

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax: (718) 662-5661 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 03/05/2009 - 03/17/2009*
	<small>FEI NUMBER</small> 3002119179

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Javier (nmi) Peregrina, President**

<small>FIRM NAME</small> Peregrina Cheese Corp.	<small>STREET ADDRESS</small> 342 Ten Eyck Street
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Brooklyn, NY 11206-1723	<small>TYPE ESTABLISHMENT INSPECTED</small> Cheese 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**

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically,

- On 3/5/09, a male employee cleaning the stainless steel production table in the mozzarella production room was throwing buckets of hot water on top of the production table creating a large splash of water onto the wet soiled production floor which then splashed from the soiled production floor onto plastic bags of mozzarella cheese curd that are used to produce ready-to-eat mozzarella balls as well as onto a stainless steel knife with a black handle that is used to cut open the bags of mozzarella cheese curd and come into direct contact with the product.
- On 3/5/09, a male employee was observed cleaning equipment including production tables, cheese grinding equipment, and carts used to transport the finished cheese products in the finished product packaging room by using a hose to spray down the equipment. The water spray from the hose was splashing onto the wet soiled production floor and then onto clean racks and trays as well as creating an aerosol spray from the soiled floor throughout the finished product packaging room. Exposed finished product packaging was observed to be stored in the finished product packaging room while the employee was spraying down the equipment.

**OBSERVATION 2**

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

Specifically, during production on 3/6/09 condensate was observed in several areas of the production facility directly over exposed food products, food-contact surfaces, and food-packaging materials as follows:

- Condensation was observed on the ceiling with apparent spots of a black mold like substance in the finished product packaging room directly above exposed ready-to-eat wheels of Queso Fresco that were being shaped, formed, and cooled before packaging. The exposed ready-to-eat wheels of Queso Fresco were on production tables located near the north east corner of the finished product packaging room.
- Condensation was observed on the red pipe on the ceiling in the mozzarella production room directly above exposed

<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Michael R. Dominick, Investigator <i>[Signature]</i> Manhar R. Patel, Microbiologist <i>[Signature]</i> Jose V. Obando, Microbiologist <i>[Signature]</i> Sarah A. Wangseng, Investigator <i>[Signature]</i>	<small>DATE ISSUED</small> 03/17/2009
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ready-to-eat mozzarella cheese balls being stored on a perforated red plastic tray along the east wall near the south east corner of the mozzarella production room.

- Condensate drip from the red pipe on the ceiling in mozzarella production room was observed to drip directly onto a red perforated plastic tray used to hold ready-to-eat mozzarella cheese balls. The red perforated plastic tray used to hold the ready-to-eat mozzarella cheese balls was being stored along the east wall near the south east corner of the mozzarella production room.
- Condensation and apparant black mold like substance was observed on the east wall of the mozzarella production room directly above exposed ready-to-eat mozzarella cheese balls. The cheese balls were stored along the east wall near the south east corner of the mozzarella production room.
- Condensate drip from the red pipe on the ceiling in mozzarella production room was observed to drip directly onto the stainless steel mozzarella cheese block cutter that was stored in the north east corner of the mozzarella production room. The mozzarella cheese block cutter is used to cut large blocks of mozzarella cheese curd into pieces before melting and forming the mozzarella cheese.
- Condensation was observed on the ceiling and on a white pipe on the ceiling directly above exposed mozzarella cheese in cold water in the stainless steel 2-bay sink located on the west wall of the mozzarella production room. The exposed mozzarella cheese in the cold water was already melted and formed before being placed in the cold water to cool.

**OBSERVATION 3**

Failure to handle work-in-progress in a manner that protects against contamination.

Specifically, on 3/6/09 an uncovered white plastic pail with exposed mozzarella cheese curd pieces was observed to be stored directly below a rusted metal hose reel with peeling paint. The underside of the hose reel was encrusted with excessive accumulation and build up of product residue. A red rubber hose that had been dragged on the wet soiled floor in the mozzarella production room was also observed to be stored on this rusted metal hose reel directly above the exposed product during production. The mozzarella curd pieces are used to melt and mold into the ready-to-eat mozzarella cheese balls.

