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**SUMMARY**

This assignment was conducted in response to food borne illness outbreak at multiple schools in Peoria, IL. On 12/14/05 CHI-DO was alerted was EMOPS of this outbreak. The children experienced a rapid onset of gastrointestinal associated symptoms including vomiting, diarrhea, nausea and abdominal cramping. This establishment inspection was conducted under CP 7303.803 (Domestic Food Safety), CHI-DO FY'06 Work Plan and FACTS assignment number 701609.

On 12/16/05 an inspection was initiated at Del Rey Tortilleria. FDA Investigators were accompanied by Illinois Department of Public Health (IDPH) Environmental Health Specialist Timothy Shekelton. On 12/19/05 Helen Schurz-Rogers and Sharon Greene from Center of Disease Control (CDC) along with Lyn James, an Epidemiologist from the Chicago Department of Health (CDH). Henry Milan, a sanitarian with CDH, arrived later that day to also conduct an inspection. Mr. Shekelton was also present on 12/19/05 and 12/20/05. CDC employees were also present on 12/20/05. Ms. Maria Diaz, with IDPH, also accompanied Mr. Shekelton on 12/20/05.

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Del Rey Tortilleria, Inc.  
Chicago, IL 60639-3007

FEI: 1000115118  
EI Start: 12/16/2005  
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Del Rey Tortilleria located at 5201 W. Grand Ave Chicago, IL 60639 is a manufacturer of flour tortillas, corn chips, tostadas and masa (corn flour). They also repack spices at this location. The firm has two other manufacturing sites in Chicago, IL that manufacture corn tortillas. Del Rey also has a retail store at their Grand Ave location. This inspection primarily focused on tortilla manufacturing.

The previous inspection conducted at Del Rey Tortilleria was on 8/16/04 to verify corrections from the previous inspection and as a preventive measure for the upcoming school year. This inspection was classified [REDACTED] for the following GMP violations:

- Failure to operate fans in a way that minimizes the potential for contamination
- Failure to hold ingredients in suitable containers
- Failure to properly store equipment
- Failure to properly store toxic cleaning compounds
- Lack of adequate screening for pests
- Ceiling is not kept in good repair
- Failure to hold ingredients in suitable containers
- Failure to properly store equipment
- Failure to properly store toxic cleaning compounds

The current inspection revealed several GMP violations including:

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

During the inspection we observed the production of:

- 6 inch tortillas
- 10 inch tortillas
- Burrito #2
- Burrito #3
- Burrito #3 ½
- Tostadas
- Masa
- Corn Chips

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- Repacking of dried peppers

Numerous samples were collected for mycotoxins, pesticides and industrial chemicals and metals. Samples were sent to ARL, SRL, and KAN-LAB.

Photographs were taken.

No insect, rodent, or avian activity was observed during the inspection.

No refusals were encountered.

The firm is registered under the Bioterrorism Act.

**ADMINISTRATIVE DATA**

Inspected firm: Del Rey Tortilleria, Inc.  
Location: 5201 W Grand Ave  
Chicago, IL 60639-3007  
Phone: 773637-8900  
FAX:  
Mailing address: 5201 W Grand Ave  
Chicago, IL 60639-3007

Dates of inspection: 12/16/2005, 12/19/2005, 12/20/2005, 12/21/2005, 1/11/2006

Days in the facility: 5

Participants: Joseph D. Cooper, Investigator  
Nicole J. Clausen, Investigator

**HISTORY**

Del Rey Tortilleria, Inc. is a three-story brick building with the entire manufacturing and packaging operations taking place on the first floor. There is a basement located underneath the tortilla

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processing room which is basically empty except for some old business receipts. There is also an office space above the East mixer which is accessed by the roof stairwell. This office space is locked. Del Rey has been in business for over 42 years and employees [REDACTED] full time employees.

The plant is a 58,784 square feet and manufactures tortillas and corn tortilla products. Del Rey Tortilleria is located at 5201 W Grand Avenue Chicago, IL and has been in this current facility for about 18 year. The firm has two other manufacturing locations at 1023 W. 18<sup>th</sup> Street Chicago, IL and 2701 S. Trumbull Chicago IL. Both of these sites manufacture corn tortillas.

The firm office operates 9a-5p Monday through Friday and from 8a-1p on Saturdays. Manufacturing operates from 6a-6p Monday through Friday. Ms. Marcellina Toledo stated a thorough cleaning of the plant is conducted every Saturday. The Del Rey retail store operates 6a-6p, Monday through Sunday. Ms. M. Toledo informed me (JDC) that the firm generates annual sales varying between \$ [REDACTED] and \$ [REDACTED]

**As per FMD-145:**

(a copy of this report should be sent to)

Ms. Marcellina M. Toledo, General Manager  
c/o Del Rey Tortilleria, Inc.  
5201 W. Grand Ave.  
Chicago, IL. 60639

**INTERSTATE COMMERCE/JURISDICTION**

Ms. M. Toledo stated that Del Rey Tortilleria, Inc. owns [REDACTED] trucks that distribute locally. Ms. M. Toledo also informed me (JDC) approximately [REDACTED]% of all products manufactured at Del Rey Tortilleria, Inc. is shipped in interstate commerce. Del Rey produces flour tortillas and corn tortilla and other corn bases food products which are sold retail and wholesale. The firm has two brand names. These brands include the Del Rey brand and Mi Abuelita. Mi Abuelita tortillas are manufactured with lard instead of vegetable shortening.

