

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878
EI Start: 06/07/2011
EI End: 06/07/2011

TABLE OF CONTENTS

Summary 1
Administrative Data 2
History 2
Interstate Commerce/jurisdiction 3
Individual Responsibility and Persons Interviewed 3
Manufacturing/Design Operations 4
Objectionable Conditions and Management's Response 4
Refusals 7
General Discussion with Management 7
Additional Information 8
Samples Collected 13
Voluntary Corrections 13
Exhibits Collected 13
Attachments 13

SUMMARY

This initial targeted inspection of a shell egg producer for the table market is directed by Amended Assignment – FY11—Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG # 11-04, ORA Concurrence #2011012601; and was conducted under CP7303.803, Domestic Food Safety Program, FACTS WAID #1258067, OPID #5518931 for PHI-DQ FY'11 work plan.

^No previous inspection history exists for this firm.

During the current inspection of a poultry farm with one laying hen house with a manure pit, shell egg production and storage areas were inspected for compliance with respect to the requirements in 21 CFR 118. A walk through of the interior and exterior of the poultry houses was also conducted as directed by the assignment. In addition, the SE Prevention Plan, Refrigeration Temperature Logs, and Rodent Monitoring Records were reviewed from 07/09/10 to the present. The inspection revealed that the poultry farm is managed by b4, a poultry farm and management firm located in b4. A representative from the firm was not present during the inspection.

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878

EI Start: 06/07/2011

EI End: 06/07/2011

On 6/7/2011, an FDA-483, Inspection Observations, was issued to the owner which included observations such as: performing the 40-45 week SE environmental testing outside of the required timeframe; not monitoring or keeping fly records documenting fly control from 7/9/2010 through 3/9/2011; not monitoring or keeping records for refrigeration requirements from 7/9/2010 through 2/28/2011; producing and shipping shell eggs for the table market and not having a written SE Prevention Plan from 7/9/2010 through 3/1/2011; and not including all required elements on required records such as initials and time. The owner cooperatively agreed to fix and initiate changes to the observed deficiencies.

An Attachment A, Inspectional Tool for Targeted Egg Inspections, was inserted into the body of this report.

Information and guidance was given to the owner during the closeout meeting of the inspection.

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

ADMINISTRATIVE DATA

[This report was written by INV Brandon J. Brookens]

Inspected firm: Lamar Horst Farm
Location: 11559 Koons Road
Waynesboro, PA 17268
Phone: 717-762-4289
FAX:
Mailing address: 11599 Koons Road
Waynesboro, PA 17268
Dates of inspection: 6/7/2011
Days in the facility: 1
Participants: Brandon J. Brookens, Investigator
Michael J. Mero, Investigator

On 6/7/2011, LCDR Michael J. Mero and I, Brandon J. Brookens, presented our credentials and issued an FDA-482, Notice of Inspection, to Mr. Lamar D. Horst, Owner of the Lamar Horst Farm. Mr. Horst stated that he is the most responsible individual and owns the farm. On 6/7/2011 the inspection came to a close as LCDR Mero and I issued an FDA-483, Objectionable Conditions, to Mr. Horst, which included multiple deficiencies in regards to 21 CFR 118, Shell Eggs. Mr. Horst cooperatively agreed to fix all FDA-483 observations in a timely manner.

HISTORY

Mr. Horst told us that he is the sole owner of his farm located at 11599 Koons Road, Waynesboro, PA 17268. He said that this is the only poultry farm that he owns and is also involved in a dairy

Establishment Inspection report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878
EI Start: 06/07/2011
EI End: 06/07/2011

operation nearby. Mr. Horst explained that his poultry farm consists of one poultry house, a bulk egg packing room, and a cooler, which collectively total b4 square feet. He also said that his b(6) Mr. Horst said that his poultry house was built in 1992 and currently contains a flock of approximately b4 laying hens that are approximately b4 weeks old. He also said that he intends to molt his current flock. Mr. Horst said that b6 and b7c Owner b4 (b4), set up a contract with him to market the eggs produced from his flock and provide the poultry feed. He said that the only thing he does is care and maintenance for the birds and poultry house such as watering and pest controls.

