

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 2/28/2017-3/22/2017*
	FEI NUMBER 3010229269

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Johannes H. Vulto , Owner

FIRM NAME Vulto Creamery LLC	STREET ADDRESS 44 West St
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CITY, STATE, ZIP CODE, COUNTRY Walton, NY 13856-1479	TYPE ESTABLISHMENT INSPECTED Manufacturer
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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 and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically:

- A finished product sample of your firm's Ouleout soft raw milk cheese product bearing lot #617 was analyzed by an FDA laboratory and found to be positive for *Listeria monocytogenes*, a foodborne pathogen.
- A finished product sample of your firm's Ouleout soft raw milk cheese product bearing lot #623, collected by the New York State Department of Agriculture and Markets in your facility on 2/28/2017 during the FDA inspection, was found to be positive for *Listeria monocytogenes*, a foodborne pathogen.

OBSERVATION 2

Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination.

Specifically, a review of your environmental sampling test records noted the following:

- You have conducted environmental sampling during 20 months from 7/28/2014 through 2/19/2017. Your records show 54 out of 198 results positive for *Listeria spp.* taken from various locations throughout your manufacturing facility, which include, but are not limited to: floor drains in the manufacturing room, wash room and cheese aging room; outside of brine tanks in

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the walk-in cooler; door handles to the cheese aging room, walk-in cooler and entry door; various areas of the floor in the cheese aging room; bottom of a squeegee in the cheese aging room; employee aprons; and wooden cheese rack dollies in the cheese aging room. The most recent positive finding being a swab taken from the floor in the manufacturing room on 2/19/2017. You have not conducted an investigation to provide identification of the *Listeria spp.* to Genus and species and you have also failed to identify its source or point of entry/harborage in your facility.

- A total of 10 of the 54 positive results were found on food contact surfaces between 10/30/2014 and 4/28/2015. You did not conduct microbial testing of finished products to confirm that your finished products were not contaminated with the organism found by your environmental testing program. According to your sample records, the food contact surface locations were as follows:
 - Wooden cheese aging board in cheese aging room; positive result from 10/30/2014.
 - The cheese brush used to brush Ouleout and Miranda soft cheeses and two wooden cheese aging boards in cheese aging room; positive results from 12/3/2014.
 - The cheese brush used to brush Ouleout and Miranda soft cheeses and two wooden cheese aging boards in cheese aging room; positive results from 1/6/2015.
 - Two cheese brushes used to brush the Andes and the Walton Umber hard cheeses; positive results from 2/3/2015.
 - Two cheese brushes used to brush the Andes and the Walton Umber hard cheeses; positive results from 3/22/2015.
 - A cheese brush (not specified to product); positive result from 4/28/2015.
- You did not continue sampling food contact surfaces after 4/28/2015 to determine if *Listeria spp.* was still present on these surfaces representing a continued contamination risk to your cheese products.
- Upon finding a *Listeria spp.* positive result on a surface, you re-cleaned and re-sanitized the area, but did not re-swab that location until a month or more later, after additional lots of cheese had been produced, to determine if your cleaning and sanitizing was effective and to determine if the

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Listeria spp. was still present.

OBSERVATION 3

The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.

Specifically, review of your environmental sampling results across 20 months from 7/28/2014 through 2/19/2017 showed positive results for *Listeria* species on several food contact and non-food contact surfaces in your facility. Per your documented corrective actions, upon getting a positive result you re-cleaned and re-sanitized the affected areas using your routine cleaning and sanitizing operations. However, when you re-sampled these locations a month or more later and tests showed repeated positive results, you did not investigate the use of a more effective method of cleaning and sanitizing.

OBSERVATION 4

Failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination.

Specifically, you are storing wood boards that have been cleaned and sanitized in your facility attic, where exposed insulation and other debris were observed. Your ready-to-eat Hamden, Blais Blue, Andes and Walton Umber cheese products sit directly on these boards during the aging process.

Additionally, you stated that the attic gets very hot during the summer months, and that it can take approximately (b) (4) for the wood boards to completely dry.

OBSERVATION 5

Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms and foreign substances.

Specifically, on 3/1/2017 the following was observed during the manufacturing of your Walton Umber hard cheese product:

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- You and your employee were observed placing your bare hands and arms, up to your elbows, directly into the cheese making vat in order to manually break up recently formed cheese curds. Although you washed your hands, neither of you washed your lower or upper arms. Additionally, your employee was observed to have multiple cuts and abrasions on his arms, which came in direct contact with cheese curds and whey.
- A stainless steel ladle, used to scoop milk for pH analysis, had buildup of a rust-like substance on its inner surface. You stated you use this same ladle in the same manner during the manufacturing of all cheese products.

OBSERVATION 6

The design and materials of equipment does not allow proper cleaning and maintenance.

Specifically, a large majority of the wooden boards used for aging in the cheese aging room are of a design that does not allow them to be appropriately cleaned and sanitized. The boards, which you stated are made from (b) (4) have uneven surfaces, are rough cut, and have knots, frays, and splinters, which allows for the collection of moisture and debris, representing a potential harborage area for filth and microorganisms. These wooden boards come in direct contact with your aging Hamden, Blais Blue, Walton Umber and Andes ready-to-eat cheese products.

OBSERVATION 7

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

Specifically, on 3/1/2017, condensation was noted dripping from the horizontal stainless steel bar on the cheese press directly onto the food contact surface of the draining table below. This table is used to allow molded cheese products to drain off whey. Additionally, rust-like particles were noted in the condensation puddle on the table.