**OBSERVATION 4**

Failure to construct and maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

Specifically, On 3/6/09 a build up of black residue, food residue, and dry food particles were observed on several carts used to convey, hold, and store in-process cheese products and finished ready-to-eat cheese products throughout the production facility as follows:

- Heavy accumulation and build up of dried food residue was observed inside large crevices located on the top right side corner and the top left side corner of a stainless steel production cart that is used to transport exposed ready-to-eat Queso Fresco from the milk pasteurization room/Queso Fresco production room into the finished product packaging room. At the time that the observation was made the cart was located in front of the Queso Fresco grinder on the east wall of the

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- finished product packaging room after an employee wheeled exposed ready-to-eat Queso Fresco from the milk pasteurization room/Queso Fresco production room.
- Black residue observed in cracks in unsmooth welded surface on the stainless steel bars located underneath the Queso Cotija Molido grater and located on the north wall near the storage room in the finished product packaging room. This cart is used to hold the Queso Cotija Molido grater.
  - Build up of food residue on the bottom of a stainless steel vat (large stainless steel bucket on wheels) directly above the front wheel in the mozzarella production room. The stainless steel vat was being used to transport the ready-to-eat mozzarella from the cold water bath on the west wall of the mozzarella production room to the stainless steel production table on the east wall of the mozzarella production room.
  - Orange and black residue observed in black rubber wheel well on the front right wheel of the jello/flan cart located on the west wall of the finished product packaging room. The cart is used to transport ready-to-eat jello and ready-to-eat flan from the finished product packaging room to the cooler located outside of the finished product packaging room.

**OBSERVATION 5**

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

Specifically,

- On 3/6/09, a stainless steel production knife with a black handle that was cleaned and stored in a white plastic bucket on the west wall of the finished product packaging room was observed to have orange residue on the stainless steel knife blade (food contact surface) as well as a build up of orange and black residue on the stainless steel knife blade where the blade meets the black handle (food contact surface). This knife is used to cut blocks of ready-to-eat Queso Cotija that is cut with the knife, grated, and packaged with no further processing steps.
- On 3/6/09, a build up of orange product residue was observed in the gouged plastic surface on the side of the white plastic salt bin used to store salt for mixing the Queso Fresco. The plastic salt bin is stored on the east wall next to the Queso Fresco mixer in the finished product packaging room.
- On 3/6/09, heavy build up of dry food residue encrusted on the front right leg of the electronic scale that is located on top of a stainless steel production table on the east wall next to the Queso Fresco mixer in the finished product packaging room. The scale is used to weigh exposed ready-to-eat Queso Fresco.

**OBSERVATION 6**

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

Specifically, on 3/5/09 & 3/6/09 accumulation and build up of visible black residue, filth, and apparent mold like substance were observed as follows:

- The tiled wall below the 3-bay sink on the west wall of the milk pasteurization room / Queso Fresco production room was observed to be soiled with a build up of black residue.
- Heavy build up of a wet orange and black substance was observed on the horizontal white plastic (PVC) piping directly below bay #1 and bay #2 (bay #1 is the closest bay to the hand washing sink) of the stainless steel 3-bay sink on the

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Brooklyn, NY 11206-1723	Cheese Manufacturer	

west wall in the milk pasteurization room/Queso Fresco production room.

