

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

DISTRICT ADDRESS AND PHONE NUMBER

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Stoneham, MA 02180
(781) 596-7700 Fax: (781) 596-7896
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/18/2010 - 10/21/2010

FEI NUMBER

3004400214

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John C. Lough, Owner

FIRM NAME

Dorothy Egg Farms, LLC

STREET ADDRESS

Plant 1
271 Turkey Lane

CITY, STATE, ZIP CODE, COUNTRY

Winthrop, ME 04364

TYPE ESTABLISHMENT INSPECTED

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 WE OBSERVED:

OBSERVATION 1

You did not maintain records documenting compliance with biosecurity measures.

Specifically, your "Dorothy Egg / (b)(4) Bio-security Plan", Created 05/01/2010, Last Updated 09/17/2010; under the section headed "Equipment and Tools Movement Procedures" states in bullet two "When equipment is required to be used across multiple barns it will be cleaned and disinfected between barns".

You do not document cleaning and disinfection of the skid steer loader used for weekly manure removal across multiple barns.

OBSERVATION 2

Eggs were not at or below 45 deg. F beginning 36 hours after time of lay.

Specifically, during a review of your "Critical Limit Monitoring Report" provided for Plant # 1021, Winthrop Maine; the documented ambient temperature of Egg Cooler (b)(4) and Egg Cooler (b)(4) exceeded 45 deg. F as follows:

Egg Cooler # (b)(4)

- 09/01/2010, 9:35 AM, 48 deg. F
- 09/03/2010, 7:25 AM, 46 deg. F
- 09/03/2010, 9:35 AM, 50 deg. F
- 09/05/2010, 9:35 AM, 47 deg. F
- 09/08/2010, 10:05 AM, 48 deg. F
- 09/10/2010, 9:35 AM, 50 deg. F

Egg Cooler (b)(4)

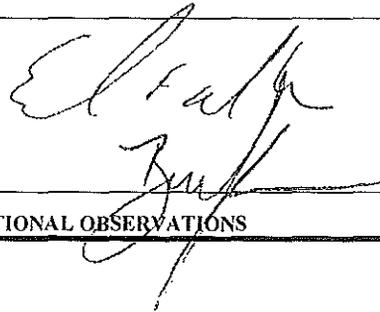
- 09/02/2010, 12:05 PM, 51 deg. F

You store shell table eggs in Coolers (b)(4) for periods of time exceeding 36 hours while holding for pending distribution.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Edmund F. Mrak, Investigator
Bruce G. Cooper, Investigator
Stephen C. King, Investigator
Nichole B. Murphy, Investigator
Thomas W. Nerney, Investigator



DATE ISSUED

10/21/2010