

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 11630 W 80th St Lenexa, KS 66214 Tel: 913-752-2100 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 05/16/2011, 05/17/2011, 05/18/2011, 05/19/2011
	FEI NUMBER 3007754995

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: David L. Hasemann, Complex Manager

FIRM NAME Sparboe Farms Inc.	STREET ADDRESS 3159 Buchanan Ave
CITY, STATE AND ZIP CODE Eagle Grove, IA 50533-8039	TYPE OF 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 (I) (WE) OBSERVED:

OBSERVATION 1

Your written SE prevention plan lacks appropriate SE prevention measures.

Specifically,

Your Salmonella Prevention Program, SOP.OPS.PRD 8 Revised on 5.16.2011 does not include cross contamination practices when persons or equipment move between poultry houses without "Flock Isolation".

OBSERVATION 2

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

Specifically,

Your documents titled (b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" fails to identify your firm by name and location.

OBSERVATION 3.

All required records do not have the signature or initials of the person performing the operation or creating the record.

Specifically,

Your documents title (b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" fails to include the signature or initials of the person performing the operation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Collins M Mason, CSO; Kathleen J. Klier, CSO Shaun M. Olson, CSO; Brittany D. Phillips, CSO Kevin E. Klommhaus, CSO; Lloyd Krutzfeldt, CSO Neal Vaughn, CSO	DATE ISSUED 05/19/2011
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OBSERVATION 4.

You lack adequate review of records created to document your SE Prevention measures.

Specifically,

1. Your Salmonella Prevention Program, SOP.OPS.PRD 8 Revised on 5.16.2011 lacks adequate review as evidenced by the following:

- A. Page 9, I. D. 5) c) states "Based on the FDA Final Rule, we have up to 10 days to send egg samples for testing." This is inaccurate.
- B. Page 18, III B. 1) a) states "Initiate egg testing within 10 days of receiving notification of the positive environmental test." This statement is not in compliance with current FDA regulations.
- C. Page 16, II D. 4) c) states "(b) (4)"; " whereas Page 17, II D. 6) g) i. - vi. specifies a different procedure for egg belt sampling.
- D. Sections "D. Pest Control Procedures"; "G. Refrigeration"; and "H. Transportation" are subtitles under "IV. Programs and Procedures on a SE Environmental Positive." indicating that these sections shall only be followed if there is a SE positive environmental sample. However these items are required regardless of the SE status of the barn.
- E. Page 24, IV. D. 3) c) states "Threshold per barn is (b) (4) fly counts or higher." This statement as written does not indicate a threshold.

2. Your documents titled "(b) (4) FLY Counts", "Sparboe (b) (4) Cooler Monitoring Log", and the document that you identified as your "Fly Control log" have not been reviewed. Additionally your document titled "(b) (4) FLY Counts" and the document that you identified as your "Fly Control log" as prepared do not include space for review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>[Signatures]</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Collins M Mason, CSO; Kathleen J. Klier, CSO Shaun M. Olson, CSO; Brittany D. Phillips, CSO Kevin E. Klomhaus, CSO; Lloyd Krutzfeldt, CSO Neal Vaughn, CSO	DATE ISSUED 05/19/2011
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