

Establishment Inspection Report

Lamar Zimmerman
Myerstown, PA 17067

FEI: 3008778376
EI Start: 06/23/2011
EI End: 06/23/2011

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SUMMARY

This targeted initial inspection of a shell egg producer is directed by Amended Assignment - FY'11- Inspection of Egg Farms for Monitoring Compliance with the Egg Safety Rule, DFPG # 11-04, ORA Concurrence #2011012601, and conducted under FACTS ASID #1258067, and OPID #5523054 for PHI-DO FY'11 work plan.

No previous inspection history exists for this firm.

During the current inspection, LCDR Margaret Di Gennaro and I (LCDR Michael J. Mero) covered shell egg production and storage. We conducted a walk through of the interior and exterior of the poultry house as directed by the assignment. In addition, we reviewed the SE prevention plan, refrigeration temperature logs, and rodent and fly monitoring records from 07/09/10 to present.

On 06/23/11, Mr. Lamar R. Zimmerman, Owner/SE Plan Administrator, was issued an FDA-483, Inspectional Observations, for the following:

- Not implementing a written SE prevention plan until 01/01/11
- Not maintaining records documenting compliance with rodent and other pest control measures
- Not maintaining records documenting compliance with refrigeration requirements

The above observations were observed corrected during the current inspection.

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I completed and inserted Attachment A – Inspectional Tool for Targeted Egg Inspections into the Additional information section of the establishment inspection report (EIR) as directed in the assignment.

We did not encounter any refusals or collect samples during the current inspection.

We provided the following handouts/educational materials on the Egg Rule to Mr. Lamar R. Zimmerman:

- “The Egg Rule at a Glance” poster and handout, FDA, September 2010, 2 pages
- Title 21: Food and Drugs, Part 118 – Production, Storage, and Transportation of Shell Eggs, 10 pages
- “Guidance for Small Egg Producers on Implementing the Egg Safety Regulation”, Guidance for Industry, FDA, 2 pages
- Guidance for Industry, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation, Draft Guidance, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, August 2010, 19 pages

ADMINISTRATIVE DATA

Inspected firm: Lamar Zimmerman
Location: 204 Farmers Drive
Myerstown, PA 17067
Phone: (717) 821-7355
Mailing address: 204 Farmers Drive
Myerstown, PA 17067
Dates of inspection: 6/23/2011
Days in the facility: 1
Participants: LCDR Michael J. Mero, Investigator
LCDR Margaret E. Di Gennaro, Investigator

HISTORY

On 06/23/11, we conducted an interview with Mr. Lamar R. Zimmerman, Owner/SE Plan Administrator, and Mr. [REDACTED], [REDACTED], from [REDACTED], to gather information about the firm. Mr. Lamar R. Zimmerman said the poultry house is family owned and operated. He explained that his wife and six children assist him as needed and he does not employ any outside workers at the farm. Mr. Zimmerman said he manages the 204 Farmers Drive poultry house from his office space adjacent to the egg packing room or from his residence [REDACTED]. [REDACTED] Mr. Tremont said the gross annual sales of the poultry house can be estimated

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by multiplying the number of laying hens by b4, which equals approximately b4 for the current flock.

Mr. Lamar R. Zimmerman said he is the sole owner of the poultry house (Sole Proprietorship) and the farm's name is Lamar Zimmerman. He said he built the poultry house at 204 Farmers Drive, Myerstown, PA in 2000 and has been the sole owner ever since. Mr. Zimmerman said he has been under contract with b4, since 2001 when the 1st flock of laying hens populated the house. Mr. Zimmerman said he has 11 years of experience as a shell egg producer and his normal business hours are b4 hours. When asked, Mr. Lamar R. Zimmerman was unable to locate a copy of the farm's FDA Egg Registration. Mr. b6 & b7c said b4 registered the farm with the FDA.

Mr. Lamar R. Zimmerman said the farm has only had one positive SE environmental sample since 2001. Mr. Zimmerman said he cannot remember very much about the SE environmental sample because to the best of his knowledge it occurred in March 2005.