- A build up of wet black residue was observed on the white plastic (PVC) connector pipe that joins the horizontal and vertical PVC pipe together located directly below bay #1 (bay #1 is the closest bay to the hand washing sink) of the stainless steel 3-bay sink on the west wall in the milk pasteurization room/Queso Fresco production room.
- Black residue observed inside metal casing on the outside of hydraulic press #1 (located closest to the west wall). The metal casing holds the steel bolts that connect the base of the hydraulic press to the legs of the hydraulic press. The hydraulic press is located on the north wall in the milk pasteurization room/Queso Fresco production room and is used to press Queso Fresco after pasteurization.
- Black residue build up observed on the white painted surface of the back of the motor that is used to pump the pasteurized milk from the pasteurizer to the cheese curd table. This motor is located near the east wall in the milk pasteurization room/Queso Fresco production room.
- Heavy build up of black residue inside the opening to a horizontal hollow beam located between the stainless steel leg and the bottom of the stainless steel cheese curd table near the south west corner of the milk pasteurization room/Queso Fresco production room.
- Heavy build up of apparent black mold like substance on the metal hose, tiled wall, and floor behind the hand washing sink located on the west wall in milk pasteurization room/Queso Fresco production room.
- Black mold like substance observed on white plastic covering on the back of the support beam facing the white tiled west wall next to the rennet mixing table in milk pasteurization room/Queso Fresco production room.
- Heavy build up of apparent mold like substance on the white tile wall in the corner of the white tiled wall where the east wall and north wall meet in the finished product packaging room.
- Heavy build up of apparent mold like substance hanging on the bottom of the condenser fans on the ceiling against the north wall in the finished product packaging room located directly above the area where production tables are temporarily stored with exposed finished product (Queso Fresco) while cooling.
- Black residue on the white plastic wall located on the west wall near the storage room in the finished product packaging room.
- Black residue on the white tiled wall located on the north wall near the storage room in the finished product packaging room.
- Heavy accumulation and build up of apparent black mold like substance on the white plastic wall behind bay #2 of the 2 bay sink (bay #1 is closest to the south wall) located on the west wall in the mozzarella production room.
- Black residue on the rusted and corroded underside of the stainless steel production table located near the south east corner of the mozzarella production room.
- Heavy build up and accumulation of black residue on the white plastic wall in the north east corner of the mozzarella production room.
- Apparent black mold like substance on white tile wall underneath bay #1 of the 3 bay sink (bay #1 is located closest to the south wall) located on the west wall of the mozzarella production room.
- Black residue on white tile wall behind the hand washing sink on the west wall of the mozzarella production room.
- Black residue on white tile wall underneath bay #1 of the 3 bay sink (bay #1 is located closest to the south wall) located on the west wall of the mozzarella production room.
- Food residue in broken plastic tape on the outside of the motor to the Queso Fresco mixer located on the east wall in the finished product packaging room. This motor was also observed to have chipped gray paint on it.

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- Black residue observed on the green start button and red stop button controls to the Queso Fresco mixer located on the east wall next to the Queso Fresco grinder in the finished product packaging room.
- Black apparent mold like substance on clear caulking on the outside of the vacuum packaging machine used to pack Queso Fresco and mozzarella cheese and is located near the west wall in front the clean utensil rack in the Finished Product Packaging Area.
- Heavy build up of black residue observed inside hole on the bottom of the stainless steel motor base of the stainless steel grinder (used to grind Queso Fresco) located on the east wall in the finished product packaging room.
- Heavy build up of wet black residue was observed in black rubber wheel well on the front right wheel located on the stainless steel cheese curd table located closest to the door way to the mozzarella room on the south wall in the milk pasteurization room/Queso Fresco production room.

**OBSERVATION 7**

The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and kept in good repair.

Specifically, on 3/5/09 & 3/6/09 floors, walls, and ceilings throughout the production facility were observed not to be adequately cleaned and not kept in good repair as follows:

- Black mold like substance in cracks in rough unsmooth white caulking on the west wall directly above the 3 bay sink where the Queso Fresco is hung in cheese cloth after pasteurization in the Milk Pasteurization / Queso Fresco Production Room.
- Rough unsmooth floor with hard to clean cracks and crevices (black residue observed in cracks and crevices) underneath the 3-bay sink on the west wall of the Milk Pasteurization / Queso Fresco Production Room.
- Gap in the floor between the white drain pipe and the red tile floor underneath the 3-bay sink on the west wall of the Milk Pasteurization / Queso Fresco Production Room. Standing water and black residue were observed in this gap.
- Chipped exposed tile on the south wall of the Milk Pasteurization / Queso Fresco Production Room near the cheese curd tables. Black residue was observed in the exposed tile.
- Cracked, chipped, and missing tile pieces and chipped plastic corner guard leaving exposed tile and large cracks were observed on several tile squares on the tiled wall (south wall) around the door way into the Mozzarella Production Room from the Milk Pasteurization / Queso Fresco Production Room.
- Cracked and missing grout leaving a gap around a red square tile on the floor behind the support beam on the west wall of the Milk Pasteurization / Queso Fresco Production Room.
- Rotted wood on the bottom of the wooden door frame (left hand side of door) for the wooden door to the storage room located on the west wall in the north west corner of the finished product packaging room. Black residue and debris were observed on the floor in between the rotted wood and the cracked seal on the bottom of the door frame.
- Cracked missing tile and cracked white plastic doorframe on the bottom left side of the door way on the south wall of the Finished Product Packaging Room leading into the Milk Pasteurization / Queso Fresco Production Room. Black residue and debris observed in the cracks.
- Cracked, chipped, and missing tile pieces around door way leading from the Mozzarella Production Room into the boiler

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room.

