

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 250 Marquette Ave., Ste. 600 Minneapolis, MN 55401 Phone 612-334-4100 Fax 612-334-4134 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 06/20-22/11
	FEI NUMBER 3001615902

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Michael A. Kellen- Farm Owner**

FIRM NAME Kellen Egg Farm	STREET ADDRESS 17959 SD Highway 15
CITY, STATE AND ZIP CODE Clear Lake, SD 57226	TYPE OF ESTABLISHMENT INSPECTED Egg Farm

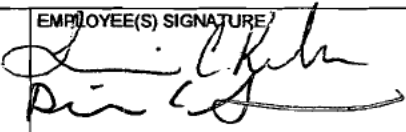
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO 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:

Your written SE Prevention Plan is not fully implemented and followed.

Specifically,

- Your SE Plan states that appropriate measures such as closing access holes and removing of the varmints are essential to protect the birds. On 06/20/11 during an inspection of the exterior of:
  - o Barn 1 multiple burrow holes, gaps in the doors, and nesting material was observed;
  - o Barn 2 multiple burrow holes, gaps in the doors, nesting materials, a dead mouse, two dead rats, and a live bird living in between the exterior/interior wall were observed.
- Your SE Plan states that a Rodent Index (RI) over **b** will trigger increased baiting until the RI drops back to **b** indicating appropriate rodent control:
  - o According to your **b4** rodent inspection monitoring you do not control the rodents within your rodent index parameters. You have a rodent index exceeding **b4 b** in a given **b4** in the following areas: in Barn 1 from 04/08/11 to 05/06/11, 05/20/11 to 06/03/11 and 06/17/11 and in Barn 2 on 05/20/11.
  - o No corrective action was taken when an increase in the RI was documented.
- Your SE Plan states that eggs are removed from the farm **b4**.
  - o You stated that eggs are removed from the facility when there are **b4** pallets of eggs for **b4**. Eggs are not removed from the farm until **b4** goal has been achieved, which in some cases takes as many as **b4**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Traci C. Kelm, CSO Dianna C. Sonnenburg, CSO	ISSUED 6/22/11
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