

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 th St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10
	FEI NUMBER 3006481643, 3004793793, 3005280357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: <i>Mr. Peter A. DeCoster, COO</i> FEI: 3004797952, 3006481709, 3003073159	
FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE Galt, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (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 REPOSE 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.

Observations listed below cover inspections of your egg laying farms/plants inspected from 08/12/2010 through 08/30/2010. Inspections of Layers 1, 3 and 6 included record review and environmental assessments of all houses. Inspections of Layers 2 and 4 included record review of all houses and environmental assessments for Layer 2 – Houses 7 and 11 and Layer 4 – House 3.

- FEI: 3006481643 - Quality Egg LLC, Plant/Layer 1, 2615 280th Street, Galt, IA 50101
- FEI: 3004793793 - Wright Co. Egg, Plant/Layer 2, 2550 270th Street, Clarion, IA 50525
- FEI: 3005280357 - Quality Egg LLC, Plant/Layer 3, 2674 270th Street, Clarion, IA 50525
- FEI: 3004797952 - Wright Co. Egg, Plant/Layer 4, 2680 250th Street, Clarion, IA 50525
- FEI: 3006481709 - Quality Egg LLC Environ, Plant/Layer 6, 2865 310th Street, Dows, IA 50071
- FEI: 3003073159 - Quality Egg LLC Feed Mill, 2624 Highway 69, Galt, IA 50101

I. You failed to fully implement and follow your written SE prevention plan.

Specifically,

- a) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 8, under section (b) (4) [redacted]), (b) (4) [redacted]. This had not been accomplished as evidenced by the following observations:
- Layer 3 - House 1 - approximately 2x6 inch wood board was observed on the ground with approximately 8 frogs living underneath.
 - Layer 3 - House 15 - unused wooden structures were observed located approximately 5 feet from the exterior of the building.
 - Layer 3 - Houses 11 and 12 - grass approximately 12 inches high was observed in between Houses 11 and 12.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Katherine M. Taylor</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <i>Katherine M. Taylor Investigator</i>	DATE ISSUED <i>08/30/10</i>
	<i>[Signature]</i>	<i>Nicole J. Clausen, Investigator</i>	

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TO: FEI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
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b) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 13, under section (b) (4)), (b) (4) s". This had not been accomplished as evidenced by the following observations:

- Non-chicken feathers were observed inside Layer 3 - House 3. One live wild bird was observed flying above chicken cages inside Layer 1 - House 9. Wild birds were observed flying inside and outside of Layer 1 - Houses 11 and 12. Pigeons were observed roosting in an air vent where the screening was damaged on south side of the Layer 1 - House 14.
- Two birds' nests were observed on the outside structure of Layer 3 - between Houses 1 and 2 approximately 7 - 12 feet from the manure pit doors. Layer 3 - House 8 had a bird's nest and birds were observed under the edges of metal siding on the south wall.
- Chicken manure located in the manure pits below the egg laying operations was observed to be approximately 4 feet high to 8 feet high at the following locations: Layer 1 - House 1; Layer 3 - Houses 2, 7, 17, and 18. The outside access doors to the manure pits at these locations had been pushed out by the weight of the manure, leaving open access to wildlife or domesticated animals.
- Exterior structural damage allowing entrance to the interior of the laying houses was observed in Layer 1 - Houses 1, 3, 4, 7, 8, 11 and 12; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 2, 11, 13, 14, 15 and 18; Layer 4 - House 3. Observations include: holes in exterior siding, missing siding, holes and/or gaps in the concrete foundation and air vent screens either missing or damaged.
- The east and west doors located on the second floor egg laying areas of Layer 1 - Houses 1 - 14; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 3, 4, 5, 6, 9, 11, 15, 16, 17, and 18; Layer 4 - House 3 were observed to have gaps at the bottom and sides ranging from a 1/2 inch to 2 inches.

c) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 7, under section (b) (4)), (b) (4)". This had not been accomplished as evidenced by the following observation:

- Un-baited, unsealed holes appearing to be rodent burrows located along the second floor baseboards were observed inside Layer 1 - Houses 1 - 9 and 11 - 13; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 3, 4, 5, and 6; Layer 4 - House 3.

