

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax: (913) 752-2111 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 07/20/2011 - 07/22/2011
	<small>FEI NUMBER</small> 3008510957

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Wesley R. Hilton, Complex Manager

<small>FIRM NAME</small> New Horizon Cooperative	<small>STREET ADDRESS</small> 1979 Iowa Ave
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Britt, IA 50423-8588	<small>TYPE ESTABLISHMENT INSPECTED</small> Egg Manufacturer

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

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

Specifically,

You failed to provide appropriate justification describing that your system of rodent indexing and RI action level (b) (4) is an appropriate monitoring method.

Also, you failed to monitor for rodents in house (b) (4) for the following weeks; week of 7/13/10, week of 7/27/10, week of 8/24/10, and the week of 9/7/10.

Also, you failed to monitor for rodents in house (b) (4) for the following weeks; week of 9/7/10, and week of 9/21/10.

OBSERVATION 2

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

Specifically,

You failed to perform an appropriate method to achieve satisfactory rodent control after recording a RI over (b) (4) 11/2/2010 for house (b) (4). Although your SE plan being used during the time of 11/2/2010 did not require an action at any RI level, it was acknowledged by management there was a problem which needed to be addressed at that level. According to the (b) (4) (b) (4) Service Report dated 11-2-10 and the following report dated 11-10-10, there are no comments or actions pertaining directly to house 3 and its high level of rodent activity.

OBSERVATION 3

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Weston K. Szymanski, Investigator <i>[Signature]</i> Andrew A. Hoopes, Investigator <i>[Signature]</i>	<small>DATE ISSUED</small> 07/22/2011 7/22/11
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You failed to have the method for calculating rodent index (RI) in your Salmonella Prevention Program - Sparboe Farms, Inc. & New Horizon Cooperative Farm dated 7/1/2011. Page 24 of 27, A. 1) a) states that "Rodent Monitoring is done under the Rodent Index Procedure." but there is no description of how to calculate the RI in the Salmonella Prevention Program.

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,

You failed to have any of the environments of your flocks environmentally tested for SE using the "Environmental Sampling and Detection of Salmonella in Poultry Houses." most current edition as of the first day of our inspection on 7/20/11. Management stated that all of the environmental tests done prior to the first day of the inspection were done using the testing technique outlined in the previous edition of the Salmonella Prevention Program dated 4/1/2011 on page 16 of 29, E 1). You failed to provide any justification which shows your previous method was equivalent to the method described in "Environmental Sampling and Detection of Salmonella in Poultry Houses.", in accuracy, precision, and sensitivity in detecting SE.

OBSERVATION 5

Your written SE prevention plan is not implemented and followed.

Specifically,

You failed to follow your Salmonella Prevention Program - Sparboe Farms, Inc. & New Horizon Cooperative Farm in multiple ways. Page 24 of 27 B 5) states "Record Monitoring Counts. The log includes the Facility name, Address, the date, time of the day (either AM or PM) and Initial of the person gathering the date. These should be initialed (b) (4) by either of the on-site Administrator(s) of this program." The House Fly Activity log does not have the time recorded for the fly indexing occurring on 7/3/2011 and 7/10/2011. Also, on the Fly Control Log, the applications that occurred on 7/5/2011 and the two applications that occurred on 7/20/11 do not have the time nor are initialed (b) (4) by the on-site administrator.

Also, the Salmonella Prevention Program - Sparboe Farms, Inc. & New Horizon Cooperative Farm states on page 24 of 27 under A. 1) f) ii. "There are (b) (4) mouse traps and (b) (4) tracking tubes in each house". Since the revision date of the current Salmonella Prevention Program of 7/1/2011, there are (b) (4) traps in house (b) (4) of the first day of the inspection on 7/20/2011.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Weston K. Szymanski, Investigator
Andrew A. Hoopes, Investigator

DATE ISSUED

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OBSERVATION 6

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

Specifically,

You failed to provide justification for the fly index action level of (b) (4) fly's average per index cards as an appropriate monitoring method.

OBSERVATION 7

All your required records do not include the time of the activity that the records reflect.

Specifically,

You failed to record the time of the activity on multiple records.

- House Fly Activity record: The House Fly Activity record is where the fly index is recorded for each house. The fly index is recorded approximately (b) (4) The fly index is recorded, with no associated time, for 45 weeks from 7/11/2010-6/26/2011.
- Fly Control Log: The Fly Control Log is used to record the chemical used to control the fly population, as a corrective action initiated by the Fly index, in each house. There are 55 events recorded, with no associated time, between 7/12/2010 and 6/29/2011.
- Rodent Index Monitoring Record: The Rodent Index Monitoring Record is used to record the rodents found in each of the traps per house. Each record contains the amount of rodents found in the traps on the recorded date. There is no associated time recorded on the 46 records of when the rodent counts were collected between 7/13/2010 and 7/13/2011.

OBSERVATION 8

Potential harborage for pests in and outside your poultry house have not been eliminated by removing debris and vegetation outside the poultry house.

Specifically,

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	<i>[Handwritten Signatures]</i>	<i>[Handwritten Initials]</i>

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You failed to eliminate potential harborage for pests outside your poultry house. During our tour of the outside of the chicken houses we observed approximately 5-6 2X4 pieces of lumber piled together in between chicken houses (b) (4) and (b) (4). As we approached the lumber, an employee (b) (4) lifted up one end of the 2X4's and a rodent ran out of underneath it. Between chicken houses (b) (4) and (b) (4) we also observed grass standing up to approximately 4.5 feet tall. The grass is thick enough and tall enough to provide potential harborage for pests.

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