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

On 12/16/05, Investigator Joseph D. Cooper and Investigator Nicole J. Clausen displayed our credentials and issued an FDA 482, Notice of Inspection, to Marcellina M. Toledo, General Manager of Del Rey Tortilleria. During this inspection we verified some corrections from the previous

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inspection. Information in this report was provided by Ms. M. Toledo, Mr. Perez, Mr. Garcia, and Mr. Laub.

**Ms. Marcellina (Marcy) M. Toledo, General Manager** - Ms. M. Toledo stated that she was the most responsible individual at the firm at the time of inspection. Ms. M. Toledo also stated she is responsible for and has knowledge of all day-to-day operations, safety/quality, development, receiving raw material, hiring / firing powers and facility inspections. Ms. M. Toledo stated she works at the other two Del Rey facilities, but is currently in charge at the 5201 W Grand Avenue facility. I witnessed Ms. Toledo giving directions to employees to perform specific tasks. Ms. M. Toledo reports to her mother, **Jeanette A. Toledo, President**, who is the owner of Del Rey Tortilleria, Inc.

**Ms. Jeanette A. Toledo, President** - Ms. M. Marcy Toledo stated 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 was not available for the FDA inspection.

**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 is not present. Mr. Perez has been with the company for about 15 years and reports to Ms. M. Toledo. Mr. Perez accompanied us throughout the inspection of the facility.

**Mr. Raul Garcia, Production Manager** - Mr. Garcia handles all the production lines and its employees. Mr. Garcia states that he works about six times a week. The line employees report to him. Any problems that occur with machines on the line are reported to him. Mr. Garcia has been employed by this company for about 18 years. He reports to Ms. M. Toledo.

**FIRM'S TRAINING PROGRAM**

The firm does not have a formal training program. All training is OJT.

**MANUFACTURING/DESIGN OPERATIONS**

Del Rey Tortilleria is a manufacturer of flour and flavored tortillas, corn chips, tostadas, and masa. They also repack spices, dried peppers and lard for sale in the attached retail store.

According to the East mixer employee, translated by Ms. M. Toledo, the current formula for tortillas is:

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- ████████ flour
- ████████ vegetable shortening
- ████████ baking powder
- ████████ calcium propionate
- ████████ salt

Approximately ██████████ water

Calcium propionate levels vary slightly depending on the expiration date placed on the package.

<u>Expiration date</u>	<u>Calcium Propionate</u>
30 days	████████
45 days	████████
90 days	████████

*Handwritten note:*  
 A label  
 for  
 calcium  
 propionate

Raw ingredients are obtained from multiple suppliers. These suppliers are listed below. Ms. M. Toledo stated that flour is usually shipped directly from ██████████ to Del Rey.

Raw ingredient

Supplier

████████ Flour (bromated)	████████
Baking Powder	████████
████████ Vegetable Shortening	████████
Salt	████████
Calcium Propionate	████████

Ingredients are mixed for ██████████ and are then transferred to ██████████. Employees who run the mixer have been in their current positions for a minimum of four years. From the ██████████ the ██████████ are either ██████████ via ██████████ or ██████████ to ██████████. The conveyer then transports the tortillas ██████████ for approximately ██████████. Afterwards, the tortillas then ██████████ where the tortillas go through an ██████████ and onto a ██████████. The tortillas are then ██████████ in a plastic bag which receives an expiration code from an ink jet printer. These tortillas are then packed in cardboard boxes for shipment. For some companies the firm will pack tortillas in bulk. Bulk packaging consists of stacking tortillas in a clear plastic bag inside a cardboard box. The expiration date is stamped on the outside of the box.

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Del Rey currently has seven production lines. Line 7 was installed on the Western most end of the production room, located next to Line 1, in November 2005. The tortillas produced on each line are as follows:

Line 1	8 in. (Fajita size)
Line 2	6 in.
Line 3	6 in.
Line 4	Burrito #2
Line 5	Burrito #3 and Burrito #3 ½
Line 6	Burrito #3 and Burrito #3 ½
Line 7	Burrito #3

The West mixer produces dough for Lines 1, 2 and 3. The East mixer produces dough for Lines 4, 5, 6 and 7. Dough balls for Line 6 and 7 are formed on either Line 4 or 5. The dough balls are placed on stainless steel trays which are placed on rolling carts and are hand fed into the press. This practice is the same for Lines 5 and 6. For all other lines, the dough balls are formed and are then transported and dropped onto the press by wire mesh dough ball conveyers.