Mr. Horst also told me that his farm participates in PEQAP and normally operates b4 days per week. Mr. Horst said that the normal business hours for the firm are b4 through b4. Mr. Horst also presented a copy of his FDA Egg Registration number, which was dated 06/17/2010. (see Additional Information Section for Attachment A - Inspection/Data Collection Tool for Targeted Inspections).

Post inspectional correspondence should be addressed to:

*The Lamar Horst Farm
ATTN: Mr. Lamar D. Horst
11599 Koons Road
Waynesboro, Pa 17268*

INTERSTATE COMMERCE/JURISDICTION

Mr. Horst said that b4 will market all his eggs explicitly for the table market. He also said that all his eggs are sold to b4, an egg marketing firm in b4.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

We presented our credentials and issued an FDA-482, Notice of Inspection, to Lamar D. Horst, Owner/SE Prevention Plan Administrator and most responsible individual of his poultry house. On 6/7/2011, Mr. Horst presented a copy of his *Salmonella enteritidis* (SE) Prevention Plan (**Exhibit 1**). Mr. Horst explained and answered questions regarding the SE Prevention Plan and acted as our primary contact for all aspects of the inspection. At the close of the inspection, we held a meeting with Mr. Horst and we issued him an FDA-483.

Mr. Lamar D. Horst, stated that he is the Owner and SE Prevention Plan Administrator of his poultry farm. He said he is responsible for the poultry house maintenance and care for all the birds. He also said that he owns b4 of the chickens in his house. Mr. Horst said that he owns the poultry house and is contracted out by b4, a poultry management company in b4 who owns b4 of Mr. Horst birds. He said that he primarily holds and cares for the birds, and performs pest monitoring. On 6/7/2011, we displayed credentials and issued an FDA-482 to Mr. Horst who identified himself as the most responsible individual at his the farm. He was present during all of the inspection and provided information on the firm's history, cleaning and disinfecting procedures, and showed all records of pertaining to the SE Plan. He also stated that b4, provided him their standard SE Plan. As the Owner/SE Prevention Plan Administrator he said he does not report to any other individual besides b4.

Establishment Inspection report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878
EI Start: 06/07/2011
EI End: 06/07/2011

who contracts him out to raise the birds in his poultry house. Mr. Horst explained that he is responsible for all rodent bait stations, monitoring and recording refrigeration temperatures, and conducts b4 monitoring. On 6/7/2011, an FDA-483, Inspectional Observations, was issued to Mr. Horst during the closeout meeting who was very cooperative and agreed to fix all the issues we observed.

MANUFACTURING/DESIGN OPERATIONS

Mr. Horst provided LCDR Mero and I all information pertaining to all environmental testing of his flock. He told us that b6 & b7c, an independent contract poultry technician, performs all pullet and layer hen SE environmental testing for both FDA required timeframes and PEQAP timeframes. Mr. Horst also said that b6 & b7c owns b4 of his birds.

Mr. Horst said that his current flock came from one shipment of chicks which were hatched at b4, located at b4. This shipment is documented in NPIP report #W116408, dated 11/10/2009. We noted that all boxes on the NPIP form were checked "SE Clean". Mr. Horst provided us copies of all NPIP test results which were faxed to him from b6 & b7c. (EXHIBIT #2).

Mr. Horst said that for his current flock the 14-16 week SE environmental test was performed at a contract pullet farm before they arrived; however, he did not know which pullet house they were raised on. On 6/7/2011, he provided us copies of the 14-16 week environmental test results, which were taken at the pullet farm. We noted that this test was collected during the correct timeframe, however, it was before the egg rule was enacted on 7/9/2010. (EXHIBIT #3)

He also provided us with a copy of the 40-45 week environmental test results that were taken from his poultry house. We noted that this environmental test was applicable after the egg rule went into effect and was performed outside the required 40-45 week timeframe. (EXHIBIT #4) [FDA-483 Observation #1].