d) Your "Quality Egg Bio-Security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 12, under section (b) (4)), (b) (4)". This had not been accomplished as evidenced by the following observations:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE KMT NSC	EMPLOYEE(S) NAME AND TITLE (Print Last Name) Katherine M. Taylor Investigator Nicole J. Clausen, Investigator	DATE ISSUED 08/30/10
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		FEI NUMBER 3006481643, 3004793793, 3005280357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Peter A. DeGoster, CEO FEI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE Galt, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer

- Dark liquid which appeared to be manure was observed seeping through the concrete foundation to the outside of the laying houses at the following locations: Layer 1 - Houses 1, 2, 3, 4, 5, 8, 11, 12 and 14; and Layer 3 - Houses 1, 8, 13 and 17.
- Standing water approximately 3 inches deep was observed at the southeast corner of the manure pit located inside Layer 1 - House 13.

2. You failed to take steps to ensure there is no introduction or transfer of SE into or among poultry houses. This was evidenced by the following observations:

Specifically,

- a) There was only one entry doorway to access egg laying areas located on every other house. Entrances for houses on Layer 1 and Layer 2 were located on even numbered houses. Entrances for houses on Layer 3 and Layer 4 were located on odd numbered houses. For example, at Layer 3 and Layer 4 - House 1 had a doorway and this same doorway had to be used to gain entrance to House 2.
- b) Employees working within the houses did not wear or change protective clothing when moving from house to house. An employee at Layer 6 - House 3 was observed walking out of House 3 with a metal scraper and into House 2 without changing protective clothing and without cleaning/sanitizing equipment between the houses.
- c) Un-caged birds (chickens having escaped) were observed in the egg laying operation in contact with the egg laying birds at Layer 3 - Houses 9 and 16. The un-caged birds were using the manure, which was approximately 8 feet high, to access the egg laying area.
- d) Layer 3 - House 11, the house entrance door to access both House 11 and 12 was blocked with excessive amounts of manure in the manure pits.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <u>KMT</u> <u>NJC</u>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <u>Katherine M. Taylor Investigator</u> <u>Nicole J. Clausen Investigator</u>	DATE ISSUED <u>8/30/10</u>
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: <u>Mr. Peter A. DeCoster, COO</u>		FEI NUMBER 3006481643, 3004793793, 3005280357
FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69	
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3. You failed to achieve satisfactory rodent and pest control as evidenced by the following.

Specifically,

- a) There were between 2 to 5 live mice observed inside the egg laying houses as follows:

Layer #	House #	Total Live Mice Observed
1	1	2
1	5	2
1	10	2
2	11	5
3	2	4
3	5	4
3	7	2
3	9	2
3	11	2
3	14	3
4	3	3

b) Live and dead flies too numerous to count were observed at the following locations inside the egg laying houses: Layer 1 – Houses 3, 4, 6, 8, 9, 11 and 12; Layer 2 – Houses 7 and 11; Layer 3 – Houses 3, 4, 5, 6, 7, 8, 15, 16, 17 and 18. The live flies were on and around egg belts, feed, shell eggs and walkways in different sections of each egg laying area. In addition, live and dead maggots too numerous to count were observed on the manure pit floor located in Layer 2 – House 7.

4. You did not document the monitoring of rodents and other pest control measures.

Specifically, your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 7, under section (b) (4), bullet 3), (b) (4) "Inspection of traps and bait stations were not conducted every 7 -14 days as evidenced by:

- Layer 1 did not have documented ((b) (4)) rodent inspections of Houses 1 - 14 after 7/15/10.
- Layer 2 did not have documented ((b) (4)) rodent inspections of Houses 1 and 2; Houses 3 – 14 had rodent inspections documented for 7/7/10 and an additional week that was not dated. The two inspections conducted would not adequately cover inspections every 14 days from 7/7/10 – 8/12/10.
- Layer 3 did not have documented ((b) (4)) rodent inspections of Houses 1 - 11 after 7/14/10; Houses 12 – 18 after 7/15/10.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <u>KMT</u> <u>NSC</u>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <u>Katherine M. Boyle, Investigator</u> <u>Nicole J. Clausen, Investigator</u>	DATE ISSUED <u>8/30/10</u>
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TO: Mr. Peter A. DeCoster, COO FEI: 3004797952, 3006481709, 3003073159

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- Layer 4 did not have documented (b) (4) rodent inspections of Houses 1, 2, 6, 7, 13 and 16; Houses 3 and 4 after 7/8/2010; Houses 10, 11, 12, 14, 15, 17 and 18 after 7/9/2010. Houses 5, 8, and 9 had a single week of rodent inspections documented but the date the inspection occurred was not recorded.

