

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/07/2011 - 02/16/2011*
	FEI NUMBER 3002527924

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Scott A. Culwell, Vice President of Operations

FIRM NAME Nature Pure LLC	STREET ADDRESS 26560 Storms Rd
CITY, STATE, ZIP CODE, COUNTRY West Mansfield, OH 43358-9662	TYPE ESTABLISHMENT INSPECTED Egg Grower

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 I OBSERVED:

OBSERVATION 1

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, the lab you are utilizing to test your firm's environmental samples is not conducting testing by the "Environmental Sampling and Detection of Salmonella in Poultry Houses" method, or an equivalent method in detecting SE. The lab is using (b) (4) method. No scientific data or studies were provided that prove that it is an equivalent method in accuracy, precision, and sensitivity in detecting SE.

OBSERVATION 2

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

Specifically,

a.) Pullets at Farm 1, pullet house (b) (4) located at 26586 St. Rt. 739, Raymond, OH 43067, were not tested for SE between 14 to 16 weeks of age. The pullet house was sampled on 01/25/2011, when the pullets were approximately 12 weeks and two days of age. This house was populated on 10/29/2010 and will be depopulated on or around 02/22-25/2011, and will be used to populate layer houses (b) (4) and (b) (4) at Farm (b) (4).

b.) Pullets at Farm 1, pullet house (b) (4) located at the address above, were not tested for SE. The house was populated on 08/25/2010 and depopulated between 12/20-22/2010. The birds from this house were sent to one of your customer's layer houses.

OBSERVATION 3

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

a.) Your SE prevention plan states that pullet houses are to be sampled at 10 to 15 weeks of age, instead of 14 to 16 weeks as

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael E. Campbell, Investigator	DATE ISSUED 02/16/2011
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required.

b.) Your firm's SE prevention plan does not include a cleaning and disinfection procedure for when the environment of a poultry house is SE positive.

c.) Your SE prevention plan does not cover fly monitoring.

*** DATES OF INSPECTION:**

02/07/2011(Mon), 02/09/2011(Wed), 02/10/2011(Thu), 02/15/2011(Tue), 02/16/2011(Wed)

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 OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Michael E. Campbell, Investigator

DATE ISSUED

02/16/2011