

Establishment Inspection Report

Cal-Maine Farms, Inc.
Edwards, MS 39066

FEI: **3004327090**
EI Start: 05/31/2011
EI End: 06/02/2011

SUMMARY (AKW)

This preannounced, targeted egg safety inspection of a shell egg producer was conducted in accordance with NOL-DO FY'11 work plan per FY'11 Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, amended February 8, 2011, DFPG Assignment #11-04, ORA Concurrence #2011012601 and FACTS #1258067. The turbo number is 260625.

The previous inspection of this facility, dated 11/29/99, was indexed as in compliance. The current inspection focused on the firm's *Salmonella Enteritidis* (SE) plan which included procurement of pullets that are SE monitored, biosecurity measures, rodent/ pest control measures, cleaning and disinfecting measures, adequate refrigeration of shell eggs, environmental and egg sampling/testing program, and a review of the firm's environmental testing results.

Separate inspectional assignments were issued for Complex I (FEI #3004327090) & II (FEI #3004327968). This complete report encompasses descriptions, observations, and deficiencies noted inclusively for both complexes. A separate summary will be entered to satisfy Turbo and FACTS for Complex 2 (FEI #3004327968).

At the time of preannouncement, it was determined that these inspections would be conducted jointly due to same firm management and SE Prevention plan. It should be noted that, per the assignment, only one FDA-483 was issued for Complex I, although both complexes operate under the same SE Prevention plan. An FDA-483, List of Inspectional Observations was issued to firm management denoting the following discrepancy: failure to have written procedures that address egg testing for *Salmonella Enteritidis* following a positive environmental test result. Warnings were given to management at the close of the inspection including information concerning untitled letter, warning letter, and other sanctions available to FDA. Firm management promised to correct and submit a written response to NOL-DO. No samples were taken and no refusals were encountered. (b) (3)

All FDA correspondence to the firm (Edwards, MS) should be addressed as follows: **Cal-Maine Foods, Inc., Mr. Robert Wilford (Wil) Webb, III, Director of Production, P.O. Box 168, Edwards, MS 39066.**

All official FDA correspondence to the corporate office should be addressed to: **Cal-Maine Foods, Inc., Mr. Fred Adams, Jr., Chairman of Board, 332 Woodrow Wilson Ave., Jackson, MS 39209.**

ADMINISTRATIVE DATA (AKW)

Inspected firm: Cal-Maine Foods, Inc.

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Location: Complex 1- 3280 Adams Lane, Complex 2- 2695 Adams Lane
Edwards, MS 39066
Phone: 601-852-2015
FAX: 601-852-8225
Mailing address: P.O. Box 168
Edwards, MS 39066
Dates of inspection: 5/31/2011, 6/1/2011, 6/2/2011
Days in the facility: 3
Participants: Amanda K. Willey, Investigator
Sidney M. Smith, Investigator
Wayne S. Fortenberry, Investigator

Investigators Fortenberry, Smith, & Willey wrote parts of the inspectional report. Each section was written and **is** identified by the investigators initials.

Prior to conducting this inspection, a flock health status letter was obtained from the Mississippi Board of Animal Health for the Cal-Maine facility (Edwards, MS) stating that the farm was not under any disease quarantine. This is included as [Attachment A](#).

INDIVIDUAL RESPONSIBILITY & PERSONS INTERVIEWED (SMS)

On 05/26/11, Investigators Amanda K. Willey and I conducted a pre-announcement conference call with Mr. Robert Wilford Webb, III, Director of Production, to discuss the scope of the inspection and the firm's biosecurity policy for Cal-Maine Foods, Inc., Edwards, MS. At the beginning of the inspection on 05/31/11, the decision was made to inspect Complex I and 2 simultaneously. As a result, Investigators Fortenberry, Smith, and Willey exhibited our FDA credentials and issued an FDA-482, Notice of Inspection, separately for each complex, to Mr. Robert Wilford Webb, III, Director of Production. Per the assignment each facility (complex) was to be issued a separate FDA-482. Also present at this time, we met and displayed credentials to Mr. Ed Scott, General Manager, Ms. Ryn Laster McDonald, Ph.D., Director of Food Safety, and Mr. William Ward Field, Compliance Manager. The above listed people provided relevant business and operational information that is contained in this report. Mr. Webb and Mr. Scott accompanied us during the inspection of Complex 1 and Complex 2.

