

Establishment Inspection Report	FEI:	1000115118
Del Rey Tortilleria, Inc.	EI Start:	11/08/2007
Chicago, IL 60639-3007	EI End:	02/07/2008

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SUMMARY

This assignment was conducted in response to food borne illness outbreaks at three middle schools in Racine, Wisconsin and another report of food borne illnesses at a school in Iowa. On 11/7/2007, CHI-DO was alerted of these illnesses. The children who became ill experienced a rapid onset of gastrointestinal associated symptoms including vomiting, diarrhea, nausea and abdominal cramping.

This establishment inspection was conducted under Compliance Program 7303.803 (Domestic Food Safety FY08). This inspection was performed as part of the CHI-DO FY 08 work plan and reported under FACTS assignment number 916826. During the inspection, the production of flour tortillas, tostadas, masa and corn chips was observed. This inspection focused on the production of 6 and 8 inch flour tortillas.

The current inspection was initiated on 11/8/2007 at Del Rey Tortilleria by FDA. A FDA-483 (Inspectional Observations) was issued to one of the firm’s General Managers. This inspection revealed the following GMP deficiencies including:

The use of wooden yardsticks to properly position balls of dough into the wire mesh baskets of the conveyor

An employee of the firm that was handling raw dough with his bare hands had an open cut on one of his hands

A tear in the raw dough conveyor belts on Line 3 and Line 4

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Uncovered and unlabeled buckets of raw ingredients on top of bags of wheat flour in the prep area near the east mixer

A dead rodent in a storage room used to store records in the basement

A replacement roll of metal conveyor belt was on the floor of the machine shop. This belt is used on a conveyor used to cool corn chips

Dirt like substances on the white cooling fans that were running and located above the tostada and corn chip lines.

Firm's management corrected these issues or promised to correct these issues. Before the current inspection was completed, the firm purchased a tortilla premix for use that contained a new formulation of preservatives.

On 11/9/2007, the Illinois Department of Public Health (IDPH) placed an embargo on all flour tortillas located at the firm and informed Del Rey that they could not ship any flour tortillas. Del Rey could still manufacture flour tortillas and burritos. On or around 11/29/2007 IDPH lifted its embargo and the firm was able to distribute flour tortilla products. The IDPH embargo did not cover other products made at the firm. The firm was allowed to continue to produce and distribute corn based products during the embargo. On 12/3/2007, IDPH began to witness the destruction of the embargoed flour tortillas. The firm received permission to have the embargoed flour tortillas transferred to a hog farm for use as animal food on 12/7/2007. More than 31,000 lbs of flour tortillas were disposed of for use as animal feed.

The previous inspection was conducted by FDA from 3/10/06 – 3/20/06. This inspection was limited to accompanying IDPH in their verification of corrections and to obtain Del Rey's new tortilla formula. This formula is the same as the firm's formula in use at the start of the current inspection.

On 1/24/2006 – 2/9/2006 FDA conducted an inspection as the result of additional reports of food borne illness at schools on 1/18/2006 in Peoria, Illinois. This inspection was initiated to determine the firm's intent to recall these flour tortillas. The flour tortillas served at the Peoria schools were the same tortillas that were served on 12/5/2005 and 12/7/2005 at schools in Peoria, Illinois. Illnesses from school lunches served on 12/5/2005 and 12/7/2005 at Peoria schools were reported. These incidents were covered during the FDA inspection conducted 12/6/2006 – 1/11/2007.

An inspection was conducted by FDA from 12/16/2005 – 1/11/2006 in response to a food borne illness outbreak on 12/5/2005 and 12/7/2005 in multiple schools in Peoria, Illinois. This inspection was classified [REDACTED] A FDA-483 was issued to the firm's General Manager. This inspection cited repeat GMP violations including:

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Holding raw ingredients in unsuitable containers
Improper storage of maintenance and cleaning compounds
Failure to properly maintain food contact surfaces
Employees with illnesses handling finished food products
A dripping pipe in the processing room
Dirty fans in tortilla chip processing room.

There were no refusals.

Samples were collected see Sample Collected Section.

As per FMD-145:

A copy of this report should be sent to: Ms. Jeanette A. Toledo, President
(at the address listed below)

ADMINISTRATIVE DATA

Inspected firm: Del Rey Tortilleria, Inc.
Location: 5201 W Grand Ave
Chicago, IL 60639-3007
Phone: 773-637-8900
FAX: 773-637-5195
Mailing address: 5201 West Grand Avenue
Chicago, IL 60639
Dates of inspection: 11/8/2007, 11/9/2007, 11/15/2007, 11/16/2007, 11/20/2007, 11/27/2007,
11/28/2007, 11/29/2007, 12/18/2007, 1/28/2008, 1/29/2008, 2/7/2008
Days in the facility: 12
Participants: Mark I Kaspar, Investigator,
Nicole J. Clausen, Investigator

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On 11/8/07, Investigator Nicole J. Clausen and I (MIK) displayed our credentials and issued a FDA- 482 (Notice of Inspection) to Ms. Jeanette A. Toledo, the President and owner of Del Rey Tortilleria.

