

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

|  |  |
|--|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER<br><br>60 8th St NE<br>Atlanta, GA 30309<br>(404) 253-1161<br><br>Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION<br>03/26 - 4/11/18 |
|  | FEI NUMBER<br>2000023438                 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Nathan K. Nickolisen, Complex Manager**

|  |   |
|--|---|
| FIRM NAME<br>Rose Acre Farms - Hyde County Egg | STREET ADDRESS<br>1560 Hyde Park Canal Road |
|--|---|

|   |   |
|---|---|
| CITY, STATE AND ZIP CODE<br>Pantego, NC 27860 | TYPE OF ESTABLISHMENT INSPECTED<br>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 (I) (WE) OBSERVED:

**Observation 1:**

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

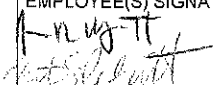
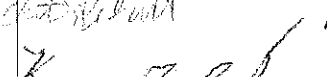
Specifically, a review of your pest control records from September 2017 to present indicate an ongoing rodent infestation. The corrective actions taken by your firm have not been effective at reducing the rodent levels within your poultry houses to an acceptable level that is below the threshold established in your SE Prevention Plan.

Additionally, the following conditions were observed in the poultry houses:

On 03/26/2018:

- House 9 - one (1) live apparent rodent in manure pit while swabbing about halfway down row two (2) in the pit, and one (1) live apparent rodent observed running across the upper level floor last row 10; two (2) dead apparent rodents observed on the ground, 10+ feet from the front of the houses; daylight observed through an area with spray foam creating a potential pest entrance in the manure pits around the closed roll up door at the front of the house near row four (4).
- House 13 - multiple live apparent rodents running around the staging area in pit, and burrowing in and out of manure piles; five (5) live apparent rodents observed in the manure pits.

Add Continuation Page

|                          |  |  |                        |
|--------------------------|--|--|------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br> | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>James R. Boetz, CEO<br>Anthony S. Roberts, CEO | DATE ISSUED<br>4/11/18 |
|                          |                           | INSPECTIONAL OBSERVATIONS<br>Nathan K. Nickolisen, CEO                                       |                        |

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

|  |   |  |
|--|---|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER<br>60 8th St NE<br>Atlanta, GA 30309<br>(404) 253-1161<br><br>Industry Information: www.fda.gov/oc/industry |   | DATE(S) OF INSPECTION<br>03/26 - 4/11/18 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED<br><b>TO: Nathan K. Nickolisen, Complex Manager</b>  |   | FEI NUMBER<br>2000023438                 |
| FIRM NAME<br>Rose Acre Farms - Hyde County Egg   | STREET ADDRESS<br>1560 Hyde Park Canal Road           |  |
| CITY, STATE AND ZIP CODE<br>Pantego, NC 27860  | TYPE OF ESTABLISHMENT INSPECTED<br>Shell Egg Producer |  |

On 03/27/2018:

- House 2 - one (1) live apparent rodent, downstairs in row 4, pit area.
- House 6 - one (1) live apparent rodent, in row 1, pit area.
- House 10 - approximately 4-5 apparent live rodents in the pit were observed near the staging table and several were observed while dragging swabs, in the pit area; more than 10 apparent rodents observed in pit staging area including baby mice.
- Approximately five (5) apparent rodents seen while walking rows during swab collection; also, a large spill/pile of what appeared to be feed with large flying insects too numerous to count between house numbers 10 and 11, directly beside canal.
- House 11 - one (1) live apparent rodent in manure pit while swabbing approximately halfway down row 5; possible apparent rodent burrows observed in the manure piles; apparent dead rodent carcass on row 5; possible apparent rodent hole/burrow observed in the large gravel in the front of the house; and 1 apparent live rodent on the bird platform.

On 03/28/2018:

- House 5 - three (3) live apparent rodents were observed downstairs, in rows 4 & 5.
- House 8 - two (2) live apparent rodents were observed downstairs, in rows 4 & 1.

Observation 2:

There were insanitary conditions and poor employee practices observed in the egg processing facility that create an environment that allows for the harborage, proliferation and spread of filth and pathogens throughout the facility that could cause the contamination of egg processing equipment and eggs.

Specifically,

On 03/28/18, a review of the firm's sanitation procedure, Cleaning Procedure for (b) (4) Form # 6.7.0 F-3, Version #3, found that the procedure for cleaning the (b) (4) in the egg processing facility was not being implemented by management and followed by sanitation employees. Employees were observed bypassing the (b) (4) step, and observed spraying on the detergent and immediately wiping off, not allowing the detergent to soak for the prescribed (b) (4) minutes.

