#### DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION One Montvale Avenue 05/02/2011 - 05/10/2011 FEI NUMBER Stoneham, MA 02180 (781) 587-7500 Fax: (781) 587-7556 3001056284 Industry Information: www.fda.gov/oc/industry George S. Bass, Owner FIRM NAME STREET ADDRESS 16 Williamsville Rd The Country Hen Inc

TYPE ESTABLISHMENT INSPECTED

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:

01452-1311

### **OBSERVATION 1**

CITY, STATE, ZIP CODE, COUNTRY

Hubbardston, MA

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically, we observed that the items listed below are inadequately covered in the SE prevention plan.

### 1) Biosecurity measures:

 Practices limiting the transfer of SE from one farm to another as a result of the farm's use of re-usable flats to collect eggs are not listed in the SE prevention plan.

### 2) Refrigeration:

 The SE prevention plan does not include requirements to refrigerate eggs in the pre-cooler once 36 hours after time of lay has passed.

## **OBSERVATION 2**

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

Specifically, with regard to biosecurity procedures we observed:

- Stray animals are not prevented from entering poultry houses. We observed a bird flying in house number #2. We also observed numerous holes in the poultry wires covering open windows in house numbers 2, 3 and 5/10. The current poultry netting covering the windows in these houses allows the entry of small birds into the layer houses when the windows are open.
- Visitors are not limited on the farm.

	AMENDMENT 1	
	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Wendy A. Johnecheck, Investigator Werdy A. Thereholder A. Khatib, Investigator Werdy A. Thereholder Wendy A. There	06/06/2011

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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

	NT OF HEALTH AND HUN OD AND DRUG ADMINISTRA		
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(781) 587-7500 Fax:(781) 587-7556	3001056284		
Industry Information: www.fda.gov/			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
TO: George S. Bass, Owner	STREET ADDRESS		
The Country Hen Inc	16 Williamsville Rd		
CITY, STATE, ZIP CODE, COUNTRY			
Hubbardston, MA 01452-1311 Egg Pro		oducer	
OBSERVATION 3  Environmental testing for SE, using approved meth laying hens, when each group of laying hens was 4		poultry house containing more than one group of	
Specifically, houses 8/11 have 4		ch level holding layers of different ages. Based or level of these houses was swabbed when the group	

# **OBSERVATION 4**

Eggs intended to be processed as table eggs were held at room temperature for more than 36 hours just prior to processing.

Specifically, at approximately 12:30 pm on 5/2/2011 we observed eggs collected from production at 3:00 pm on Saturday 4/30/2011 being held in a pre-cooler located inside the farm's on-site, off-line processing facility. The thermometer in the pre-cooler read 50 degrees F. Further, based on the production schedule provided by the farm's General Manager, we noted basis eggs are collected from the barns a and then held in the pre-cooler to be processed The pre-cooler is not turned on during this period, resulting in the eggs being held at 45 degrees or higher after the 36 hour period of time of lay has passed.

# **OBSERVATION 5**

You did not maintain records documenting compliance with biosecurity measures.

Specifically, we observed that Country Hen Inc. has developed the following forms for documenting biosecurity measures:

- 1) Forms for documenting visitors on the farm: a Farm Visitor Questionnaire, a Main Farm Visitor Log Form, a Barn # Visitor Log Form, a Delivery Log - Office Form, and a Delivery Log-Loading Dock Form;
- 2) A "Check List" form that documents the measures taken to prevent stray poultry, wild birds, cats and other animals from entering poultry houses: Repair Entry Points for Wild Birds, Etc.; Inspect for Wild Birds, and Pen Doors Closed; and a
- 3) A Foot Bath Inspection Log documenting the concentration of the foot bath at the entrance of each house/barn.

We noted that these records currently reside in the SE Prevention plan folder, but have not yet been implemented on the farm.

### AMENDMENT 1 EMPLOYEE(S) SIGNATURE Wendy A. Johnecheck, Investigator SEE REVERSE Osama A. Khatib, Investigator 06/06/2011 OF THIS PAGE

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Hubbardston, MA 01452-1311	Egg Producer		

### **OBSERVATION 6**

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

Specifically, we observed that Country Hen Inc. has developed the following forms for documenting rodent and other pest control measures:

- 1) Forms for documenting the level of products used for controlling rodents and other pests: Barn interiors, Barn Exteriors Normal Materials, Barn Exteriors Level 4 Materials Usage Log, and Usage Log;
- 2) A form for monitoring average flies on a basis. This form does not include name and location of the farm, the date and time of activity that record reflects, and the signature or initials of person creating the record;
- 3) A "Check List" form used to ensure that are monitored and replaced.

We noted that these records currently reside in the SE Prevention plan folder, but have not yet been implemented on the farm.

### **OBSERVATION 7**

You do not maintain records documenting compliance with refrigeration requirements.

Specifically, we observed that Country Hen Inc. does not maintain records for the pre-cooler refrigeration unit located in the on-farm, off-line processing facility. This walk-in cooling unit holds eggs after time of lay until the eggs are processed at the farm.

AMENDMENT 1

SEE REVERSE OF THIS PAGE Wendy A. Johnecheck, Investigator Osama A. Khatib, Investigator

anthated

06/06/2011