See Additional Information section of the EIR which contains Attachment A – Inspectional Tool for Targeted Egg Inspections for details on the poultry house design for all other information.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483**

OBSERVATION 1

Environmental testing for SE, using approved methods, was not done in a poultry house when any group of laying hens constituting the flock was 40 to 45 weeks of age.

Specifically, you performed SE environmental testing outside of the 40-45 week required timeframe.

Annotation:

Reference: 21 CFR 118.5(a)

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878

EI Start: 06/07/2011

EI End: 06/07/2011

Supporting Evidence and Relevance:

Mr. Horst provided us a copy of his 40-45 week SE environmental test results. We noted that the collection date was 9/24/2010. By using the ship date on the NPIP form of 11/10/2009 and calculating 40-45 weeks after this date, this applicable test should have been performed, or collected, within the timeframe of 8/17/2010 through 9/21/2010. [please refer to EXHIBITs #2, #4]

Discussion with Management:

We stated to Mr. Horst that he tested 3 days after the required timeframe for his 40-45 week SE environmental test. He told us that he contracts Mr. b6 & b7c and has not worried as to when the test were being performed. We stated to Mr. Horst that he is ultimately responsible for ensuring that his flock is tested within the required timeframes.

OBSERVATION 2

You did not maintain records documenting compliance with rodent and other pest control measures. Specifically, you did not monitor or keep records documenting fly control as required from 7/9/2010 through 3/9/2011.

Annotation:

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

Supporting Evidence and Relevance:

During our record review, we observed that Mr. Horst fly monitoring records started at 3/10/2011. Mr. Horst said that this is when he first began keeping fly monitoring records.

Discussion with Management:

We told Mr. Horst that since he has greater than 50,000 laying hens and his eggs are going to the table market, he was required to keep fly monitoring records starting on 7/9/2010. We also noted that he has since corrected this issue. He said that he will continue to keep fly monitoring records.

OBSERVATION 3

You do not maintain records documenting compliance with refrigeration requirements.

Specifically, you did not monitor the temperature of your egg cooler or keep records documenting such action from 7/9/2010 through 2/28/2011.

Annotation:

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

Supporting Evidence and Relevance:

During our record review, we observed that Mr. Horst refrigeration monitoring records started on 3/1/2011. Mr. Horst said that this is when he first began keeping refrigeration monitoring records.

Discussion with Management:

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: **3008962878**

EI Start: 06/07/2011

EI End: 06/07/2011

We told Mr. Horst that since he was required to keep refrigeration monitoring records starting 7/9/2010. We also noted that he has since corrected this issue. He said that he will continue to keep refrigeration monitoring records.

OBSERVATION 4

Your firm does not have a written SE prevention plan that is specific to the farm where you produce eggs.

Specifically, you produced shell eggs for the table market from 7/9/2010 through 2/28/2011, and did not have a written SE Prevention Plan as required. Your current SE Prevention Plan is dated 3/1/2011.

Annotation:

Reference: 21 CFR 118.4

Supporting Evidence and Relevance:

During our review of Mr. Horst's SE Prevention Plan, we noted that it was dated on 3/1/2011. Mr. Horst said that prior to this date, he did not have a plan and continued to produce eggs for the table market.

Discussion with Management:

We observed that Mr. Horst's currently has a signed SE Prevention Plan dated of 3/1/2011. Mr. Horst explained that [b4] gave him a generic template on or around 3/1/2011. He said that he will always continue to keep a signed, up-to-date, SE Prevention Plan at his farm. He also said he plans on making some corrections in his current plan.

OBSERVATION 5

All required records do not include your name and the location of your farm.

Specifically, your rodent, fly, and refrigeration monitoring records do not contain the location of your farm. Furthermore, rodent control records did not contain the name of your farm from 7/9/2010 through 3/11/2011.

Annotation:

Reference: 21 CFR 118.10(b)(1)

Supporting Evidence and Relevance:

We noted that all of Mr. Horst required records did not contain the location of his poultry farm. Further more, we noted that his rodent control records did not contain the name of his farm from 7/9/2010 through 3/11/2011.

