

**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: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/20/2011 - 06/21/2011
	FEI NUMBER 3004387762

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Shad H. Strong, Complex Manager

FIRM NAME Humboldt Egg Farms	STREET ADDRESS 2088 120th St
CITY, STATE, ZIP CODE, COUNTRY Humboldt, IA 50548-7711	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 written SE prevention plan is not fully implemented and followed.

Specifically,

1. Your SE Plan dated "Revised 7/1/11" states under Section IV-A-3-e "We follow FDA Industry Guidance for the RI". Your Rodent Monitoring records dated 3/1/11- 6/12/11 indicate an RI for the entire facility and not a RI for each barn. FDA Industry Guidance states an RI for each house/barn be monitored on a weekly basis.
2. Your plan states you will follow FDA Industry Guidance for the RI. FDA Industry Guidance for RI is a scale from 1-3 for each house and your plan states an RI threshold of ^(B) for the entire facility. Your Rodent Monitoring Records dated 3/1/11- 6/14/11 document an RI for the entire facility and does not have an RI calculated for each barn.

OBSERVATION 2

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

Your SE Plan dated 4/1/11 and your SE Plan dated "revised 7/1/11" states pullets will be tested at 12 weeks.

OBSERVATION 3

When your monitoring indicated unacceptable rodent activity within a poultry house, appropriate methods were not used to achieve satisfactory rodent control.

Specifically,

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Erin C. Dugan, Investigator <i>E. C. Dugan</i> Bonnie E. Pierson, Investigator <i>Bonnie E. Pierson</i>	DATE ISSUED 07/05/2011
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According to your procedure written in your SE Plan action will be taken when a RI of (B) is reached. Your Rodent Monitoring Logs indicate an unacceptable rodent activity level above (B) for Houses (B) dated 6/14/11, (B) dated 6/14/11 (B)(4) for 6/14/11, (B) for 5/31/11, (B) for 5/31/11, (B) for 5/24/11, (B) for 5/17/11, and (B) for 5/10/11. No (4) written corrective action methods were documented for these houses. (4) (4) (4)

OBSERVATION 4

Your pullet environment is not tested for SE when pullets are 14 to 16 weeks of age.

Specifically,

1. There was no environmental SE test performed on the pullets housed in Laying House (B) NPIP dated 6/3/10 pullets were not tested at all for SE prior to being housed in Laying House (B)(4) on 9/26/10. (4)

2. Pullets housed in Laying Houses (B)(4) environmental testing was done at 12 weeks of age

- a. (B) pullets NPIP dated 8/10/10 with environmental pullet sample taken on or about 11/17/10 (4)
- b. (B) pullets NPIP dated 8/10/10 with environmental pullet sample taken on or about 11/17/10 (4)
- c. (B) pullets NPIP dated 10/21/10 with environmental pullet sample taken on or about 2/2/2011 (4)

The above observation was removed based on a calculation performed on NPIP sheets and sample test results showing samples were taken between 14-16 weeks of age.

OBSERVATION 5

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 SE Plan dated 4/1/11 page 16, E; was still in effect for environmental sampling as of 6/20/2011. The SE Plan states: Cage Layer Sampling 1). "Use commercially available (B)(4) (B)(4) commercially available like (B)(4) for each of the environmental sampling." The (B)(4) are not recognized as an equivalent method. Samples taken on 6/19/2011 used the above unapproved method for sampling the environment of

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TYPE ESTABLISHMENT INSPECTED

Shell Egg Producer

Laying Houses (B)(4)

Pullet Sampling Procedures is the same as stated above in SE Prevention Plan dated 4/1/2011. The (B)(4) are not recognized as an equivalent method. Pullet environmental samples taken for Laying Houses (B)(4) were all taken using (B)(4)

OBSERVATION 6

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 created and performed by (B)(4) states "Service Person: (B)(4) the record does not carry the signature or initials of the person performing the monitoring.

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**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Erin C. Dugan, Investigator
Bonnie E. Pierson, Investigator

E. Dugan
Bonnie E. Pierson

DATE ISSUED

07/05/2011