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SUMMARY

The current comprehensive egg safety inspection of an egg producer was conducted in accordance with FDA PHI-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, FACTS # 1258067, OP ID # 5359904.

There is no previous FDA or FDA-contracted inspectional history associated with the farm.

The current inspection revealed that Berkshire Layers produces eggs sold to (b) (4) (b) (4) for breaking and pasteurizing or cooking.

An FDA-483, Inspectional Observations (Attachment 2), was issued for: 1. Not maintaining records documenting compliance with refrigeration requirements. 2. All required records do not contain the time of the activity. 3. All required records do not have the signature or initials of the person performing the operation or completing the record.

Discussion points were as follows: 1. 1 cat was observed in house 3 and 2 cats were observed in house 2. 2. Several areas of the houses needed repair to prevent pest entry; exhaust fans with covers missing; doors damaged to the point they cannot close properly; damage and holes in the walls of the houses. 3. Dead rodents were not being removed from traps.

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No refusals were encountered during the inspection. Samples INV665843 and INV665844, environmental swabs of the manure pits of houses 3 and 2 respectively were collected to test for SE.

ADMINISTRATIVE DATA

On 04/05/2011 Inv.'s Bradley E. Benasutti, Brian S. Keefer, James M. Mason, and I presented credentials and issued an FDA-482, Notice of Inspection (Attachment 1), to Christopher M. Smith, Manager. According to Mr. Smith he oversees day to day operations and is the most responsible person present for this farm. Mr. Smith stated that Patrick Shea is the owner and most responsible for the farm overall. Credentials were also presented to (b) (4), (b) (6), service technician for (b) (4) (b4) is the owner of the flock. On 04/06/2011 we presented credentials to (b) (4) (b4), Egg Production Manager for (b) (4) Correspondence should be addressed to Mr. Shea at the address below.

Inspected firm: Berkshire Layers
Location: 3304 Mountain Road
Hamburg, PA 19526
Phone: 610-488-9764
FAX:
Mailing address: 3304 Mountain Road
Hamburg, PA 19526

Dates of inspection: 4/5/2011, 4/6/2011
Days in the facility: 2
Participants: Joshua C. Schafer, Investigator
Bradley E. Benasutti, Investigator
James M. Mason, Investigator
Brian S. Keefer, Investigator

Inv. Mason participated on 04/05/2011 only. This report was written by Inv. Schafer except where noted.

HISTORY

According to Mr. Smith, Patrick Shea is the owner of this farm and the most responsible person overall. (b) (4) is the owner of the flock and has servicemen that routinely visit the farm and participate in the management of the flock.

Mr. Shea has owned the farm for approximately 20 years and operates (b4) (b4). Mr. Shea is planning (b4) not planning to repopulate the houses once the current flocks are removed. The farm has 3 houses. House #1 has been depopulated and is empty. The farm currently

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has (b) (4) layers producing (b) (4) eggs per day. House # 2 is a high rise with (b) (4) rows and (b) (4) tiers containing (b) (4) layers. House # 3 is a high rise with (b) (4) rows and (b) (4) tiers containing (b) (4) layers.

House # 3 had a SE positive environmental sample in the flock previous to the flock that is currently in the house. That flock was depopulated in August 2009. The house was washed and disinfected. The current flock has had no SE positive environmental swabs.

There was no previous FDA inspection of this farm.

This firm is registered with the FDA as per 21 CFR 118.11(a).

INTERSTATE COMMERCE /JURISDICTION

All eggs are sold to (b) (4) for breaking and cooking or pasteurizing.

Feed is provided by (b) (4)

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Patrick Shea: Owner and most responsible overall for the farm according to Mr. Smith. Mr. Shea was not present and did not participate in the inspection.

Christopher M. Smith: Manager and responsible for day to day operations of the farm. Mr. Smith provided limited information about the firm and did not participate in the inspection. An FDA-483, Inspectional Observations (Attachment 2), was given to Mr. Smith at the close of inspection.

(b) (4), (b) (6): Serviceman (b) (4), (b) (6) works with the firm in the management of the flock. (b) (4), (b) (6) participated in the inspection on 04/05/2011 and provided information about the firm. (b) (4), (b) (6) accompanied us during inspection and sampling of the houses.

(b) (4) Egg Production Manager, (b) (4) is (b) (4), (b) (6) supervisor. (b) (4) participated in the inspection on 04/06/2011 and provided records and information about the firm. (b) (4) also provided us with a copy of the firm's SE prevention plan (Exhibit 1).

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OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

You do not maintain records documenting compliance with refrigeration requirements.

Specifically, for the time period of 08/15/2010 to 09/04/2010 egg cooler temperatures were not recorded on the temperature log.

