

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

DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/09/2009 - 07/15/2009*
	FEI NUMBER 2117605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Dallas V. Moe, General Manager

FIRM NAME Plainview Milk Products Cooperative	STREET ADDRESS 130 2nd St SW
CITY, STATE, ZIP CODE, COUNTRY Plainview, MN 55964-1314	TYPE ESTABLISHMENT INSPECTED Food Manufacturer

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

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, FDA's samples analyses of environmental evidence collected during this inspection confirmed the presence of several different serotypes of *Salmonella* on food contact and non-food contact surfaces and environmental areas.

Process and controls are inadequate to remove the presence of *Salmonella*.

OBSERVATION 2

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials.

Specifically, employees use spray foamers to clean and sanitize equipment, floors, walls and ceilings; these foamers may atomize microorganisms, which may contaminate food, food-contact surfaces and food packaging materials.

After cleaning and sanitation has ceased, equipment, floors, wall and ceilings are air-dried, which results in pools of standing water; throughout this inspection, standing water was observed in areas where low moisture products are manufactured including the agglomerator #1 and #2 rooms and the dry blending room.

OBSERVATION 3

Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food.

Specifically, on 6/29/09, in the agglomerator #2 room, the cooling coils on the fluid bed cooling unit had extensive build-up of extraneous material. Filtered air passes through these cooling coils; after which, the air directly contacts product in the fluid bed. No additional air filters are used after the cooling coils.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Elizabeth P. Mayer, Consumer Safety Officer <i>Elizabeth P. Mayer</i> Mada A. Tautges, Consumer Safety Officer <i>Mada Tautges</i> Zachary P. Wachlarowicz, Consumer Safety Officer <i>Zachary Wachlarowicz</i>	DATE ISSUED 07/15/2009
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OBSERVATION 4

Effective measures are not being taken to protect against the contamination of food on the premises by pests.

Specifically, on 6/29/09, twenty-one pigeons were observed perched on the exterior exhaust vents of the (b) (4) spray dryer.

Specifically, on 7/1/09, in the impinger room, apparent pigeon feces and feathers were observed on the walls, floor and equipment. The impinger room is located above the evaporator #1 room; the man door to the impinger room is adjacent to the staircase, which leads downstairs to the evaporator #1 room. On 7/1/09, a 1" gap was observed at the bottom of this man door.

OBSERVATION 5

Suitable outer garments are not worn that protect against contamination of food, food contact surfaces, and food packaging materials.

Specifically, the firm has a captive footwear program. However, during this inspection, the following was observed:

- employees wear their plant designated shoes/boots outside
- employees walk from the offices to the dry blend room and agglomerator #1 and #2 rooms through the warehouse; there are no foot foamers in the dry blend area, agglomerator #1 and #2 rooms or the warehouse.
- on 6/9/09, an employee did not walk through the foot foamer as he entered the plant from the outside

Specifically, on 7/7/09, in the agglomerator #2 room, an employee was observed repairing and re-installing equipment while wearing street clothes.

OBSERVATION 6

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically, in the dump #1 and #2 room, the following was observed during this inspection:

- brown colored stains on the ceiling above the bag dump for agglomerator #2

Specifically, in agglomerator #1 room, the following was observed during this inspection:

- the platform for the baghouse had extensive dust build-up
- a soiled plastic sheet covered the exhaust fan on the north wall
- brown colored stains and drip trails on the east wall directly behind the sifter and final conveyor

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- brown colored stains on the horizontal beam directly above the final conveyor
- brown colored stains on the ceiling adjacent to the west support beam and brown colored drip trails on the west support beam

Specifically, in agglomerator #2 room, the following was observed during this inspection:

- brown colored stains and drip trails on the support beam of the southwest wall
- brown colored stains behind the support beam (southeast wall) for the baghouse

OBSERVATION 7

Failure to maintain buildings and fixtures in repair sufficient to prevent food from becoming adulterated.

