4) employees.

**Post Inspectional Correspondence** should be addressed to:

Mr. Joshua R. Moore

247 NW Hillandale Glenn

Lake City, FL 32055

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

**INTERSTATE COMMERCE**

According to Mr. Moore, 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) (b) (4) and (b) (4). However, the firm may receive pullets from company owned farms in (b) (4) and (b) (4).

Eggs produced on the farm are either distributed with company trucks or picked up by customers. (b) (4) of all shell eggs are shipped within the state of Florida with approximately (b) (4) of all eggs shipped to (b) (4). Major customers include (b) (4) and (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. According to Mr. Moore, (b) (4) of all eggs produced are sold to egg product facilities.

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

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

Mr. Joshua R. Moore, 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. Moore reports to Mr. Christopher K. Myers, Operations Manager, and Mr. Myers reports to Mr. Bob Scott, V.P. of Operations.

We were accompanied by Mr. Moore, Mr. Carver, Mr. Myers, Mr. Glenn H. Boyette, Compliance Manager, Mr. Jeffrey P. Hull, General Manager ((b) (4)), Mr. Jonathan D. Gray, Complex

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Manager (b) (4), Mr. John H. Small, Production Manager (b) (4), and Mr. Richard F. Elmore, Production Manager throughout the inspection. Ms. Emily M. Latowski, Compliance Manager, was present during SE Prevention Plan review.

Mr. Moore identified and provided a copy of Cal-Maine Foods, Inc. Southeast Operations organizational chart (**Exhibit #1**).

**FIRM'S TRAINING PROGRAM**

As administrator of the firm's SE Prevention Plan, Mr. Moore has 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 also has a degree in Poultry Science and has been with the company for 10 years.

**MANUFACTURING/DESIGN OPERATIONS**

**Attachment A**

*Section I: Information for assessing future inspectional priority*

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. I printed a "Google maps" satellite photo of the farm which shows the lay-out of the houses (**Attachment**). Each house has an average of (b) (4) hens. At the time of our inspection, <sup>b4</sup> houses were empty and, according to Mr. Moore, there were (b) (4) hens at the farm. Approximately (b) (4) eggs are produced daily and <sup>(b)(4)</sup> of all eggs produced are sold to egg product facilities.

Mr. Moore 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.

*Section II: Inspectional Tool*

The farm is registered according to the Egg Rule. Its 'P' number, which is the number given to the firm by the USDA, is 1310. All birds are owned by Cal-Maine Foods, Inc. and all eggs are packed by Cal-Maine Foods, Inc., Lake City, FL.

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We reviewed the firm's SE Prevention Plan and noted that it covers all areas as required by 21 CFR 118.4. Mr. Moore identified and provided a copy of this plan. Some pages are noted as exhibits below.

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. Moore, all birds at this firm have been vaccinated to prevent SE.

The firm uses (b) (4) 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 (**Exhibit #2** is an example of the firm's Rodent Pest Log). All stations observed were functional and accessible. We did not observe any rodents during our inspection.

The firm monitors for flies with (b) (4) (b) (4) are observed for (b) (4) in designated areas of each house.

(b) (4) If the monitoring finds the (b) (4) (b) (4) We reviewed the firm's fly monitoring logs for December 2010 through March 2011 and noted no deficiencies (**Exhibit #3** is an example of the firm's Fly Monitoring Log). We did not observe an over-abundance of flies during our inspection.

According to Mr. Moore, 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 houses 6, 7, 14, and 16 and noted no discrepancies. The firm has had no positive sampling results.

On 04/05/2011, we inspected houses 6, 3, 14, 17, 8, and 5. All houses appeared to be relatively well kept. Eggs are brought to the processing area on (b) (4) through an enclosed and (b) (4) running perpendicular to all houses. We observed a black animal, appearing to be a cat, in the hallway between houses 1 & 2 [**FDA 483 Observation #1**]. We also noted 12 clusters of feces, appearing to be larger than a rodents', on walk ways between rows of empty cages in house 5 (this house had been depopulated due to age of hens). Mr. Moore confirmed the animal to be a cat and promised to amend his SE Prevention Plan to account for any stray animals.