It was noted that the firm requested that we sign Cal-Maine Foods, Inc. Production House Visitor Guidelines as per the firm's biosecurity program. The general guidelines section of the form stated that photographic equipment may not be used on the property. We informed Mr. Webb that not allowing photographs to be taken during this inspection would be considered a refusal. This statement was redacted by firm management. Copies of the redacted and signed forms are included as [Exhibit #1](#).

Mr. Webb provided a copy of the firm's management organizational chart as [Exhibit #2](#).

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Mr. Robert Wilford Webb, III, Director of Production, stated that he was the most responsible individual present at the firm on a daily basis. He stated that he is responsible for overseeing all operations at Complex 1 and 2. He demonstrated his responsibility by accepting the FDA 482s, Notices of Inspection, and FDA-483, Inspectional Observations, promising corrections, providing documents, and giving employees instructions that were followed without question. He has the duty, responsibility, and power to prevent, detect, and correct violative conditions. Mr. Webb stated that he is responsible for approximately (b) (4) of the firm's breeder and pullet operations and the egg production of complexes I & II. Mr. Webb has been employed at the firm for approximately 14 years. Mr. Webb stated that he reports directly to Mr. Jack Self, Vice President of Operations. Mr. Self is located at the corporate office at: 3320 West Woodrow Wilson Avenue, Jackson, MS.

Mr. Ed Scott, General Manager, stated that he is responsible for the marketing, distribution, and packaging of the eggs once they enter the processing areas of Complex I and II. Mr. Scott reports directly to Mr. Self. Mr. Scott was present for the close-out discussion and issuance of the FDA-483.

Ms. Ryn Laster McDonald, Ph.D., Director of Food Safety, was present for the inspection on 05/31/11. She stated that she is responsible for regulatory compliance and maintaining and approving the firm's SE prevention plan. She is located at the corporate office. Ms. McDonald has been employed at the firm for approximately 13 years. Ms. McDonald was not present at the close out discussion or issuance of the FDA-483.

Mr. William Ward Field, Compliance Manager, is responsible for DOT log books, safety, employee training, SQF, FDA, Animal Husbandry, and employee OJT training. Mr. Field was not present at the close out discussion and issuance of the FDA-483.

The above individuals' duties and responsibilities apply to each of the complexes inspected.

Mrs. Nikki Powell, USDA AMS Grader (Complex I) and Mr. Crosby Simmons, USDA AMS Grader (Complex II) were onsite. We introduced ourselves to them during the inspection.

INTERSTATE COMMERCE/JURISDICTION (SMS)

Cal-Maine Foods, Inc. operates as an egg laying farm with in-line processing. There are approximately (b) (4) (Complex 1) and (b) (4) (Complex 2) (b) (4) hens used for processing eggs. According to management, the firm processes approximately (b) (4) eggs per day. The eggs are primarily manufactured for table use. The firm's eggs produced range in size from medium to extra large. The firm packs the eggs in a variety of sizes ranging from half dozen to 30 count cartons. Cal-Maine Foods, Inc. sells eggs to customers in (b) (4). Some of the firm's largest customers are (b) (4). The firm packages eggs under the (b) (4) and

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(b) (4) brand labels. Exhibit #3 is a copy of the firm's truck load out sheet and associated shipping record documenting the shipment of b4 cases of shell eggs to (b) (4) on 11/2/2010. Exhibit #4 is an example of the firm's labeling related to the production during the first day of the inspection. The firm ships the majority of the eggs via the customer owned refrigerated trucks. Any breaker eggs produced by the firm are shipped to (b) (4)

FIRM'S TRAINING PROGRAM (AKW)

Mr. W. Ward Field, Compliance Manager, is responsible for employee training. Employees receive training in the following areas: new hire orientation training, Safe Quality Food (SQF), FDA, animal husbandry, and on-the-job training. In addition, the firm requires each employee to sign a code of conduct for poultry caretakers. This form addresses biosecurity, security, and animal welfare issues. A representative copy of this form is included as Exhibit #5.

