



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 Food and Drug Administration  
 Cincinnati District Office  
 Central Region  
 6751 Steger Drive  
 Cincinnati, OH 45237-3097  
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**WARNING LETTER**  
**CIN-WL-99-345**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Elliot Jones  
 Chief Operating Officer  
 Buckeye Egg Farm L.P.  
 11212 Croton Road  
 Croton, Ohio 43013-0173

September 9, 1999

Dear Mr. Jones:

Public health officials linked an outbreak of *Salmonella enteritidis* serotype *enteritidis* (SE) that occurred in Massachusetts on May 12, 1999 to brown eggs. We inspected your shell egg production facility on July 7, 9 and 16, 1999 because our traceback of the implicated brown eggs lead to your site number 3 located at 11652 Clover Valley Road, Croton, Ohio 43013. As you know, this is the second instance within the last two years that your shell eggs are implicated as the source of *Salmonella* that caused a foodborne outbreak.

During our inspection, we aseptically collected environmental swab samples from egg belts, manure pits, and fans and samples of chicken feed within Houses #29, #30, and #40. We found *Salmonella enteritidis* (SE) in environmental and feed samples from House #39 (FDA sample number 60594) and House #29 (FDA sample number 60596). We also observed insanitary conditions and objectionable practices at your facility. Our findings show that your brown shell eggs are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act in that your shell eggs have been prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health. The introduction or delivery for introduction into interstate commerce of any food that is adulterated or misbranded is prohibited by the Act (21 USC 331[a]).

We observed the following insanitary conditions or objectionable practices during our inspection:

1. Lack of a formal control program to address the SE positive houses (6) found in 1998 and to prevent the 2 positive SE houses found during this inspection.
2. Depopulation/repopulation practices fail to prevent possible cross-contamination from one flock to another within the same house in that:
  - a. A downtime of 2 days between flocks does not allow for the SE cycle to be broken.
  - b. Manure is removed approximately once per year and is not always timed to be between flocks. For example, depopulation for house #29 was completed on 7/7/99 and firm employee stated no manure removal was planned before the next flock was to be in place. On 7/7/99 the manure was observed to be up to approximately three feet deep in places.

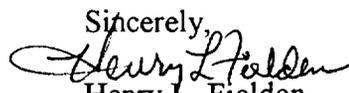
- c. Live white hens, reported to be from a previous flock, were observed on 7/7/99 to be present in the manure pits of house #40 and #29. These houses contain brown hen flocks.
  - d. Extensive dust covered cobwebs were observed on 7/7/99 throughout houses #29, #39 and #40. The manure pits in house #29 had cobwebs which hung over three feet down from the rafters.
3. Egg collection belt maintenance and cleaning practices fail to prevent possible cross-contamination within the house and from one house to another within the same side of the site in that:
    - a. On 7/7/99, crushed eggs were observed on the common egg belt and on row belts including areas of accumulated residue from several crushed eggs.
    - b. On 7/7/99, several belts were observed with an accumulation of eggs not collected during the morning collection.
  4. On 7/7/99, live beetles in quantities too numerous to count were observed in houses #29, #39 and #40.
  5. On 7/7/99, live flies in quantities too numerous to count were observed in house #29.
  6. On 7/7/99, a pile of dead chickens, approximately 10 feet by 4 feet by 3 feet in size, and 6 trash containers, were observed inside at the front end of house #40 and more than two trash containers full of dead chickens in house #29 and #39.

The above identification of violations is not intended to be an all-inclusive list of deviations at your facility. It is your responsibility to meet all requirements of the Act and the applicable regulations.

We received your letter of July 29, 1999 and attachments that you sent to us in response to the FDA-483 Inspectional Observations. Your responses that the insanitary conditions and practices that we found are common to the egg industry, however, are not acceptable responses. You should take prompt action to correct these deficiencies and to prevent further contamination of your shell eggs with SE. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and injunction.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrent of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,  
  
Henry L. Fielden  
District Director  
Cincinnati District