OBSERVATION 8

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Employees did not sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

Specifically, during the inspection on 3/1/2017, it was observed that you and your employee did not sanitize your hands or arms prior to using them to stir and break up the in-process Walton UMBER cheese curds.

OBSERVATION 9

Failure to maintain physical facilities in repair sufficient to prevent food from becoming adulterated.

Specifically, the following was observed throughout the inspection:

- Heavy buildup of apparent rust-like substance on the white painted vertical support bars that hold the cheese presses in place. These bars are located directly over the draining table closest to the window in the manufacturing room; flakes of this rust-like substance were observed on the top surface of the drain table where molds of cheese are set to drain.
- Heavy buildup of apparent rust-like substance on painted white metal storage shelf in wash room. This shelf is used to store cheese molds and other equipment and utensils.
- A heavy buildup of apparent black and green mold-like substance was noted on the cement walls in the manufacturing room and wash room. Several cleaning brushes, storage racks and cheese molds were noted to come in direct contact with these walls. Additionally, these walls were moist from condensation.
- Heavy buildup of rust-like and black mold-like substance on stainless steel storage shelf in walk-in cooler. This shelf was being used to hold boxes of wrapped finished cheese products.
- A large piece of ceiling tile was missing in the cheese aging room. Uncovered, ready-to-eat cheese was being stored directly below this area.

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- The exhaust fan on the ceiling in the manufacturing room has a buildup of dirt-like and mold-like substances. This fan is directly above a stainless steel draining table where molded cheeses are placed to drain whey.

OBSERVATION 10

Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact surfaces.

Specifically, during the inspection, the following was observed:

- On 3/2/2017, a fan in the attic that was in operation to dry cleaned and sanitized wood boards regularly used for cheese aging was noted to have dirt and dust debris buildup on the spinning arms and face of the fan. These wood boards come in direct contact with Hamden, Blais Blue, Walton Umber and Andes ready-to-eat cheese products during the aging process in the cheese aging room.
- On 2/28/2017, a fan in the manufacturing room was noted to have a very heavy buildup of unknown debris on the spinning arms and face of the fan. You stated your firm uses this fan to help dry the floor in the manufacturing room after cleaning.

OBSERVATION 11

Lack of an automatic temperature alarm system for each freezer and cold storage compartment used to store food capable of supporting the growth of microorganisms.

Specifically, your firm's cheese aging room and walk-in cooler lack an automatic temperature alarm system that would provide indication that a significant temperature change occurred. Your finished cheese products are stored in the cheese aging room.

Additionally, you stated that you do not calibrate and never have calibrated the thermometers located in the cheese aging room and walk-in cooler.

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OBSERVATION 12

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

Specifically, throughout the inspection the following was observed:

- The concrete floors in the manufacturing room and cheese aging room were noted to be cracked and pitted; an accumulation of moisture was noted to be stuck in the cracks and pits of the floor.
- A buildup of apparent black mold-like substance was noted on the window sill in the wash room.
- There is an uneven layer of concrete/mortar around the (b) (4) in the manufacturing room. There are also cracks where the mortar meets the (b) (4) port.
- The door to the manufacturing room does not have a door handle, but instead has plastic packing tape covering part of the hole.
- The walk-in cooler door does not have a door handle, but instead has a dirty cloth rag plugging up the hole.
- A heavy buildup of rust-like debris was noted on the lower part of the manufacturing room door.
- There was buildup of a black mold-like substance on the wall between the walk-in cooler and cheese aging room.
- A hole was noted at the bottom of the wall near the foot bath in the packaging room.
- A black mold-like substance was observed on the ceiling in the packaging room, near the wash room entrance.

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OBSERVATION 13

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically, during the inspection on 2/28/2017, a long piece of sticky fly tape, heavily populated with dead insects, observed hanging directly over exposed, uncovered ready-to-eat cheese products in your cheese aging room was pointed out to you. This fly tape was observed hanging in the cheese aging room in the same condition on 3/1/2017 and 3/7/2017.

OBSERVATION 14

Plumbing constitutes a source of contamination to equipment and utensils.

Specifically, during the inspection the following was observed:

- A hose with a nozzle on the end was directly connected to the potable water supply in the manufacturing room without a proper backflow prevention device installed. This hose is used during cleaning operations.
- A hose with a nozzle on the end was directly connected to the potable water supply in the wash room without a proper backflow prevention device installed. This hose is used during cleaning operations.
- The drain pipe from the 3-basin sink in the manufacturing room is approximately 2.5 inches wide. The air gap between the drain pipe and the waste funnel is only 1.5 inches, which does not provide an adequate air gap between your sink drain and waste pipe.
- The wash room 3-basin sink does not have an air gap installed between the sink drain pipe and the waste pipe.

OBSERVATION 15

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You did not submit a reportable food report to FDA within 24 hours after you determined that a food was a reportable food.

Specifically, you were notified via telephone on 3/3/2017 that your firm's Ouleout soft raw milk cheese product bearing lot #617 was found to be positive for *Listeria monocytogenes*, a foodborne pathogen, and that you would need to file a reportable food report to the FDA within 24 hours. At this present time, you still have not filed a reportable food report with the FDA.

***DATES OF INSPECTION**

2/28/2017(Tue),3/01/2017(Wed),3/02/2017(Thu),3/07/2017(Tue),3/13/2017(Mon),3/17/2017(Fri),3/22/2017(Wed)

3/22/2017

Melissa A Henaghan

Me issa A Henaghan
Investigator
Signed by: Melissa A. Henaghan -5

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."