HISTORY (AKW)

Cal-Maine Foods, Inc. (Edwards, MS location) was established in 1967 and operates as an integrated egg production enterprise. A copy of the firm's shell egg producer registration for complex I and II are included as Exhibit #6. The firm's Chairman of the Board is Fred Adams, Jr. The Edwards, MS location consists of approximately (b) (4). This location consists of multiple complexes which house breeders, pullets, and laying hens. The remaining acreage for this location consists of row crop farming (corn) and beef cattle production. According to Mr. Webb, the firm's hatchery is located in Mendenhall, MS. The firm raises their own replacement pullets at the Edwards, MS location in one of two complexes. According to Mr. Webb, the Edwards, MS location also supplies replacement pullets for other Cal-Maine facilities, such as Pine Grove, LA. The flocks are (b) (4) in advance for production purposes. The farm's shell egg production consists of Complex #1 and Complex #2. The firm employs approximately (b)(4) individuals at each complex. The firm's hours of operation are from (b) (4)

MANUFACTURING/DESIGN OPERATIONS (WSF)

Each shell egg production complex consists of (b) (4) houses. The houses located at Complex #1 measure (b) (4) and house approximately (b) (4) hens per house. Complex #2 houses measure (b) (4) hens per house. There are approximately (b) (4) hens at the combined locations producing approximately (b) (4) daily. At each complex, the hens are housed (b)(4) birds per cage and the cages are configured with (b) (4) with each row located above a shallow flush manure pit. The manure pits are flushed daily. Eggs are transferred via conveyor belts to a central processing area. All eggs produced at each location are packaged on site

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for the ultimate consumer and are USDA inspected. Grade “A” eggs. These eggs are transported via refrigerated tractor trailer truck provided by the receiving industry. The eggs that do not meet Grade “A” specifications are packaged for shipment to a breaker facility. The breaker eggs are transferred via Cal-Maine owned refrigerated tractor trailer trucks. All packaged eggs awaiting transfer are stored in a walk in cooler at 45 degrees F or below.

Mr. Webb stated that each flock is placed into the egg production houses when they are approximately (b) (4). The current flocks at these locations range from (b) (4) of age. The pullets that arrive at the location are SE monitored before arrival and hens undergo induced molting at (b) (4). Environmental testing is performed (b) (4) after (b) (4) post molt production. All houses are depopulated when birds reach approximately (b) (4) of age. The depopulated flocks are sent to the USDA slaughter facility in (b) (4). Exhibit #7 is a representative example of the firm’s records per flock, which includes a date log, NPIP certificate, and SE testing results for the hens in Complex II, House (b) (4).

Cal-Maine Foods, Inc., Edwards, MS has established a SE prevention plan for both complexes. Each complex uses the same SE plan. The firm’s SE plan is included as Exhibit #8. The firm’s SE plans were established on June 7, 2010 and revised on July 7, 2010 based on FDA’s Final Rule for Prevention of SE during production, transport, and storage. The most current version of the firm’s SE plan was dated 3/25/11 and signed by Mr. Webb and Ms. McDonald on 4/25/11. It is to be noted that Complex #1 & #2 both house flocks that were transferred before and after the final rule was enacted. A memorandum is included stating Cal-Maine’s transition during this time frame. A copy of the memorandum is included in the firm’s SE prevention plan.

SE prevention plans for both Complexes include:

Procurement of pullets that are SE monitored

All chicks and pullets that arrive at each complex will be procured from NPIP “SE monitored” breeder certified flocks. Also the pullet environment is tested for SE when the pullets are 14 to 16 weeks of age. A NPIP certificate is provided for each flock as of July 9, 2009.

Bio-security Measures

The firm has bio-security measures in place for the prevention of SE and other industry related diseases. All visitors must check in and out at the each complex and meet specific guidelines before being given authorization to enter the firm. The bio-security program includes in-house guidelines as well as guidelines for contract workers. Bio-security logs/journals were reviewed and no objectionable conditions were found. The bio-security program is included in the SE prevention plan as Exhibit #8.