5. You did not maintain records documenting compliance with biosecurity measures.

Specifically, your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 08/11/10, reads in part (Page 5, under section (b) (4), (b) (4))

- You did not document washing and disinfection of your dead hen truck and manure equipment prior to moving from farm to farm.
- You did not maintain records documenting the washing and disinfection of the trailers used for the movement of pullets to laying houses under (b) (4).

6. You failed to document the signature or initials of the person performing the operation of inspecting rodent activity logs at the time in which the inspection is performed.

Specifically, review of your (b) (4) documentation for Layer 1 - Houses 1 - 14; Layer 2 - Houses 3 - 13; Layer 3 - Houses 1 - 18; Layer 4 - Houses 3, 4, 5, 6, 8, 9, 10, 11, 12, 14, 15, 17 and 18 did not contain a signature(s) or initial(s) of the person(s) performing the rodent inspections at the time they were performed.

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

Specifically, your (b) (4) form, (b) (4), (b) (4) and (b) (4) form for monitoring fly activity, rodent activity and evaluation of hen house cleaning (respectively) did not contain your name. Additionally, some of the (b) (4) forms and (b) (4) did not identify the layer site location where the monitoring occurred.

8. On 8/14/10, the following observations were noted at the Quality Egg LLC Feed Mill located at 2624 Hwy 69 Galt, IA 50101 FEI: 3003073159

- Specifically,
- Birds were observed roosting and flying, chicks heard chirping in the storage and milling facility. In addition, nesting material was observed in the feed mill closed mixing system, ingredient storage and truck filling areas.

SEE REVERSE OF THIS PAGE	EMPLOYER(S) SIGNATURE <u>KMT</u> <u>MSC</u>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <u>Kathleen M. Taylor, Investigator</u> <u>Nicole J. Clausen, Investigator</u>	DATE ISSUED <u>8/30/10</u>
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- Raw ingredient bins and feed sensors accessible from roof of facility had rusted holes and feed grain level sensors ajar to the outdoor environment. These included:
 - Ingredient storage bin 12, containing salt, had a rusted gap about a ½ inch wide the length of the lid of the roof level covered ingredient bin chute.
 - Ingredient storage bin 21 containing ground corn had a hole approximately 3 inches by ½ inch wide at the base of the roof level covered ingredient bin chute.
 - At the base of the feed grain level sensor leading into ingredient storage bin 21, containing ground corn, there was an open hole.
 - Feed grain level sensor leading into ingredient storage bin 7, containing meat and bone meal, was off to the side with approximately a 2 inch gap. Avian like feces was observed on top of this feed sensor.
 - Finished feed tanks 4 and 18 did not have covers on top of the finished feed tank chutes.
- Outdoor whole kernel corn grain bins 4 and 6 observed to have the topside doors/lids open to the environment and pigeons were observed entering and leaving these openings. Birds were also observed sitting/flying around and over the openings.

9. Samples collected during the course of this inspection and tested by an FDA laboratory revealed the following positive analytical results for *Salmonella* Enteritidis:

Specifically,

- On 8/13/2010, an environmental sample was collected from Layer 2, house 7 manure swab from row 1 – left side.
- On 8/16/2010, an environmental sample was collected from Layer 2, house 11 at manure scraper blade from row 3 - right side.
- On 8/13/2010, an environmental sample was collected from Layer 4, house 3 at walkway 1 – right side and walkway 3 - right side.
- On 8/14/2010, a sample of meat and bone meal was collected from ingredient bin 7 located at your feed mill.
- On 8/17/2010, a sample of finished feed “Developer” pullet feed was collected from the feed mill.
- On 08/16/2010, an environmental sample was collected from the roof level covered ingredient bin chute 8; Second Floor ingredient bin cover 19 (ingredient bin 19 holds ground corn) located at your feed mill.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Katherine M. Taylor</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Katherine M. Taylor Investigator	DATE ISSUED 08/30/10
	<i>Nicole J. Clauson</i>	Nicole J. Clauson, Investigator	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to the health. A copy of such report shall be sent promptly to the Secretary."