Reference: 21 CFR 118.10(a)(3)(iv)

Supporting Evidence and Relevance:

In the egg cooler temperature log no record of cooler temperatures were entered from the between the dates of 08/15/2010 to 09/04/2010.

Discussion with Management:

(b) (4) stated that was the time period before the previous manager had quit. He said she must have stopped recording the temperature because she knew she was leaving.

OBSERVATION 2

All your required records do not include the time of the activity that the records reflect.

Specifically, the time that the temperature is taken is not recorded on the temperature log.

Reference: 21 CFR 118.10(b)(2)

Supporting Evidence and Relevance:

On the egg cooler temperature log the time the temperature is observed is not recorded.

Discussion with Management:

(b) (4) stated he is aware of this issue. He said that (b) (4) was made aware of this issue during inspections of other farms. He said (b) (4) has updated their SE plans to include recording of the time the temperature is observed, but this farm has not switched over to the new SE plan. The (b) (4) flocks on this farm are (b) (4) and (b) (4) weeks old and the farm owner has no plans to

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repopulate the houses after depopulation. He stated that if the farm decides to repopulate the houses with (b) (4) owned flocks the updated SE plan will be used. I explained to Mr. Smith that if the farm decides to repopulate with someone other than (b) (4) this issue must be addressed.

OBSERVATION 3

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

Specifically, the temperature log is not signed or initialed by the person recording the temperature at the time the temperature is recorded.

Reference: 21 CFR 118.10(b)(3)

Supporting Evidence and Relevance:

On the egg cooler temperature log the signature or initials of the person making the entry is not recorded.

Discussion with Management:

(b) (4) stated he is aware of this issue. He said that (b) (4) was made aware of this issue during inspections of other farms. He said (b) (4) has updated their SE plans to include recording of the initials or signature of the person making the observation, but this farm has not switched over to the new SE plan. The (b) (4) flocks on this farm are (b) (4) and (b) (4) weeks old and the farm owner has no plans to repopulate the houses after depopulation. He stated that if the farm decides to repopulate the houses with (b) (4) owned flocks the updated SE plan will be used. I explained to Mr. Smith that if the farm decides to repopulate with someone other than (b) (4) this issue must be addressed.

REFUSALS

No refusals were encountered during this inspection.

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GENERAL DISCUSSION WITH MANAGEMENT

A copy of the "Egg Rule at a Glance" poster was provided.

{begin Inv. Benasutti}

Record Review

The SE testing, fly & rodent and cooler temperature records were reviewed during the inspection. Records for SE testing for the date 09/16/10 for all 3 houses were reviewed with no SE positive results.

The fly and rodent logs were reviewed with no discrepancies in the fly log. For the rodent log, the SE plan states that the firm's entries must include a rodent index. The rodent index was not included in the firm's entries.

In reviewing the cooler temperature log, there was a period of 3 weeks where there were no temperatures recorded. The missing data was for the period of 08/15/10 to 09/04/10. (b) (4) stated that the missing records were from a period where the farm was transitioning in management. It was also noted that the temperature logs did not include the time the temperatures were taken or the initials of the individual taking them.

{end Inv. Benasutti}

Discussion points were as follows:

1. One cat was observed in the manure pit of house 3 and two cats were observed in the manure pit of house 2.
2. Several areas of the houses needed repair to prevent pest entry; exhaust fans with covers missing; doors damaged to the point they cannot close properly; damage and holes in the walls of the houses.
3. Dead rodents were not being removed from traps.

Both (b) (4) and Mr. Smith acknowledged these issues and stated that if the farm decides to repopulate these issues will be addressed.

(b) (4) stated that Mr. Shea is (b) (4) and has no plans to repopulate the houses once they are depopulated. He said house 1 has been depopulated and is empty. He stated the flock in house 2 is (b) (4) weeks old and the flock in house 3 is (b) (4) weeks old. He said the entire farm will be depopulated in approximately 6 weeks. (b) (4) said he is aware that the registration must be canceled if the farm does not repopulate.