Rodent/Pest Control Measures

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The firm conducts the majority of its pest control measures and receives consultation from (b) (4) Mr. Webb oversees the pest control operations at both Complexes I & II. We reviewed the pest control logs during our inspection and found no objectionable conditions. No significant insect or rodent activity was observed during the inspection. The pest control procedures are included in the SE prevention plan as [Exhibit #8](#).

Cleaning and Disinfecting

Cal-Maine Foods, Inc. executive committee has made the decision that all houses are cleaned and disinfected at depopulation. The firm has developed procedures for cleaning both SE negative and SE positive houses. Cleaning and disinfecting journals were reviewed during the inspection and no objectionable conditions were found. The same procedures are used by each complex and are provided in the SE Prevention plan as [Exhibit #8](#).

Adequate refrigeration of shell eggs

All shell eggs are stored in a walk-in cooler at 45 degrees F or below. The firm performs a (b) (4) inspection to ensure that the cooler temperatures are maintained at this temperature. During the inspection, we walked through the cooler at both complexes and took ambient temperatures. Refrigeration journals and logs were reviewed during the inspection and no objectionable conditions were found. At the onset of the inspection, all refrigeration procedures/guidelines were maintained in the firm's HACCP plan. After further discussion, management decided to also include the refrigeration of shell egg guidelines in their SE plan. A copy of the firm's HACCP procedures and associated inspection forms related to refrigeration are included as [Exhibit #9](#). A review of the firm's thermometer calibration records revealed no discrepancies.

Environmental & egg sampling/testing program

Environmental testing is performed in each poultry house when the hens are 40 to 45 weeks of age. When the flock reaches (b) (4) production, an environmental test is performed within (b) (4). To date, neither Complex has had a positive environmental sample nor have eggs been diverted for sampling/testing. The firm's environmental samples are sent to (b) (4). The firm's test results were reviewed during the inspection and no objectionable conditions were noted. The environmental sampling/testing program procedures are included in the SE prevention plan as [Exhibit #8](#).

Upon review of the firm's written SE plan, it was determined that the firm failed to have specific written procedures which address egg sampling/testing for *Salmonella Enteritidis*. Mr. Webb stated that if a positive environmental sample result was detected, the executive committee would discuss what actions would be taken and determine if the eggs would be diverted and further egg testing conducted or if the flock would be depopulated. See Objectionable Conditions section of [Observation #1](#) of the FDA-483.

Daily operations of the houses at each complex also include general repairs to cages/barn structure and cleaning houses of dust and excess feed. Houses are walked through daily to ensure that eggs that remain in cages are placed on the conveyor system and transferred to the production/packaging areas. The flock is inspected for general health and dead birds are removed from cages. Each house

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is designed with (b) (4) located above shallow flush pits. Scraper blades remove the manure from each tier causing it to drop into the shallow pit located directly below the cages. The shallow pits are flushed (b) (4). Each Complex has (b) (4) one located in the front of the houses and one located behind the houses. When houses are flushed solids are separated in covered pits and effluent is held in the lower (b) (4). The (b) (4) is then irrigated as needed onto large fields. The large fields are routinely planted and harvested following EPA guidelines. The solid waste is removed as needed and used by local farmers for fertilizer.

MANUFACTURING CODES (AKW)

Cal-Maine assigns a code to each size of product. This code is stamped directly onto the end of the cartons. An example of a manufacturing code used by this firm is:

P1050C- (b) (4)
P1050- (b) (4)
001- Julian date (pack date) January 1

The firm also places a best buy date with (b) (4) expiration. The firm purchases specialty eggs from other entities to fill customer requests. These specialty products are received fully packaged and labeled. No further processing is involved with the specialty eggs.