Specifically, on 7/1/09, in the impinger room, several holes were observed in the roof; the sky was visible through these holes. The impinger room is located above the evaporator #1 room; the man door to the impinger room is adjacent to the staircase, which leads downstairs to the evaporator #1 room. On 7/1/09, a 1" gap was observed at the bottom of this man door.

Specifically, on 6/29/09, in the basement near the heater room, the ceiling pipe was observed to be leaking water; this pipe is plumbed to the agglomerator #2 room.

Specifically, in the dump #1 and #2 room, the following was observed during this inspection:

- garage door did not completely seal; 1" gaps were observed along the top and the sides
- an approximate 4" in diameter uncapped wall sleeve on the west wall
- on the east wall, three open dead end pipes approximately 2" each in diameter and one uncapped wall sleeve approximately 4" in diameter
- exposed insulation at the ceiling/wall juncture above the bag dump, tote dump and tote bin dump for agglomerator #1

Specifically, in agglomerator #1 room, the following was observed during this inspection:

- an approximate 3 foot long crack in the floor under fluid bed C
- several pits in the floor
- an approximate 1" gouge in the bottom of the door jam for the doorway, which leads from the processing area to the packaging area
- an approximate 4" in diameter uncapped wall sleeve on the east wall

Specifically, in agglomerator #2 room, the following was observed during this inspection:

- cracks in the floor/wall juncture on the southeast wall
- garage door did not completely seal; gaps along the top and bottom and gasket also hanging on the right side of the door

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OF THIS PAGE**

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OBSERVATION 8

Proper precautions to protect food, food-contact surfaces, and food-packaging materials from contamination with microorganisms, filth, and extraneous material cannot be taken because of deficiencies in plant construction and design.

Specifically, on 6/29/09, the window directly across from the man door leading into agglomerator #1 room was observed open; the screen for this window had two pigeon feathers and other extraneous material caught in its mesh. Air is pulled into the facility through this screen; this window is left open during the warmer months.

OBSERVATION 9

The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food-contact surfaces.

Specifically, on 6/29/09, in the agglomerator #1 room, brown colored stains were observed on the glass of the skylight above the holding belt; an approximate 2" crack in the glass was also observed. Brown colored drip trails were also observed on the transoms of this skylight and two other skylights also located above the holding belt.

OBSERVATION 10

Non food-contact equipment in manufacturing areas is not constructed so that it can be kept in a clean condition.

Specifically, on 6/29/09, in the dump #1 and #2 room, the following was observed:

- the gasket on the agglomerator #1 tote bin was cracked and had brown colored stains
- the gasket on the agglomerator #2 tote dump was cracked, frayed and had brown colored stains

Specifically, on 6/29/09, in the agglomerator #2 room, the following was observed:

- the gasket on the fluid bed was cracked and was no longer tightly sealed to the flange
- the gasket on the fluid bed cooling unit was frayed and had brown colored stains
- the gasket on the fan for the wetting tube was frayed

OBSERVATION 11

Failure to provide adequate screening or other protection against pests.

Specifically, on 6/9/09, in the old warehouse, the west screen door leading to the outside did not shut completely; 1" gaps

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were observed.

On 6/10/09, in the "spare parts room" located in the basement, the screen door leading to the outside did not shut completely; 1" gaps were observed.

OBSERVATION 12

Failure to properly store equipment and remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

Specifically, on 6/10/09, random items including a lawn chair were stored adjacent to the building near the screen door leading into the "spare parts room" located in the basement. The screen door did not shut completely; 1" gaps were observed.

OBSERVATION 13

Employees failed to remove unsecured jewelry or other objects which might fall into equipment.

Specifically, on 6/16/09, in the butter area, an employee was observed operating packaging equipment while wearing a wrist watch.

*** DATES OF INSPECTION:**

06/09/2009(Tue), 06/10/2009(Wed), 06/11/2009(Thu), 06/12/2009(Fri), 06/16/2009(Tue), 06/25/2009(Thu), 06/26/2009(Fri), 06/29/2009(Mon), 06/30/2009(Tue), 07/01/2009(Wed), 07/02/2009(Thu), 07/07/2009(Tue), 07/15/2009(Wed)

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