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ADDITIONAL INFORMATION

Attachment B: Inspection/Data Collection Tool for *Comprehensive Inspections*

Information that needs to be obtained in addition to the general FDA information

Section I: Information for assessing future inspectional priority)

(b) (7)(E), (b) (5)

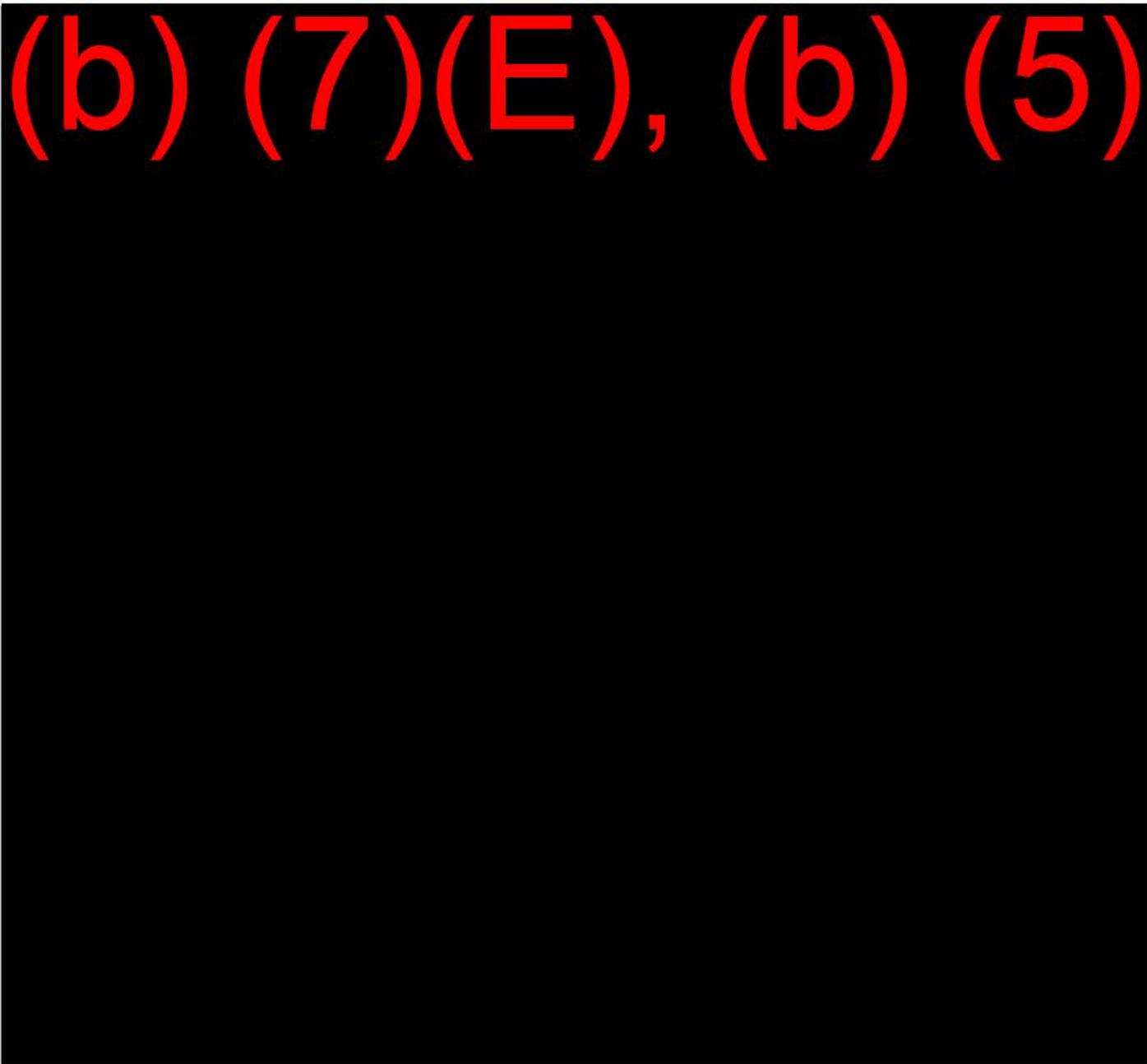
Section II: Inspectional Tool (*NR = No Reference for the observation in Egg Safety Regulation, but information will be useful for risk assessment to determine which firms to subsequently reinspect.)

(b) (7)(E), (b) (5)

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SAMPLES COLLECTED

Environmental samples of houses 2 & 3 were collected for testing for SE.

INV665843 consists of 20 manure pit drag swabs from house 3. INV665844 consists of 12 manure pit drag swabs from house 2.

EXHIBITS COLLECTED

1. Berkshire Layers SE Prevention Plan

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EI Start:

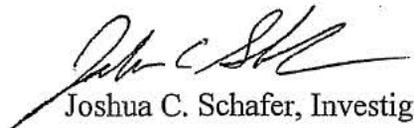
04/05/2011

EI End:

04/06/2011

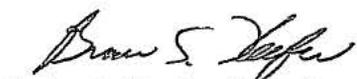
ATTACHMENTS

1. FDA-482, Notice of Inspection
2. FDA-483, Inspectional Observations


Joshua C. Schafer, Investigator


Bradley E. Benasutti, Investigator


James M. Mason, Investigator


Brian S. Keefer, Investigator