We discussed with Mr. Moore the absence of a policy to clean any equipment used in a SE positive house before the positive result was found. He agreed that it may be important and would discuss it with his corporate office.

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**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 "P1310" which is the firm's USDA number.

**COMPLAINTS**

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

**RECALL PROCEDURES**

The firm maintains a written recall procedure and, according to Ms. Latowski, has never had to recall any eggs. Mock recalls are conducted on a (b) (4) basis. The most recent was completed in January 2011.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

On 04/06/2011, a close-out meeting was held with and Form FDA 483, Inspectional Observations, issued to Mr. Joshua R. Moore, General Manager. Also present at the meeting were Mr. Kenneth E. Carver, Operations Manager, Mr. Christopher K. Myers, Operations Manager, Mr. Richard F. Elmore, Production Manager, and Mr. Glenn H. Boyette, Compliance Manager. The following observation was discussed:

**Observations listed on form FDA 483**

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**OBSERVATION 1**

Stray animals are not prevented from entering poultry houses.

Specifically, on 04/05/2011 we observed a black stray animal, appearing to be a cat, in the hall between chicken houses 1 & 2 where eggs were being held on belts for transport to the processing area. We also observed 12 clusters of animal feces on walkways between rows of empty chicken cages in house 5. The feces ranged from 1"-3" in length and 1/2"-1" in diameter. Further, your SE Prevention Plan does not include the biosecurity measure of preventing "cats, and other animals from entering poultry houses" as stated in 21 CFR 118.4(b)(4).

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Reference: 21 CFR 118.4(b)(4)

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**Discussion with Management:**

Management agreed with this observation and had already amended the SE Prevention Plan to include monitoring for cats. According to Mr. Moore, clean-up of feces in house 5 was started the evening before and a trap had been set for the cat.

**REFUSALS**

There were no refusals.

**GENERAL DISCUSSION WITH MANAGEMENT**

I warned Mr. Moore that the item listed on the Form FDA 483 was our observation of a deviation from current regulations and we are not the final authority regarding decisions made by the FDA on this inspection. I explained that it is his responsibility to assure compliance with all regulations and legal sanctions available to the FDA may include warning letters, seizure, injunction, civil money penalties and/or prosecution, if he does not correct any serious violations.

I requested that he send a written response to the item listed on the Form FDA 483 to Ms. Emma R. Singleton, District Director within 15 business days. He agreed to do so.

**ADDITIONAL INFORMATION**

Per assignment, I pre-announced this inspection.

**SAMPLES COLLECTED**

No samples were collected.

**VOLUNTARY CORRECTIONS**

The firm has amended its SE Prevention Plan to include monitoring for stray animals, including cats.

**EXHIBITS COLLECTED**

- 1) Copy of organizational chart for Cal-Maine Foods, Inc. Southeast Region (1 page)
- 2) Copy of a blank Rodent Pest Log (1 page)
- 3) Copy of a blank Fly Monitoring Log (1 page)

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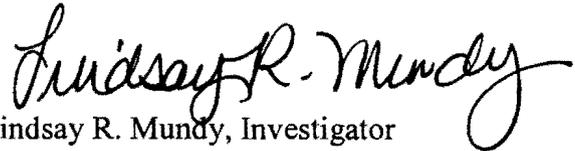
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**ATTACHMENTS**

- Form FDA 482, Notice of Inspection, dated 04/05/2011
- Form FDA 483, Inspectional Observations (1 page)
- Printout of Google Maps satellite image of firm (1 page)
- FACTS assignment # 1258067 sheet (3 pages)



Jason D. Tenney, Investigator



Lindsay R. Mundy, Investigator