Post inspectional correspondence should be addressed to:
Lamar Zimmerman
Mr. Lamar R. Zimmerman, Owner/SE Plan Administrator
204 Farmers Drive
Myerstown, PA 17067

INTERSTATE COMMERCE

The shell eggs are sold wholesale to:

b4 b4
b4
b4

or

b4 b4
b4
b4

The firm could not verify that b4 b4 (Egg Products Plant) treats all eggs as defined by 21 CFR 118.3. Mr. b6 & b7c said this is the reason why b4 requires all farms they manage to have and implement a SE prevention plan. b4 b4 reserves the right to sell surplus eggs to the table market. The majorities of eggs are treated via hard cooking or pasteurization and are not intended for the table market.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Lamar R. Zimmerman and Mr. [REDACTED] explained and answered questions regarding the SE prevention plan and acted as our primary contacts for all aspects of the inspection. Mr. [REDACTED] explained that he is filling in for the farm's normal service technician, Mr. [REDACTED]. Mr. [REDACTED] said he normally provides the same services to a farm as Mr. [REDACTED].

Mr. Lamar R. Zimmerman, Owner/SE Plan Administrator is responsible for all aspects of the business and identified himself as the most responsible individual at the firm. When asked he affirmed that he is responsible to correct and/or fix any identified violations. He was present during all phases of the inspection and provided information on the firm's history and organization. As the Owner/SE Plan Administrator he does not directly report to any other individual. However, Mr. Zimmerman does work closely with his firm's management company ([REDACTED]) on the development and implementation of the firm's SE prevention plan. Mr. Lamar R. Zimmerman also said [REDACTED] is his firm's egg marketer. Mr. Zimmerman explained he is responsible for all repairs/maintenance to the poultry house; ensuring visitors are limited and properly sign in, maintaining all rodent bait stations, monitoring and recording refrigeration temperatures, and for conducting and documenting fly and rodent monitoring. Lastly, Mr. Zimmerman said he does not bait rodent [REDACTED] stations located in the poultry house. Mr. Zimmerman said he hired [REDACTED] to place bait in all [REDACTED] stations [REDACTED]. Mr. Zimmerman also said his daughter maintains the foot bath by changing it [REDACTED] with [REDACTED] (disinfectant).

Mr. [REDACTED], **Service Technician** said [REDACTED] is the firm's management company and egg marketer. Mr. [REDACTED] said he reports directly to Mr. [REDACTED], [REDACTED], Egg Production Manager. Lastly, he said Mr. [REDACTED] is the normal Service Technician who is assigned to work directly with the poultry house owner and described the following job duties:

Management Responsibilities:

- Provides animal feed for the laying hens
- Provides and assists with the development and implementation of a basic SE prevention plan (**Exhibit 1**)
- Provides documentation that the pullets were procured from SE Clean conditions (UDSA Form 9-3) (**Exhibit 2**)
- Conducts all required SE environmental testing and provides copies of the results (**Exhibit 3**)
- Oversees the Cleaning and Disinfection of the poultry house in between flocks and provides the PEQAP – Cleaning and Disinfection Evaluation form (**Exhibit 4**)

Egg Marketing Responsibilities:

Markets and sells 100% of the shell eggs to [REDACTED]

[REDACTED]

[REDACTED]

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MANUFACTURING/DESIGN OPERATIONS

Mr. [b6 & b7c] said the farm participates in the Pennsylvania Egg Quality Assurance Program (PEQAP). Mr. Zimmerman said he was unsure of the date of the last PEQAP inspection. Mr. [b6 & b7c] also said that the United Egg Producers (UEP) inspects the firm with emphasis on the number of birds per cage. Mr. [b6 & b7c] said the next scheduled UEP inspection is 06/29/11. We did not interact with government or other inspectional agents during the current inspection.

Biosecurity Measures:

During the establishment inspection, we observed the following:

- Signs restricting/limiting access to the poultry house were posted/present
- One foot bath was located just inside the entrance to the poultry house. Mr. Zimmerman said he is responsible to maintain the foot bath and he normally has his daughter perform this task. Mr. Zimmerman said his daughter changes the footbath [b4] with [b4] [b4] (disinfectant).
- A visitor's sign in sheet was present and is in use at the farm. LCDR Di Gennaro sign us in after we entered the poultry house

We observed that the above three components of the farm's written SE prevention plan (biosecurity section) were implemented and followed by the farm.

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

OBSERVATION 1

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

Specifically, from 07/09/10 to 12/31/10 your firm did not implement a SE prevention plan while producing shell eggs for the table market. The current SE Prevention Plan on file is dated 01/01/11.

Reference: 21 CFR 118.4**Supporting Evidence and Relevance:**

On 06/23/11, Mr. Lamar R. Zimmerman provided a copy of the firm's SE prevention plan. The current plan was signed and dated on 01/01/11 by Mr. Lamar R. Zimmerman. Mr. Zimmerman said the plan dated 01/01/11 is the first SE prevention plan in use at his poultry house.