COMPLAINTS/ RECALL PROCEDURES (AKW)

A review of the firm's complaint file was conducted. The complaint file contained 56 complaints which were logged for various quality issues such as missing date, missing eggs, broken eggs, or wrong shipment. There were no complaints logged for food safety related illnesses. The firm maintains a written recall procedure. The firm stated that there have been no recalls in the past at this facility.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (AKW)

This inspection conducted on 5/31-6/2/2011, observed one deficiency that was listed on the [FDA-483, Inspectional Observations](#). Mr. Robert Wilford Webb, III, Director of Production and Mr. Ed Scott, General Manager attended the close-out meeting on June 2, 2011.

An [FDA-483, Inspectional Observations](#) was issued to Mr. Robert Wilford Webb, III, Director of Production at that time. Firm management promised corrections. (See objectionable conditions section of this report for additional information) Mr. Webb was informed that we were not the final Agency authority if charges of violations of the law would be brought against the firm. We also

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explained that the conditions listed may be determined by the FDA, after review of all the facts, to be violations of the Egg Rule. The firm was advised of the various penalties for violations of the law including, but not limited to, warning letter, civil money penalties, seizure, injunction, or criminal penalties. We also explained that the FDA-483 was not an exhaustive list of violative conditions. We recommended that the firm access a copy of 21 CFR Part 118 to help bring the firm into compliance.

Observations listed on form FDA 483

OBSERVATION 1

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically, your firm failed to have written procedures that address egg testing for *Salmonella Enteritidis* following a positive environmental test of the pullet environment.

Reference: 21 CFR 118.4

Supporting Evidence and Relevance: The firm is required to have and implement a written SE prevention plan as a shell egg manufacturer.

Discussion with Management: The firm's SE prevention plan ([Exhibit #8](#)) failed to include specific written procedures to address egg sampling and testing for *Salmonella Enteritidis* following a positive environmental test. Mr. Webb stated that the firm had not had a positive environmental test result in the past. He further explained that the firm had a program in place where the executive committee would address corrective actions for the farm. We explained to the firm that written procedures addressing egg sampling and testing following a positive environmental test should be in place before the firm receives a positive test result. We provided firm management with the applicable 21 CFR 118 references which pertain to egg testing. We informed firm management that since the firm has not had a positive environmental test result and there were no written egg testing procedures, FDA could not determine if the egg sampling and testing procedures for the firm would be in compliance with the 21 CFR 118 regulations. The firm promised corrections within one week.

***The firm provided a written response to this observation on 6/6/11 via e-mail. This response was received after the inspection had concluded and is included as [Exhibit #10](#). This response appears to adequately address the issue noted.

GENERAL DISCUSSION WITH MANAGEMENT (AKW)

