

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax: (913) 752-2111 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 06/23/2011 - 06/29/2011*
	FEI NUMBER 3008778967

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Blair J. Van Zetten, Partner**

FIRM NAME Fremont Farms, L.C.	STREET ADDRESS 3205 295th St.
CITY, STATE, ZIP CODE, COUNTRY Fremont, IA 52561	TYPE ESTABLISHMENT INSPECTED Shell Egg Producer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Your poultry house was not cleaned and disinfected by appropriate procedures before new laying hens were added to the house, when there was an environmental test that was positive for SE at any point during the life of a flock that was housed there prior to depopulation.

Specifically,

On 09/29/2010 your firm was notified that an environmental sample taken from House 1 was positive for *Salmonella Enteritidis* (SE). Your poultry house cleaning record ("Cleaning between Flocks for House 1"), from June 9 -15, 2011, does not indicate manure was removed from House 1 and this was confirmed through discussions with management. On June 17, 2011, House 1 was populated with a new flock of SE clean birds.

**OBSERVATION 2**

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,

Your firm failed to conduct environmental testing on House 2 during the time when the flock was between 40-45 weeks of age. Your firm conducted environmental testing on June 6, 2011 when the flock within House 2 was 46 weeks of age.

**OBSERVATION 3**

The poultry house environmental sampling plan was not appropriate to the poultry house layout.

Specifically,

Your firm's document entitled, "Procedure: Environmental Sampling for SE" (created 6/24/2010 and revised 05/27/2011) states (b) (4) It also states (b) (4) \*\*\* (b) (4)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Kathleen J. Close, Investigator <i>Kathleen Close</i> Brittany D. Phillips, Investigator <i>Brittany Phillips</i>	DATE ISSUED 06/29/2011
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(b) (4)

Your poultry houses contain (b) (4) tiers and (b) (4) rows of caged chickens. Your firm does not sample from any of the egg belts within the poultry house. Your sample schematic is not representative of the entire house.

**OBSERVATION 4**

For testing to detect SE in environmental samples, you did not have the sample testing conducted by the method entitled "Environmental Sampling and Detection of Salmonella in Poultry Houses," most current edition, or an equivalent method in accuracy, precision and sensitivity in detecting SE.

Specifically,

Your firm's document entitled, "Procedure: Environmental Sampling for SE" (created 6/24/2010 and revised 05/27/2011) states "(b) (4)". It also states "(b) (4) \*\*\* (b) (4)".

Management provided an internet print out listing currently used sampling tools for environmental sampling. The document and management indicated they use (b) (4) for all environmental testing. Using (b) (4) as a tool for environmental sampling for *Salmonella Enteritidis* is not recognized by the FDA as an equivalent method.

**OBSERVATION 5**

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

Your *Salmonella Enteritidis* (SE) prevention plan ("Salmonella Enteritidis Prevention Plan") does not contain the following items.

Your biosecurity policy ("Policy Statement - Bio Security", created 6/24/2010, revised 5/23/2011) lacks the following measures:

1. Maintain practices that will protect against cross contamination when equipment is moved among poultry houses.
2. Maintain practices that will protect against cross contamination when persons move between poultry houses
3. Prevention of stray poultry, wild birds, cats and other animals from entering poultry houses

Your pest control policy ("Pest Control Policy", created 6/24/2010, revised 5/23/2011) does not include the removal of debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage fro pests.

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Your cleaning and disinfection policy ("Policy Statement- Cleaning Between Flocks", created 6/24/10, revised 5/23/11) does not include the removal of all visible manure from the poultry house before new laying hens are added to the house if you have had an environmental test or an egg test that was positive for SE at any point during the life of the flock that was housed in the poultry house prior to depopulation. The manure within the bottom level of the poultry house is considered visible manure.

**OBSERVATION 6**

Your written SE prevention plan is not fully implemented and followed.

Specifically,

1. Your procedure for fly monitoring and control ("Procedure: Fly Monitoring and Control", created 6/28/2010 and revised 7/20/2010) states under 1. a. "The level of flies will be monitored inside each building (b) (4) using the (b) (4) Method". During a review of all (b) (4) fly monitoring records ("Fly monitoring Records" and "Fly Monitoring Records") from the 2011 calendar year, 5 out of 20 records were missing.

2. Your procedure for fly monitoring and control ("Procedure: Fly Monitoring and Control", created 6/28/2010 and revised 7/20/2010) states under 1. a. i. "(b) (4)" and under 1. b. "(b) (4)". This procedure does not state what your employee should do if the fly count within a house is between (b) (4) flies.

3. Your procedure for fly monitoring and control ("Procedure: Fly Monitoring and Control", created 6/28/2010 and revised 7/20/2010) states under 1. b. "(b) (4)". However, your "Fly monitoring Records" for the 2011 calendar year do not specify nor indicate that this was done on 7 occasions.

**OBSERVATION 7**

The presence of rodents is not monitored by appropriate monitoring methods.

Specifically,

Your firm's rodent monitoring procedure ("Procedure: Rodent Monitoring and Control", created 6/28/2010 and revised 6/9/2011) states under 1. a. "(b) (4)". However every other week does not provide for adequate monitoring. During a review of your firm's "Mouse numbers record" and other untitled documents you identified as rodent monitoring records for the 2011 calendar year, the time between monitoring dates ranges from (b) (4) to (b) (4). This inconsistency in monitoring time frames does not allow for comparison and adequate monitoring for rodents within your firm's poultry houses.

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OF THIS PAGE**

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Brittany D. Phillips, Investigator *BDP*

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**OBSERVATION 8**

You do not maintain practices that will protect against cross contamination when equipment is moved among poultry houses.  
 Specifically,

Your firm does not disinfect hand tools and other equipment used to remove manure from floor joists and cage curtains that is used in all poultry houses on the farm. Your firm does not take adequate precautions to ensure equipment brought in and used by an outside pressure wash company has been cleaned and disinfected prior to house entry. Your firm also does not disinfect the unloader used to remove manure within the manure pit.

**OBSERVATION 9**

You do not maintain records documenting compliance with refrigeration requirements.  
 Specifically,

Your firm does not maintain records indicating shell eggs were refrigerated at 45°F within 36 hours of lay.

**OBSERVATION 10**

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

Your firm's cleaning record entitled, "Cleaning between Flocks for House 1", dated "June 9 to June 15<sup>th</sup>" does not display your farm's name and location upon the record.

**\* DATES OF INSPECTION:**  
 06/23/2011(Thu), 06/24/2011(Fri), 06/27/2011(Mon), 06/29/2011(Wed)

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