**OBSERVATION 8**

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

Specifically, on 3/6/09 peeling paint was observed directly above finished product packaging (open and exposed plastic containers to packaged ready-to-eat Queso Fresco) on the ceiling around the skylight near the north west corner of the finished product packaging room.

**OBSERVATION 9**

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

Specifically, on 3/6/09 a build up of black residue and dust was observed on the fan blades and rusted metal protective grill covers on the cooling fans attached to the cooling unit on the ceiling along the north wall of the finished product packaging room directly above exposed ready-to-eat Queso Fresco. These fans were observed to be in operation during production and blowing air past the rusted metal protective grill covers directly above exposed ready-to-eat Queso Fresco.

**OBSERVATION 10**

Plumbing constitutes a source of contamination to equipment.

Specifically, on 3/11/09 stagnant (standing) water was observed in an opened an exposed large unused cooling water tank located on the west wall in the milk holding tank room. The stagnant standing water has been in the tank for approximately 1 month when the cooling tank was last used by your firm to test the unused milk pasteurization tank. The cooling water tank was observed to be directly connected to both of your firm's milk pasteurization tanks in order to send cold water through enclosed pipes (not coming in to direct contact with product) in the pasteurizers to cool the milk after the pasteurization step.

**OBSERVATION 11**

Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands.

Specifically, the designated hand washing sink on the south wall of the finished product packaging room is also used to wash utensils. On 3/5/09, a soiled stainless steel production knife used to cut blocks of ready-to-eat Queso Cotija was observed in

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the hand washing sink where a female employee was observed washing her hands.

**OBSERVATION 12**

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

Specifically, on 3/5/09 & 3/6/09 numerous non food-contact equipment throughout the production facility was observed not to be constructed so that the equipment could be kept in a clean condition as follows:

- A crevice with a build up of dry food residue was observed on the outside of the stainless steel grinder head attachment to the stainless steel grinder (used to grind Queso Fresco) located on the east wall in the finished product packaging room.
- Chipped paint and rust observed on the legs to the stainless steel motor base of the stainless steel grinder (used to grind Queso Fresco) located on the east wall in the finished product packaging room.
- Metal hose reel located on the floor near the hand washing sink in the finished product packaging area was observed to be heavily rusted and corroded
- The soiled white plastic casing on the hose stored on the hose reel located on the floor near the hand washing sink in the finished product packaging area was observed to be heavily cracked leaving large hard to clean cracks with black residue.
- Metal cart used to transport boxes of blocks of Queso Cotija from the cooler to the Queso Cotija Molida grater in the finished product packaging area was observed to be rusted.
- Metal cart used to store finished product labels on a cart in the north west corner of the finished product packaging room.
- Black residue in gouges located on the bottom of the white cutting board that sits on a stainless steel framed table in the north east corner of the finished product packaging room. This cutting board is used to press and form Queso Fresco wheels.
- Black residue build up on the outside of the red rubber hose that is connected to the hose reel located on the floor near the hand washing sink in the finished product packaging room.
- A build up of food residue and food particles were encrusted in hard to clean cracks on the bottom of the trash can located on the west wall of the finished product packaging room.
- Build up of food residue on white plastic surface inside the blue rusted bag sealer located on the top of the stainless steel production table closest to the Queso Fresco mixer on the east wall of the finished product packaging room. This blue rusted bag sealer also had blue chipped paint.
- The legs on the unused milk pasteurization tank located near the north east corner in the milk pasteurization room/Queso Fresco production room were observed to be rusted and corroded.
- Wet rusted screw located directly above exposed mozzarella cheese in cold water in bay #2 of the 2 bay sink (bay #1 is closest to the south wall) located on the west wall in the mozzarella production room.

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**OBSERVATION 13**

Effective measures are not being taken to exclude pests from the processing areas.

Specifically,

- On 3/11/09 an approximate 1" by 2" gap was observed below the overhead roll up door in the receiving/shipping area on the east wall leading directly outside.
- On 3/11/09 an approximate 1" by 1" gap was observed below the double wooden exit doors in the receiving/shipping area on the south wall leading directly outside.

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