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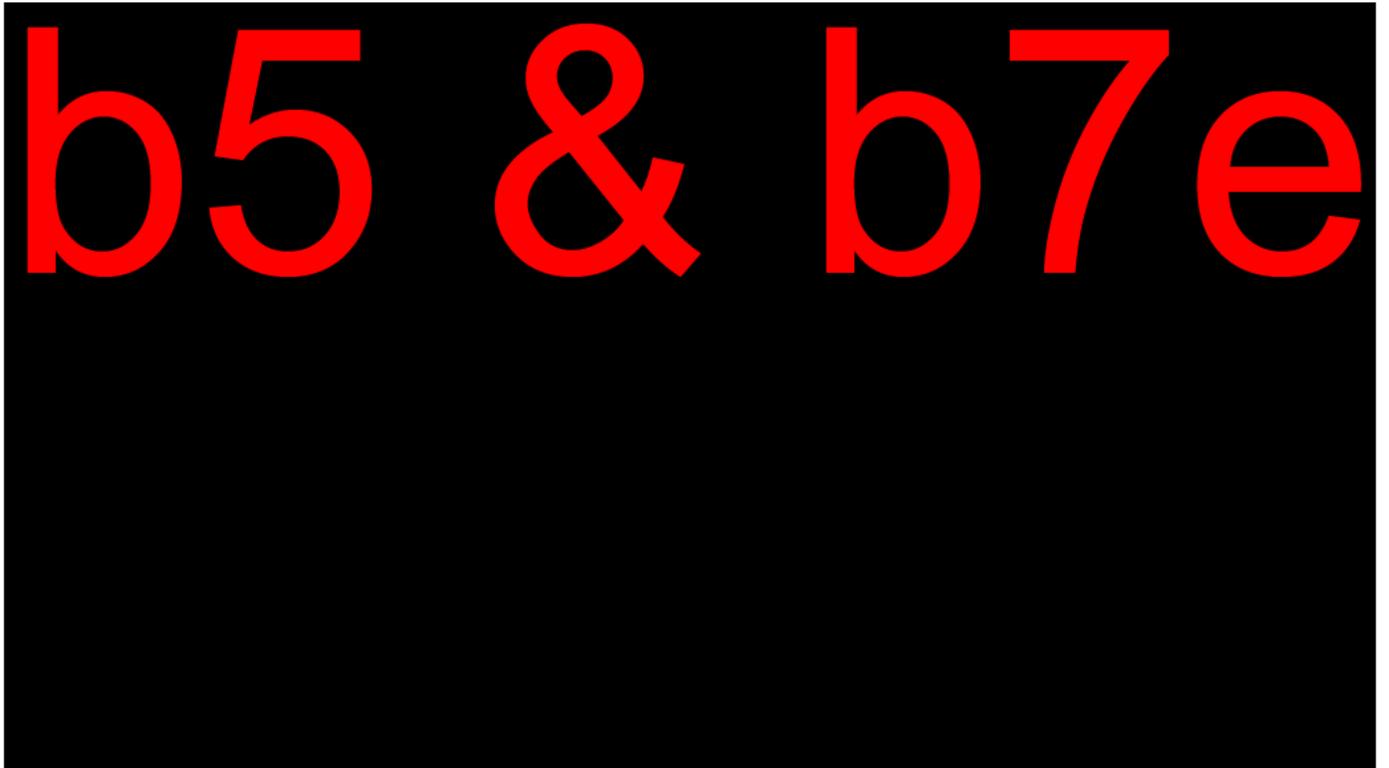
At the beginning of the inspection, firm management was provided with a copy of FDA document “The Egg Rule at a Glance” and “FDA Reportable Food Registry at a Glance”.

During the close-out meeting the following items were discussed:

1. A review of the firm’s SE prevention plan noted the lack of procedures to address refrigeration requirements. After further discussion, it was determined that the refrigeration procedures were maintained in the firm’s HACCP and SQF programs. Firm management responded that the refrigeration procedures and associated forms from their HACCP and SQF programs would be included in their SE prevention plan.
2. It was noted during a review of the firm’s records that a truck was not loaded for shell egg shipment. Further discussion determined that the truck was not loaded due to inadequate temperature. We reminded firm management to document all corrective actions related to their SE prevention plan. No additional discussion was undertaken. We thanked them for their time and cooperation and concluded the inspection.

REFUSALS

No refusals were encountered.

ADDITIONAL INFORMATION (AKW/WSF/ SMS)

