

**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 05/09/2011 - 05/10/2011 FEI NUMBER 3008780112
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: David D. Nugent, Owner**

FIRM NAME Nugent Nuggets, LLC	STREET ADDRESS 13304 260th Street
CITY, STATE, ZIP CODE, COUNTRY Radcliffe, IA 50230	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, your (b) (4) SOP.OPS.PRD 7 Salmonella Program Revised 4/1/2011, page 22, C. Cleaning and Disinfection (C/D) program and procedure. 1) Cleaning, b) states "Pullet and layer barns are to be cleaned and disinfected (C/D) between flocks according to company policy." Management states layer barns are not cleaned and disinfected between flocks.

Your (b) (4) SOP.OPS.PRD 7 Salmonella Program Revised 4/1/2011, page 22, A. Biosecurity Program and Procedures., states (b) (4) Biosecurity Program and Procedures is a prevention program and related to this Salmonella (b) (4) Your SOP.OPS.PRD.: (b) (4) Biosecurity Program and Procedures Manual, page 10, IV. FARM, BARN and SURROUNDINGS., Layer Farms: A. Outside farm and its immediate surroundings., states "1) Presence of controlled gates., 2) Warning signs (No-Admittance-Biosecurity site) posted by the gates, farm or site entrances., 3) Entrance to the premises will be secured., 4) Intercommunication device between outside gate and inside the farm or site."

Your farm has no controlled gates at the farm entrance, there is no warning signs defining the farm as a Biosecurity site, entrance to the premises is not secured and there is no intercommunication device utilized on your farm for entrance.

**OBSERVATION 2**

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 (b) (4) SOP.OPS.PRD 7 Salmonella Program Revised 4/1/2011, page 16, E. Cage Layer Sampling 1). states "Use commercially available (b) (4) commercially available like (b) (4) for each of the environmental sampling." The (b) (4) are not recognized as an equivalent method.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Candace S Tucker, Investigator Meisha R. Waters, Investigator	<i>Candace S. Tucker</i> <i>Meisha R. Waters, Investigator</i>	DATE ISSUED 05/10/2011
---------------------------------	---	---	---------------------------

**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](http://www.fda.gov/oc/industry)

DATE(S) OF INSPECTION

05/09/2011 - 05/10/2011

FEI NUMBER

3008780112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David D. Nugent, Owner

FIRM NAME

Nugent Nuggets, LLC

STREET ADDRESS

13304 260th Street

CITY, STATE, ZIP CODE, COUNTRY

Radcliffe, IA 50230

TYPE ESTABLISHMENT INSPECTED

Shell egg Producer

**OBSERVATION 3**

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

Specifically, your current Salmonella Prevention Program SOP.OPS.PRD 7, Revised on 4/1/2011, on page 17, Section E, Cage layer Sampling: 5) Collection Procedures: states, "iii. One environmental sample will come from (b) (4) (b) (4)

Sample schematic is not representative of the entire house. Houses 1 through 3 have (b) (4) rows/ (b) (4) tiers, and house 4 has (b) (4) rows/ (b) (4) tiers. Tiers (b) (4) as well as the upper level walkways of the houses are not sampled.

**OBSERVATION 4**

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

Specifically, your (b) (4) SOP.OPS.PRD 7 Salmonella Program Revised 4/1/2011, page 25, H. Pest Control, Godfather's Service., 3) states "Barn Rodent Index should be lower than (b) (4). Management stated there is no Rodent Index calculation performed.

**OBSERVATION 5**

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

Specifically, your Mice Log documents do not have available space to record the time activities such as rodent counts and baiting bait stations were performed. A review of your Mice Logs from July through April 1, determined the log lacks the year the activity was performed, as the employee recording the activity documents the month and day only.

**OBSERVATION 6**

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

Specifically, a review of your firms documents including Layer Records, Mice Log, (b) (4) Flock Summary Report, Fly Procedures and Rodent Procedures, lack the name and location of your farm.

**OBSERVATION 7**

Your written SE plan does not carry the signature(s) and not the initials of the person(s) who administer the plan.

Specifically, your (b) (4) SOP.OPS.PRD 7 Salmonella Prevention Program Revised 4/1/2011 is not signed by your SE Plan administrator.

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Candace S Tucker, Investigator  
Meisha R. Waters, Investigator

*Candace S. Tucker*  
*Meisha R. Waters*

DATE ISSUED

05/10/2011

**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](http://www.fda.gov/oc/industry)

DATE(S) OF INSPECTION

05/09/2011 - 05/10/2011

FEI NUMBER

3008780112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** David D. Nugent, Owner

FIRM NAME

Nugent Nuggets, LLC

CITY, STATE, ZIP CODE, COUNTRY

Radcliffe, IA 50230

STREET ADDRESS

13304 260th Street

TYPE ESTABLISHMENT INSPECTED

Shell egg Producer

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Candace S Tucker, Investigator  
Meisha R. Waters, Investigator

*Candace S. Tucker*  
*Meisha R. Waters*

DATE ISSUED

05/10/2011