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Discussion with Management:

Mr. Lamar R. Zimmerman and Mr. b6 & b7c said they implemented the SE prevention plan on 01/01/11 which corrected the deficiency. We observed the firm has implemented a written SE prevention plan.

OBSERVATION 2

You did not maintain records documenting compliance with rodent and other pest control measures.

Specifically,

- your firm did not monitor or keep records for flies from 07/09/10 to 02/13/11
- your firm did not monitor or keep records from 07/09/10 to 03/22/11

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

Supporting Evidence and Relevance:

During our review of fly and rodent monitoring records, we observed that the first entry for fly and rodent monitoring was 02/14/11 and 03/23/11 respectively. Mr. Zimmerman said he did not perform or document fly monitoring in his poultry house until 02/14/11. Mr. Zimmerman said he did not perform or document rodent monitoring in his poultry house until 03/23/11.

Discussion with Management:

Mr. Lamar R. Zimmerman said he is currently documenting and performing fly and rodent monitoring b4 which corrected the deficiency.

OBSERVATION 3

You do not maintain records documenting compliance with refrigeration requirements.

Specifically, your firm did not monitor and record refrigeration temperatures from 07/09/10 to 02/22/11.

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

Supporting Evidence and Relevance:

During our review of refrigeration records, we observed that the first entry was dated 02/23/11. Mr. Zimmerman said he did not record/document egg cooler refrigeration temperatures from 07/09/10 to 02/22/11.

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Discussion with Management:

Mr. Lamar R. Zimmerman said he started documenting egg cooler refrigeration temperatures **b4** on 02/23/11 which corrected the deficiency.

REFUSALS

We did not encounter any refusals during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of this targeted initial inspection of a shell egg producer, a general discussion of observations was conducted with Mr. Lamar R. Zimmerman. Mr. **b6 & b7c** was not present and left the farm approximately 30 minutes prior to the close out meeting. We issued the FDA-483, Inspectional Observations, to Mr. Lamar R. Zimmerman. We also verbally discussed three observations.

Observations	Firm's Response	Time Frame to Implement
After reviewing all of the firm's records created under 21 CFR 118.10, we did not find any evidence of a record review by the SE Plan Administrator as required.	Mr. Lamar R. Zimmerman said he would review his firm's records b4 .	06/27/11
A detailed review of the firm's SE prevention plan revealed it does not specifically cover testing/sampling for SE in the environment when the laying hens are 40 to 45 weeks of age.	Mr. Lamar R. Zimmerman said he would work with b4 to modify the current SE prevention plan to include the 40-45 weeks of age SE environmental test.	No specific date was provided
We observed a potential harborage area off of the south east corner of the poultry house where the grass was approximately 12 inches in length. We observed the potential harborage area was approximately 6 feet away from the poultry house.	Mr. Lamar R. Zimmerman said excess water from the poultry house drains in the location where the harborage area was observed. He said he was planning on running a water line to prevent the water from draining in this area which will allow him to maintain the grass.	09/30/11

Lastly, we recommended that Mr. Lamar R. Zimmerman reference the educational handouts and guidance for industry we provided if there are any questions on how to implement any part of the regulation at the firm. We also informed Mr. Lamar R. Zimmerman that each FDA-483 observation

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would be followed up on at subsequent establishment inspections. The firm's management promised corrections for all applicable FDA-483 observations (including the verbally discussed observations) that were not previously addressed.

ADDITIONAL INFORMATION

b5 & b7e

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b5 & b7e

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b5 & b7e

Recommendation for comprehensive inspection:

b5 & b7e

EXHIBITS COLLECTED

1. Copy of Lamar Zimmerman SE prevention plan, 14 pages
2. Report of Sales of Hatching Eggs, Chicks, and Poults (USDA Form 9-3)
3. 14-16 weeks of age SE environmental testing laboratory report for the current flock
4. PEQAP - Cleaning and Disinfection Evaluation form

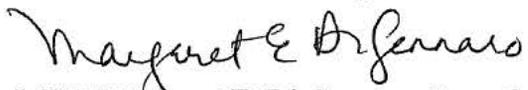
ATTACHMENTS

1. Form FDA 482, Notice of Inspection, dated 06/23/11, issued to Mr. Lamar R. Zimmerman
2. Form FDA 483, Inspectional Observations, dated 06/23/11, issued to Mr. Lamar R. Zimmerman

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