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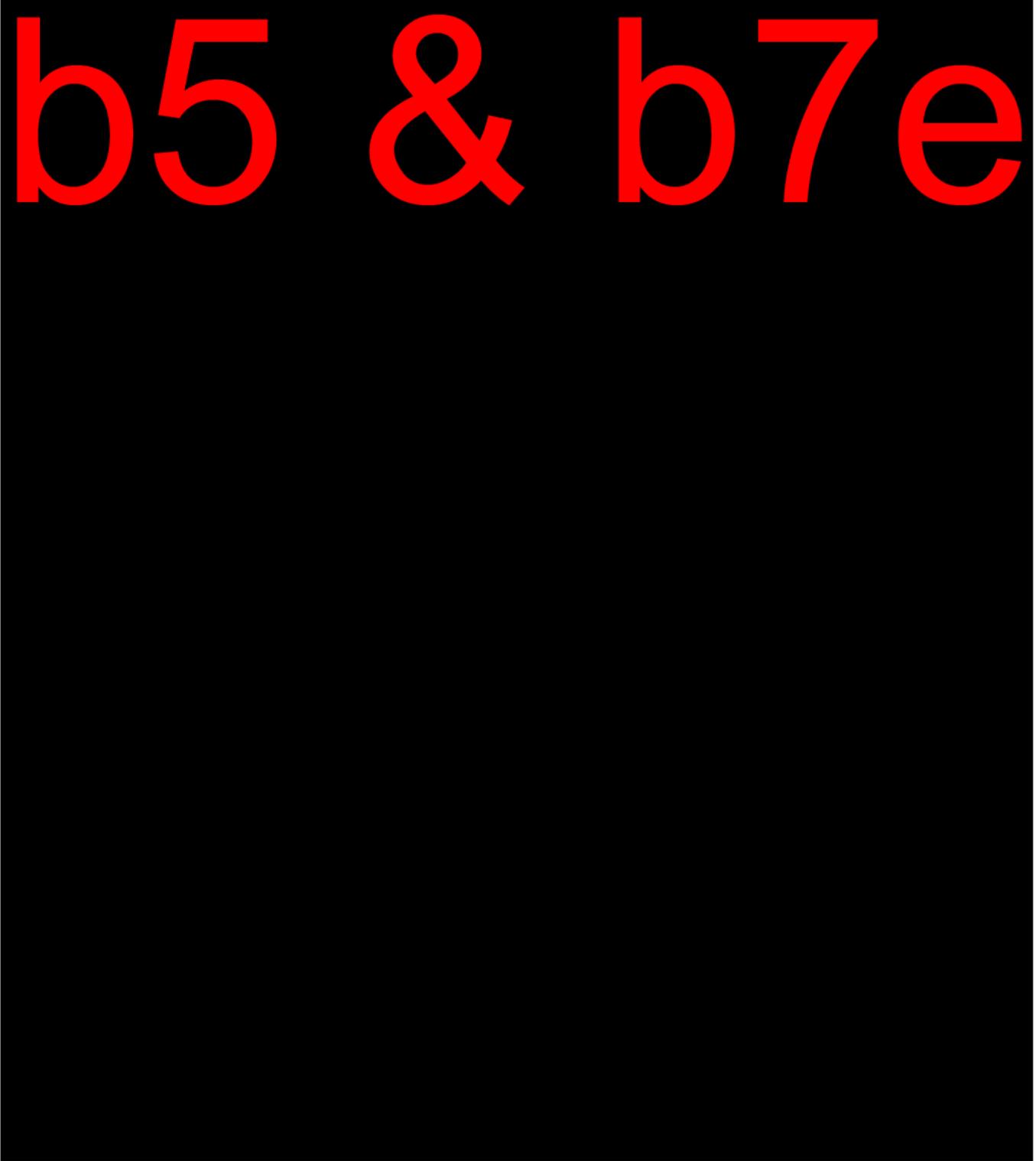
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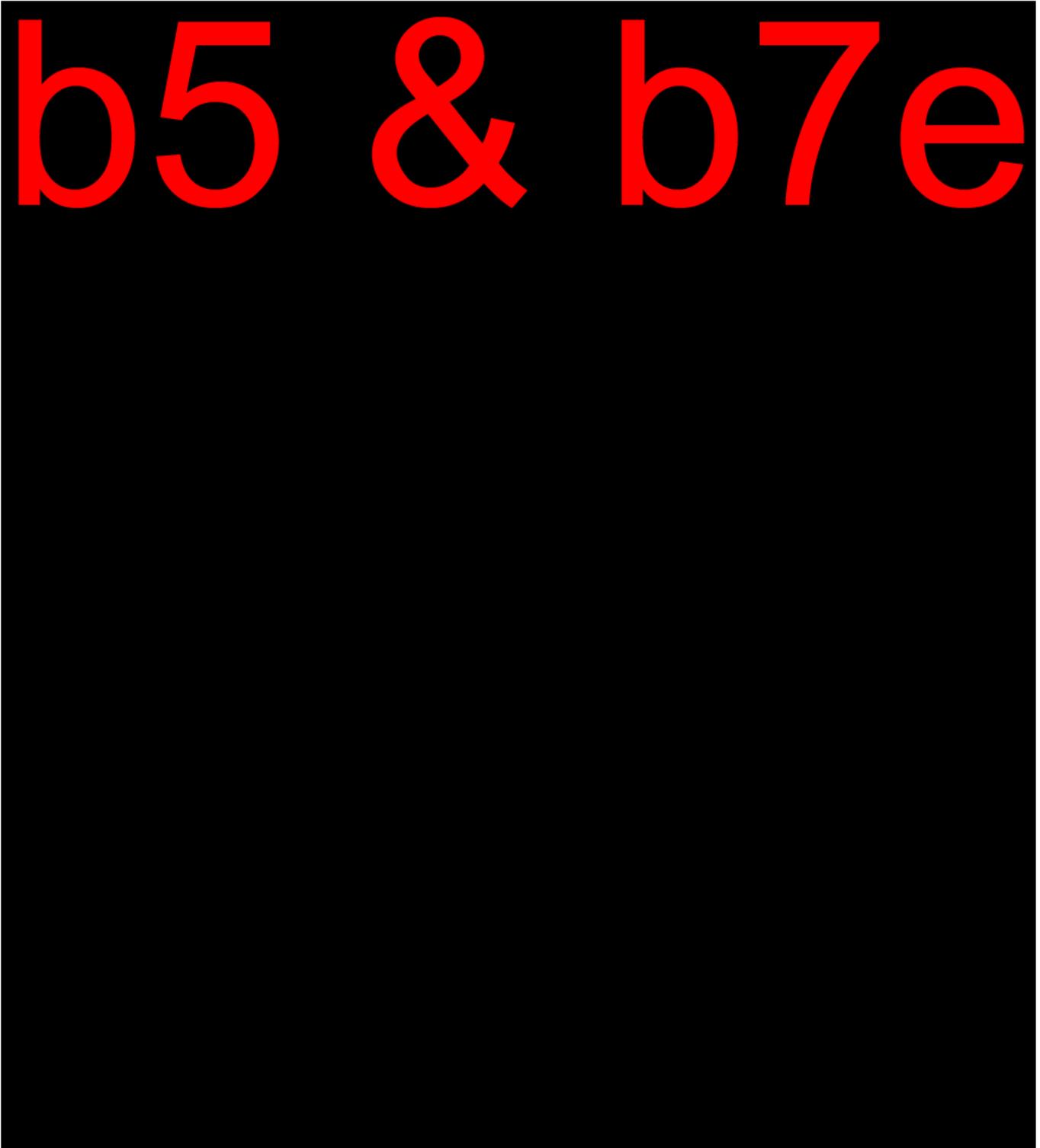
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Complex II:



