



November 30, 2010

SENT VIA FACSIMILE

Mr. Austin J. DeCoster, Owner
Quality Egg LLC
2674 Highway 69
Galt, IA 50101

Dear Mr. DeCoster:

This letter is in response to your request for FDA's concurrence to the shipment of eggs to the table market from two of your laying houses at Wright County Egg (WCE), Layer ■ located at 2680 250th Street, Clarion, Iowa: Houses ■ and ■. FDA believes that your corrective actions, if consistently implemented by WCE, are adequate to warrant shipping based on the following:

Relative to Salmonella Enteritidis (SE), the pathogen associated with a large egg-implicated outbreak and recall:

FDA and WCE have investigated to determine the plausible pathways of contamination, which include:

- Contaminated feed.
- Infected pullets (young chicken prior to the onset of egg production).
- Contaminated laying environment.
- Rodents contaminating feed and the laying house environment.

WCE reported that it has taken necessary corrective measures at Layer ■ to address each pathway of contamination, including:

- Contaminated feed
 - The feed mill was cleaned and disinfected.
 - Structural defects were corrected.
 - Birds, rodents and insects are controlled, and their activity is monitored and recorded.
 - Meat and bone meal have been eliminated from the feed (July 2010) and egg shells from egg-breaking operations have also been eliminated from the feed (August 2010) (applies to all pullets used to repopulate).
 - Suppliers of feed ingredients test routinely for SE, with notification to WCE of results.
 - WCE performs routine testing for SE of feed and maintains retain samples. If a positive feed sample is found the feed will be discarded and the feed mill will be properly cleaned and disinfected.
- Infected pullets
 - Layer ■, houses ■ and ■ were depopulated (egg market).

- Only chicks from SE-monitored breeder flocks are used for repopulation of pullet houses, as determined by USDA/NPIP certificate.
- Chick papers and hatchery trays are tested for SE. If any test results come back positive, those chicks are depopulated and the pullet house environment will be cleaned, disinfected, white-washed, and verified to be environmentally negative for SE prior to another set of chicks being placed in the pullet house.
- The pullet environment will be tested at 14-16 weeks of age. If the environment is positive, [REDACTED] chicks will be organ cultured for SE and egg testing will be carried out as outlined in the 21 CFR Part 118 (Egg Rule) at the onset of egg production. If either of these tests comes back positive the pullets or layers will be depopulated. The house will then be cleaned, disinfected, white-washed, and verified to be environmentally negative for SE prior to repopulation.
- WCE's supplier of chicks has changed to an improved automated Marek's disease and LT vaccine administration. The vaccine now includes a green dye and [REDACTED] chicks from each vaccinator are visually checked for presence of dye at the back of the neck (June 2010).
- Pullets and laying hens are now vaccinated for SE with two killed and two live vaccines. All pullets receive two killed SE vaccines.
- Contaminated laying environment
 - WCE has modified and implemented its biosecurity plan, with the help of a poultry science expert, to minimize the risk of contamination from moving to the house from other houses on the farm, other locations on the farm, or other farms. The plan addresses worker transitions and equipment usage between houses and farms, including:
 - All equipment must be cleaned and disinfected when moved from one house to another house
 - All tools used by maintenance workers must be sprayed with disinfectant.
 - Workers must change coveralls, boots, and hats at entry of each house.
 - Workers must wear clean clothing and footwear that has not been worn in or around other birds, farms or processing plants.
 - Dry foot baths, brushes and hand sanitizers for disinfection are installed and must be used. Levels of disinfectants and frequency of foot bath changes are monitored [REDACTED].
 - If a house tests positive for environmental SE, workers may not enter an SE negative house after they have been in a SE positive house on the same day.
 - Doors were installed where absent and other structural defects were corrected.
 - Layer [REDACTED], houses [REDACTED] and [REDACTED] were depopulated, dry cleaned, disinfected twice using [REDACTED], manure pits "white-washed" [REDACTED], and repopulated only after testing negative for environmental SE.
Note: white-washing began November 2010.
- Rodents
 - WCE contracted with a pest control firm and entomologist to control rodents and perform and record [REDACTED] rodent index calculations. The rodent indices have been reduced from [REDACTED] (severe) to [REDACTED] (acceptable).

WCE reported that it has implemented preventive controls at Layer [REDACTED] to prevent recurrence of the problems that led to the outbreak, including;

- Contaminated feed

- Suppliers of feed ingredients test routinely for SE, with notification to WCE of any positives.
- WCE performs routine testing of feed for SE and maintains retain samples.
- Infected pullets
 - Only chicks from SE-monitored breeder flocks are used for repopulation of pullet houses, as determined by USDA/NPIP certificate.
 - Chick papers and hatchery trays are tested for SE. If any test results come back positive, those chicks are depopulated and the pullet house environment will be cleaned, disinfected, white-washed, and verified to be environmentally negative for SE prior to another set of chicks being placed in the pullet house.
 - The pullet environment will be tested at 14-16 weeks of age. If the environment is positive, [REDACTED] chicks will be organ cultured for SE and egg testing will be carried out as outlined in the Egg Rule at the onset of egg production. If either of these tests comes back positive the pullets or layers will be depopulated. The house will then be cleaned, disinfected, white-washed, and verified to be environmentally negative for SE prior to repopulation.
- Contaminated laying environment
 - WCE monitors adherence to the biosecurity plan on a [REDACTED] basis, and records various aspects of that monitoring on a [REDACTED]
 - Layer houses for shipment to the table egg market are depopulated, dry cleaned, disinfected [REDACTED] ([REDACTED]), manure pits “white-washed” ([REDACTED] [REDACTED]), and repopulated only after testing negative for environmental SE.
- Rodents
 - WCE has a pest control firm and entomologist under contract to control rodents and perform and record [REDACTED] rodent index calculations.