Add Continuation Page

|                          |   |   |                        |
|--------------------------|---|---|------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br><i>[Handwritten Signature]</i> | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>James R. Botz, CSO<br>Staging & Control, SC<br><i>[Handwritten Signature]</i> | DATE ISSUED<br>4/11/18 |
|--------------------------|---|---|------------------------|



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

|  |  |
|--|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER<br><br>60 8th St NE<br>Atlanta, GA 30309<br>(404) 253-1161<br><br>Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION<br>03/26 - 4/11/18 |
|  | FEI NUMBER<br>2000023438                 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Nathan K. Nickolisen, Complex Manager**

|  |   |
|--|---|
| FIRM NAME<br>Rose Acre Farms - Hyde County Egg | STREET ADDRESS<br>1560 Hyde Park Canal Road           |
| CITY, STATE AND ZIP CODE<br>Pantego, NC 27860  | TYPE OF ESTABLISHMENT INSPECTED<br>Shell Egg Producer |

On 03/28/18, during a review of the firm's cleaning procedures and a walkthrough of the cleaning procedures we observed that the firm did not have in their procedures or use a sanitizing step following the wash step.

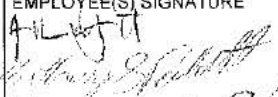
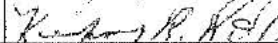

Throughout the inspection we observed condensation dripping from the ceiling, pipes, and down walls, onto production equipment (i.e crack detector, egg grader) and pooling on floors in foot traffic and forklift pathways.

On 03/28/18, we observed maintenance and sanitation employees placing buffers (food contact) and metal covers to the egg packer with buffers (non-food contact) onto floor, pallets, and equipment that was visibly dirty with accumulated grime and food debris, before placing the equipment into service. Additionally, throughout the inspection several production and maintenance employees were observed touching non-food contact surfaces (i.e. face, hair, intergluteal cleft, production equipment with accumulated grime and food debris, floor, boxes, trash cans, inedible transport cans) and then touch shell eggs and food contact surfaces (i.e. buffers, rollers, etc.) without changing gloves or washing hands. We also observed maintenance employees dragging non-food contact equipment (i.e. black electrical conduit with accumulated grime and dried food debris) on top of food contact surfaces (i.e. conveyors and rollers).

Throughout the inspection we observed equipment (i.e. conveyor belts, chains, rail guards, buffers, egg transport arms, egg clappers, production computers and exterior of production equipment surfaces) with accumulated food debris (i.e. dried egg and shells) and grime, post sanitation. The same areas of accumulated food debris were observed uncleaned on multiple days during the inspection pre-and post-sanitation.

On 03/28/18, we observed a sanitation employee on the right line, packing area, lanes (b) (4) utilizing a steel wool scrubber to scrub debris off egg buffers in service, post sanitation. The steel wool scrubber was stored on a cart in a dustpan that had a pool of water and egg mix with floating food debris and grime.

Add Continuation Page

|                          |  |  |                        |
|--------------------------|--|--|------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br> | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>James R. Butz, LLC<br>All things Egg Co. LLC | DATE ISSUED<br>4/11/18 |
|                          |                           |        |                        |

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

|  |  |
|--|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER<br><br>60 8th St NE<br>Atlanta, GA 30309<br>(404) 253-1161<br><br>Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION<br>03/26 - 4/11/18 |
|  | FEI NUMBER<br>2000023438                 |

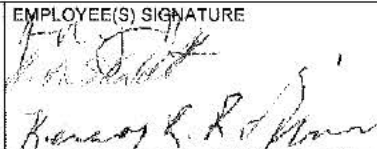
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Nathan K. Nickolisen, Complex Manager**

|  |   |
|--|---|
| FIRM NAME<br>Rose Acre Farms - Hyde County Egg | STREET ADDRESS<br>1560 Hyde Park Canal Road           |
| CITY, STATE AND ZIP CODE<br>Pantego, NC 27860  | TYPE OF ESTABLISHMENT INSPECTED<br>Shell Egg Producer |

Throughout the inspection we observed at least 25 flying insects throughout the egg processing facility. The insects were observed landing on food, food contact surfaces, and food production equipment.

On 03/28/18, we observed an employee mix and use a sanitizer on food contact equipment that was not prepared according to the manufacturer instructions. When tested with a quaternary ammonia test strip, the sanitizer was found to be 1500ppm, outside of the acceptable range of (b) (4) ppm.

Add Continuation Page

|                          |  |  |                        |
|--------------------------|--|--|------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br> | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>Kenneth R. Robinson, CSO<br>Kenneth R. Robinson, CSO | DATE ISSUED<br>4/11/18 |
|                          | INSPECTIONAL OBSERVATIONS  |  |                        |