Discussion with Management:

We discussed with Mr. Horst that all required records are official records and therefore need all the required elements. On 6/7/2011 during the closeout meeting, Mr. Horst presented us the records again, where he used white out and wrote the location of his farm. We observed this on all the required records.

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878
EI Start: 06/07/2011
EI End: 06/07/2011

OBSERVATION 6

All your required records do not include the time of the activity that the records reflect. Specifically, your rodent monitoring records did not contain a time from 7/9/2010 through 3/11/2011.

Annotation:

Reference: 21 CFR 118.10(b)(2)

Supporting Evidence and Relevance:

During the record review on 6/7/2011, we noted that rodent monitoring records did not contain a time from 7/9/2011 through 3/11/2011.

Discussion with Management:

As described in the above observation, we discussed with Mr. Horst that all required records are official records and therefore need all the required elements. Mr. Horst said that he understood and has already corrected this issue.

OBSERVATION 7

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

Specifically, your rodent monitoring records did not contain an initials as required from 7/9/2010 through 3/11/2011.

Annotation:

Reference: 21 CFR 118.10(b)(3)

Supporting Evidence and Relevance:

During the record review on 6/7/2011, we noted that rodent monitoring records did not contain a signature or initials from 7/9/2011 through 3/11/2011.

Discussion with Management:

As described in the above observation, we discussed with Mr. Horst that all required records are official records and therefore need all the required elements. Mr. Horst said that he understood and has already corrected this issue.

REFUSALS

We did not encounter any refusals during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

On 6/7/2011, we held a closeout meeting and issued an FDA-483, Inspection Observations, to Mr. Horst addressing the above observations. We also discussed that all FDA testing is regulatory and must be performed within the required timeframes. Mr. Horst said that he understood all observations and agreed to speak with Mr. **b6 & b7c** and inform him that he did not test within the timeframe mandated by 21 CFR 118. All other observations were already corrected or corrected on the spot.

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878

EI Start: 06/07/2011

EI End: 06/07/2011

ADDITIONAL INFORMATION

During the start of the inspection, we provided Mr. Horst with education and reference materials concerning the egg Rule.

Attachment A: Inspection/Data Collection Tool for *Targeted Inspections*
Section I: Information for assessing future inspectional priority)

b5 & b7e

b5 & b7e

Establishment Inspection report

Lamar Horst Farm

Waynesboro, PA 17268

FEI:

3008962878

EI Start:

06/07/2011

EI End:

06/07/2011

b5 & b7e

Establishment Inspection Report

Lamar Horst Farm

Waynesboro, PA 17268

FEI:

3008962878

EI Start:

06/07/2011

EI End:

06/07/2011



Establishment Inspection Report

Lamar Horst Farm

Waynesboro, PA 17268

FEI:

3008962878

EI Start:

06/07/2011

EI End:

06/07/2011

b5 & b7e

Establishment Inspection Report

Lamar Horst Farm

Waynesboro, PA 17268

FEI:

3008962878

EI Start:

06/07/2011

EI End:

06/07/2011

b5 & b7e

Establishment Inspection Report

Lamar Horst Farm
Waynesboro, PA 17268

FEI: 3008962878
EI Start: 06/07/2011
EI End: 06/07/2011

b5 & b7e

Recommendation: b5 & b7e

SAMPLES COLLECTED

We did not collect any samples during the inspection.

VOLUNTARY CORRECTIONS

Mr. Horst cooperatively agreed to correct all 483 observations in a timely manner.

EXHIBITS COLLECTED

1. Copy of the Lamar Horst Farm SE Prevention Plan signed and dated 3/1/2011.
2. Copy of the NPIP test results under report #W116408 dated 11/10/2009
3. Copy of the required 14-16 week SE Environmental test results for pullets under report with accession #P1005011.
4. Copy of the required 40-45 week SE Environmental test results for pullets under report with accession #P1025575.

ATTACHMENTS

1. Form FDA 482, Notice of Inspection, dated 06/7/2011, issued to Mr. Lamar D. Horst.
2. Form FDA 483, Objectionable Conditions, dated 06/7/2011, issued to Lamar D. Horst.



Brandon J. Brookens, Investigator



Michael J. Mero, Investigator