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b5 & B7e

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

- [Exhibit #1](#) - Copy of firm's Production House Visitor Guidelines
- [Exhibit #2](#) - Copy of organizational chart
- [Exhibit #3](#) - Copy of Cal-Maine load-out sheet & associated shipping record dated 11/2/2010
- [Exhibit #4](#) - Product Labeling
- [Exhibit #5](#) - Copy of Code of Conduct for Poultry Caretakers
- [Exhibit #6](#) - Copy of firm Egg Producer Registration for Complex I & II
- [Exhibit #7](#) - Copy of flock records for Complex II, House 1
- [Exhibit #8](#) - Copy of Cal-Maine SE Prevention Plan
- [Exhibit #9](#) - Copy of firm's HACCP procedure & associated inspection forms for refrigeration
- [Exhibit #10](#) - Firm's correction received on 6/6/11 in response to the FDA-483

ATTACHMENTS

- [FDA 482, Notice of Inspection \(Complex I\)](#)
- [FDA 482, Notice of Inspection \(Complex II\)](#)
- [FDA-483, Inspectional Observations, dated 6/2/2011](#)

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[Attachment A: Mississippi Board of Animal Health's flock health status letter for Cal-Maine \(Edwards, MS\)](#)

Amanda K. Willey

Amanda K. Willey, Investigator
Jackson Resident Post
New Orleans District

Wayne S. Fortenberry

Wayne S. Fortenberry, Investigator
Mandeville Resident Post
New Orleans District

S. Michael Smith

S. Michael Smith
Investigator / NOL-DO
Jackson Resident Post