On the first day of the inspection, Environmental Health Specialist Paula Poncer DeMichael, Illinois Department of Public Health (IDPH) was at the firm to conduct an inspection due to the report of illnesses.

On 11/9/2007, IDPH Environmental Health Specialist Timothy Shekeleton placed an embargo on all tortillas located at the firm and informed Del Rey that they could not ship any flour tortillas. Del Rey was still permitted to manufacture flour tortillas. The firm's corn based products were not embargoed.

On 11/15/2007, IDPH Environmental Health Specialist Timothy Shekeleton was at the firm while I (MIK) and Investigator Nicole J. Clausen were at the firm.

On 11/29 or 11/30/2007, IDPH lifted its embargo and the firm was able to distribute flour tortilla products. The IDPH embargo did not cover other products made at the firm. The firm was allowed to continue to produce and distribute corn based products during the embargo.

On 11/27/2007, I (MIK) returned to the firm. I (MIK) presented my credentials and issued a FDA-482 to Ms. Jeanette A. Toledo, President.

On 12/3/2007, IDPH Environmental Health Specialist Timothy Shekelton witnessed the beginning of the destruction of the embargoed flour tortillas. The firm received permission to have the remaining flour tortillas that had been embargoed on 11/9/2007 transferred to a hog farm for use as animal food. On 12/7/2007, IDPH Environmental Health Specialist Timothy Shekelton witnessed this transfer. More than 31,000 lbs of flour tortillas were transferred for use as animal feed.

On 12/18/2007, I (MIK) returned to the firm. I (MIK) presented my credentials and issued a FDA-482 to Ms. Dorothy De La Torre, General Manager.

On 1/28/2008, I (MIK) and Investigator Nicole J. Clausen returned to the firm. Credentials were presented and a FDA-482 was issued to Ms. Dorothy De La Torre, General Manager.

On 2/7/2008, I (MIK) presented my credentials and issued a FDA-482 to Ms. Dorothy De La Torre, General Manager. I (MIK) returned to the firm to close out the inspection. Investigator Nicole J. Clausen was not at the close out because she was attending training out of state.

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I (MIK) was present at the firm on 11/8, 11/9, 11/15, 11/16, 11/20, 11/27, 11/28, 11/29, 12/18 of 2007 and 1/28, 1/29, 2/7 of 2008.

Investigator Nicole J. Clausen was present at the firm on 11/8, 11/9, 11/15/07 and 1/28 & 29/2008. Investigator Nicole J. Clausen was not present at the closeout meeting because she (NJC) was attending an out of state training course.

HISTORY

Del Rey Tortilleria, Inc., 5201 W. Grand Avenue, Chicago, Illinois 60639 is located in a 58,784 square foot three-story brick building. All manufacturing, packaging and warehousing operations are conducted on the first floor. The basement located underneath the tortilla processing room is essentially empty except for old business receipts. There is also a small office space above the east mixer which is accessed by the roof stairwell. This office space is kept locked.

Del Rey has been in business for over 46 years and employs around [REDACTED] full time employees. Del Rey Tortilleria's main facility is located at 5201 W Grand Avenue, Chicago, Illinois. The firm has two other manufacturing locations at 1023 W. 18th Street, Chicago, Illinois and 2701 S. Trumbull, Chicago, Illinois. These two locations are used to manufacture Del Rey corn tortillas. They have been manufacturing at the Grand Ave location for approximately 20 years. Flour tortillas, fried tortilla chips, tostadas and masa are manufactured at this location. There is also a retail store in the front of the facility selling Del Rey products including multiple sizes of flour tortillas, corn tortillas, chips, tostadas and masa.

The office operates 9 am – 5 pm Monday through Friday and from 8 am – 1 pm on Saturdays. Manufacturing runs from 6 am - 6 pm Monday through Friday. Tortilla manufacturing runs from 6 am until about 3:30 pm. The other areas of manufacturing run until about 6 pm. Cleaning is conducted at the firm on Saturdays from early in the morning until early afternoon. Some cleaning is done daily. The Del Rey retail store operates 6 am – 6 pm, Monday through Sunday.

The firm is registered per the BioTerrorism Act.

On 2/7/2008, Ms. Marcellina (Marcy) M. Toledo, General Manager informed me (MIK) that the firm's operations are unchanged since the last inspection.