FDA confirmed the corrective measures and implementation of the firm’s preventive controls during two inspections at the facility, as follows:

- Contaminated feed
 - During the November 2010 inspection of Layer [REDACTED], FDA review of feed testing records disclosed none with positive SE results.
 - During the November 2010 of Layer [REDACTED], FDA observations and interviews confirmed the implementation of the preceding corrective actions and preventive controls, except for the ingredient suppliers’ SE testing program, for which review was not performed.
 - FDA inspection of feed mill in October 2010 disclosed no significant objectionable conditions.
 - During the October 2010 inspection, FDA collected two layer-hen feed samples and feed mill environmental samples. FDA analysis disclosed no positive SE results.
- Infected pullets
 - During the November 2010 inspection of Layer [REDACTED], FDA observations and interviews confirmed the implementation of the preceding corrective actions and preventive controls relative to Layer [REDACTED], except for the chick supplier’s vaccination improvements, for which review was not performed.
- Contaminated laying environment
 - The November 2010 FDA inspection of Layer [REDACTED] disclosed no sanitary objectionable conditions.
- Rodents

- The November 2010 FDA inspection of Layer [REDACTED] disclosed minimal evidence of rodent activity and a robust rodent control program.

FDA and the firm have verified the effectiveness of the corrective measures and preventive controls through the following analyses:

- Layer [REDACTED], houses [REDACTED] and [REDACTED] have tested negative twice by FDA for SE in environmental and egg samples.
- Layer [REDACTED], houses [REDACTED] and [REDACTED] have tested negative once by WCE for SE in environmental and egg samples.

WCE has committed to continuing with the following verification activities:

- All future laying houses will test negative by WCE for SE in environmental and egg samples once before shipment of eggs to the table market.
- All houses will be tested [REDACTED] by WCE for SE in environmental samples, for a period of [REDACTED]. If all [REDACTED] tests are negative for SE, that house will return to the testing schedule requirements of the Egg Rule.
- Eggs from any houses testing positive for SE in environmental samples will be immediately diverted and subject to four SE tests, in accordance with the Egg Rule.
- Any house producing the SE-positive eggs will be depopulated.

FDA will continue with the following verification activities:

- FDA will continue with environmental and egg testing for SE from future laying houses suggested by WCE for shipment to the table market, the frequency of which will be determined by the nature and consistency of the firm's monitoring and verification activities as well as FDA inspectional findings.
- FDA will periodically inspect WCE to confirm adherence to the corrective actions, preventive controls and verification activities in this document as well as to compliance with the Egg Rule.

Relative to Salmonella Heidelberg (SH), a pathogen detected by FDA in environmental samples from three [REDACTED] pullet houses tested [REDACTED]:

FDA and the firm have investigated to determine the plausible pathways of contamination, which include infected pullets. The firm has taken necessary corrective measures to address the pathways, including (beyond those above for SE):

- WCE will send [REDACTED] pullets reared in houses [REDACTED], [REDACTED], and [REDACTED], which tested positive for SH in environmental samples, to Iowa State for SH analysis.
- WCE will test the environment in the [REDACTED] pullet houses that were not tested by FDA for SH. WCE will organ culture [REDACTED] birds for SH analysis from any house which tests SH positive and will not ship eggs from the flock unless they test negative for SH.
- SH positive results will result in depopulation of the pullet house or laying house if they have already been moved.

The firm has implemented preventive controls to prevent recurrence of FDA SH findings, including (beyond those above for SE) performance of [REDACTED] environmental monitoring for SH in those laying houses into which pullets were moved from pullet houses which tested positive for SH. FDA has not confirmed these corrections to date. However, none of the corrective measures or preventive controls affect Layer [REDACTED], houses [REDACTED] and [REDACTED], because these houses were not stocked with pullets from SH positive pullet houses.

FDA and the firm have verified the effectiveness of the corrective measures and preventive controls through the following activities:

- Layer ■, houses ■ and ■ have tested negative twice by FDA for SH in environmental and egg samples.

WCE will continue with the following verification activities:

- WCE will perform ■ environmental monitoring for SH in those laying houses into which pullets were moved from pullet houses which tested positive for SH for a period of ■. If all ■ tests are negative for SH, that house will return to the testing requirements of the Egg Rule.
- All future laying houses will test negative by WCE for SH in environmental and egg samples once before shipment of eggs to the table market if pullets placed into those laying houses came from pullet houses which tested positive for SH.

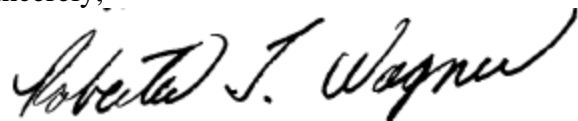
FDA will continue with the following verification activities:

- FDA will continue with environmental and egg testing for SH from laying houses considered for shipment to the table market in the future, the frequency of which will be determined by the nature and consistency of the firm's monitoring and verification activities as well as FDA inspectional findings.
- FDA will periodically inspect WCE to confirm adherence to the corrective actions, preventive controls and verification activities in this document as well as to compliance with the Egg Rule.

WCE will utilize Iowa State University for all testing to ensure consistency in testing.

On this basis, FDA concurs with WCE's request to begin shipment of eggs to the table market from Layer ■, Houses ■ and ■. FDA will determine whether it considers shipment from other houses to be appropriate on a case-by-case basis as the inspection and verification process continues. The Agency will continue to work with WCE officials before resumption of shipping eggs to the table market from other layer sites and houses.

Sincerely,



Roberta F. Wagner
Acting Deputy Director for
Regulatory Affairs
Center for Food Safety
and Applied Nutrition