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INTERSTATE COMMERCE / JURISDICTION

Del Rey Tortilleria, Inc. owns [REDACTED] trucks that distribute to local customers. Approximately [REDACTED] % of all products manufactured at Del Rey Tortilleria, Inc. are shipped in interstate commerce. Del Rey produces flour tortillas, corn tortillas, fried chips, tostadas, and masa (sold in their retail store). Flour tortillas when mentioned in this report are tortillas that are made with wheat flour.

Del Rey products are sold retail and wholesale to a variety of establishment types including motorized food vendors, restaurants, as a component for food manufacturers, fast food chains, grocery stores and distributors. The firm has three brand names. These brands include the Del Rey brand, Mi Abuelita and La Chica. Mi Abuelita tortillas are manufactured with lard instead of vegetable shortening. La Chica are 4 inch size tortillas. The firm also manufactures whole wheat flour tortillas and on occasion flavored flour tortillas.

On 2/7/2008, Ms. Marcellina (Marcy) M. Toledo, General Manager informed me (MIK) that the firm's operations are unchanged since the last inspection.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Since the previous inspection, there have been some changes in management. Mr. Refugio (NMI) Martinez formerly the Vice President of Del Rey Tortilleria passed away in spring of 2007. Ms. Marcy Toledo mainly oversees the Del Rey facility located at 1023 W. 18th Street, Chicago, Illinois. She is typically at the Grand Avenue location at least one time per day and has been the contact person for the current recall. However, Ms. Dorothy De La Torre is a General Manager at the Grand Avenue location. Information in this report was provided by Ms. M. Toledo, Ms. De La Torre, Mr. Perez, Mr. Garcia, Mr. Laub, Ms. Roja and production employees. There were no refusals.

Ms. Jeanette A. Toledo, President/Owner - Ms. Jeanette Toledo is President and owner of all three Del Rey Tortilleria, Inc. facilities. Ms. J. Toledo has been with the company for over 46 years. Ms. J. Toledo authorizes the decisions to recall tortilla products and makes large financial decisions. Ms. J. Toledo is elderly and is not at the firm on a regular basis due to age, health and her difficulty getting around.

Ms. Marcellina (Marcy) M. Toledo, General Manager - Ms. M. Toledo stated she is responsible for and has knowledge of all day-to-day operations including safety/quality, development, receiving raw material, hiring / firing powers and facility inspections. Ms. M. Toledo handles the firm's recall activities. Ms. M. Toledo works at the other two Del Rey facilities, but is currently in charge at the 1023 W. 18th Street facility. I (NJC) witnessed Ms. Toledo giving directions to employees to perform specific tasks. I (MIK) witnessed Ms. M. Toledo sign checks.

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On 1/29/2008 Ms. M. Toledo informed me (MIK) that her duties are unchanged since the last inspection. Ms. M. Toledo reports to her grandmother (whom she refers to as her mother) Ms. J. Toledo, President.

Ms. Dorothy L. De La Torre, General Manager – Ms. De La Torre is Ms. J. Toledo's daughter. She has worked for Del Rey Tortilleria intermittently in the past and took the position of General Manager at the Grand Ave location in April 2007. On 1/29/2008, Ms. De La Torre informed me (MIK) that she returned to work here in April of 2007 and she has not worked at the firm for about 5 years.

On 1/29/2008, Ms. De La Torre informed me (MIK) that she and Ms. M. Toledo take care of the day to day activities at the firm. Her responsibilities include ordering raw ingredients and parts needed to repair equipment. She has the authority to hire and fire personnel. The Production and Maintenance Managers report to her. She is in charge of daily operations but consults Ms. M. Toledo for opinions and occasionally direction. Ms. De La Torre stated that Ms. M. Toledo is the boss. Ms. De La Torre reports to Ms. J. Toledo.

Mr. Santos Perez, Maintenance Manager - Mr. Perez is the Maintenance Manager of Del Rey Tortilleria. He oversees maintenance personnel and is in charge of the plant when Ms. M. Toledo and Ms. De La Torre are not present. Mr. Perez has been with the company for about 17 years and reports to Ms. M. Toledo, Ms. De La Torre and Ms. J. Toledo. Mr. Perez accompanied us throughout the inspection of the facility. Mr. Perez was observed giving directions to production facility employees.

Mr. Raul Garcia, Production Manager - Mr. Garcia oversees all the production lines and the assigned employees. Mr. Garcia works about six days a week. The line and mixer employees report to him. Any problems that occur with the machines on the production lines are reported to him. Mr. Garcia has been employed by this company for about 20 years. He reports to Ms. M. Toledo, Ms. De La Torre and Mr. Eduardo Pacheco.

Mr. Barry A. Laub, Accountant – Mr. Laub is Del Rey's Accountant. He is employed by Del Rey and works one day a week assisting them in the office. He accompanied us on parts of the inspection, provided documents and has been observed consulting with Ms. J. Toledo, Ms. M. Toledo and Ms. De La Torre about the firm's courses of action.

Mr. Alejandro De La Cruz, Mixer – Mr. De La Cruz is the primary mixer that adds ingredients into the mixer, operates the mixer and transfers raw dough to the tortilla line hoppers. He operates the mixer on the west platform which produces 6 and 8 inch tortillas. Mr. De La Cruz is responsible for cleaning his mixer. He reports to Mr. Garcia.

Mr. Thomas Chavez, Mixer – Mr. Chavez is the primary mixer that measures and adds ingredients into the mixer, operates the mixer and transfers raw dough to the tortilla lines. He operates the east mixer for the burrito production lines. Mr. Chavez also is responsible for cleaning his mixer. He reports to Mr. Garcia.

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██████████ worked in the office answering phones, worked with the firm's customers and performed other administrative duties as needed. Ms. M. Toledo informed us that during the later part of the inspection, ██████████ left Del Rey, taking a job with another company. ██████████ no longer works here. ██████████ has taken over these responsibilities. Ms. ██████████ is Ms. M. Toledo's daughter.

MANUFACTURING/DESIGN OPERATIONS

At the beginning of the inspection on 11/8/07, Del Rey was manufacturing 6 and 8 inch flour tortillas with the following formula:

██████████ flour
██████████ water
██████████ vegetable shortening
██████████ salt
██████████ baking powder
██████████ calcium propionate
██████████ in ██████████ of water (assuming that a ██████████ of water weighs ██████████)

Note that the firm's formulation yields a calculated percentage of calcium propionate of about ██████████%. Samples of the firm's flour tortillas were collected by CHI-DO and MIN-DO at the firm, at the firm's customers and from the school district where the people became ill. The sample results range from 1.24% to 2.94% calcium propionate. See Attachment dated 12/5/2007.

Ingredients are placed in a ██████████ (Exhibit 1.) starting with the ██████████ (██████████) of wheat flour. The photographs in Exhibit 1. is the west mixer which is used in the production of 6 and 8 inch tortillas. The manufacturer of this mixer is unknown. The salt, baking powder and calcium propionate were cumulatively weighed into a ██████████. The ██████████ is added first, then the ██████████ and lastly the ██████████. The ingredients in this ██████████ are not mixed. This probably results in layering of these three ingredients in this plastic pail. The ██████████ is the bottom layer, the ██████████ the middle layer and the ██████████ is the top layer. This pail is filled about ██████████%. I (MIK) observed an employee of the firm weigh out these 3 ingredients, he always did it the same, ██████████ first, ██████████ second, and the ██████████ last. Exhibit 2. is a photograph of the plastic containers of these three ingredients for use in the area where they were weighed out. Note that they are arranged in the order of addition. These three weighed ingredients were then ██████████ in the mixer. The contents of this pail was added on top ██████████. I (MIK) did not see an employee of the firm evenly distribute these ingredients over the surface ██████████ by moving the pail back and forth, (horizontally across the opening of the mixer). The pail was just emptied into the mixer. The inside of the mixer is like a bucket that

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can be rotated along its axis. It is rotated to the open position so that ingredients can be added. I (MIK) saw that the [redacted] is added to the mixer as [redacted]. The [redacted] are [redacted] in [redacted] with [redacted], [redacted] per pail. This [redacted] is then added into the mixer. The mixer is closed by having the [redacted]. The [redacted] is [redacted]. The mixer is turned on and it automatically mixes the ingredients for [redacted]. The [redacted] were not mixed together prior to the addition of the [redacted] and [redacted].

Around the first of the year Del Rey purchased and switched to using a [redacted] of [redacted] and [redacted]. See the following EIR section entitled, New Formulation and Mixing.

The [redacted]

One batch of tortilla dough will make approximately [redacted] of finished product (based on 8 inch tortillas). Tortillas are packed into cardboard boxes for shipment. An expiration date is manually stamped on the boxes. Tortillas are packaged in the following quantities:

6 inch	12 tortillas/package	40 packages/case = 480 tortillas/case
8 inch	12 tortillas/package	24 packages/case = 288 tortillas/case
Burritos	10 tortillas/package	10 packages/case = 100 tortillas/case

(#2, #3, #3 1/2, #4)

[redacted] is added to the firm's burritos products as a conditioning ingredient. [redacted] is not added to the 4, 6 and 8 inch flour tortillas.

The west platform mixer is designated for 4 inch, 6 inch and 8 inch tortillas (Lines 1, 2 and 3). The east mixer is for burrito sized tortillas, 10 inches – 14 inches (Lines 4, 5, 6 and 7).