Del Rey conducts a wet clean on Saturdays. This cleaning consists of cleaning manufacturing equipment. All food contact surfaces are cleaned with dish soap. The floor is cleaned with [REDACTED] Cleaner, which is referred to as [REDACTED]. [REDACTED] is used to lubricate machines except where hydraulic fluid is required.

**MANUFACTURING CODES**

Currently, Del Rey is placing a 45 expiration code on their tortillas. In the fall, winter and early spring Del Rey places a 45 day expiration code on their tortilla products. In the summer and warmer months they place a 30 day expiration code on the tortillas. Packages with 90 day expirations are placed on products upon request or if product is going to be frozen. In addition, customers can request a different code date. For example, some customers request a 90 day code and another customer request a date of manufacture code placed on the packaging.

Del Rey stamps a "USE THRU" date on their cardboard tortilla boxes 45 days from the date of their production. For example we observed tortillas being produced on 12/21/05 to have a "USE THRU FEB 04" stamped on the tortilla boxes. The individual plastic bags contain an ink jet stamp of the expiration date. For example, tortillas manufactured on 12/21/05 have a code of "FEB/04/2006". Bulk tortillas only have the use thru date stamped on the outside of the box.

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**COMPLAINTS**

Management stated that they are not aware of any complaints regarding their products.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

On 1/11/06 an FDA-482 was issued and credentials were shown to Ms. Marcellina M. Toledo, General Manger for being absent from Del Rey Tortilleria for an extended period of time. On this same day, the FDA-483, Inspectional Observations, was also issued to Ms. Marcellina M. Toledo, General Manager. Ms. Marcellina M. Toledo, Mr. Barry Laub, Del Rey's accountant, and FDA Investigator Joseph D. Cooper and I (NJC) were present for the issuance of the FDA-483.

**Observations listed on form FDA 483**

**OBSERVATION 1**

Failure to hold raw materials and ingredients in bulk or in suitable containers so as to protect against contamination.

Specifically,

On 12/16/05 raw ingredient baking powder, calcium propionate and salt was being held in a 5 gallon white plastic bucket holding raw ingredient labeled in part: "\*\*\*[REDACTED]\*\*\*DECORATIVE EPOXY\*\*\*". This bucket was located on the staging platform next to the West mixer.

On 12/16/05 [REDACTED] (metabisulfite tablets) were being dissolved with hot water for the manufacturing of tortillas in a 5 gallon white plastic bucket labeled in part: "\*\*\*[REDACTED]\*\*\* [REDACTED] Cleaner\*\*\*". This cleaner is used as floor soap. This bucket was located on the staging platform next to the West mixer.

On 12/16/05 I observed the firm using 5 gallon plastic buckets labeled in part, "\*\*\* [REDACTED] Quality Paints \*\*\*" at both dough mixers to hold in process raw materials being used in production.

Reference: 21 CFR 110.80(a)(5)

Supporting Evidence and Relevance:

Raw ingredients were being held in buckets previously used to hold chemical products. Foods shall be held in a manner to prevent cross contamination. **This is a repeat violation.**

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Exhibit 1 & 2

**Discussion with Management:**

When Ms. M. Toledo was informed that employees were using these buckets she stated that they should not be using them and that the employees will go across the street to the hardware store and purchase pails. Ms. M. Toledo purchased new food grade buckets for the production room. On 1/11/05 the new pails were observed being used to hold food.

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**OBSERVATION 2**

Failure to properly store toxic cleaning compounds and sanitizing agents in a manner that protects against contamination of food and food-contact surfaces.

Specifically,

On 12/16/05 a can of [REDACTED] and dish soap was observed next to containers of raw ingredient products.

On 12/20/05 an opaque plastic container containing an oil like substance was observed on top of the hood of the raw dough ball conveyer on Line 3.

Reference: 21 CFR 110.35(b)(2)

**Supporting Evidence and Relevance:**

Chemicals should not be stored in the production room to prevent contamination of foods. **This is a repeat violation.**

Exhibit 3 & 4

**Discussion with Management:**

Ms. M. Toledo agreed that the storage of the chemicals should not be in the production room. These items were removed from the production room.

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**OBSERVATION 3**

Employees who appear to have an illness are not excluded from operations where there is a reasonable possibility of food, food contact surfaces, and food packaging materials becoming contaminated.

Specifically, on 12/16/05 a male employee working on Line 5 was observed blowing his nose and then continued to handle finished product tortillas off the conveyer belt and placing the tortillas in packages without washing his hands.

Reference: 21 CFR 110.10(a)

**Supporting Evidence and Relevance:**

Ill employees can transmit bacteria to food and food products.

**Discussion with Management:**

On 12/16/05, I (NJC) informed Ms. M. Toledo of the ill employee. Ms. M. Toledo asked me to confirm the ill employee and then sent him home. She stated that she informed all employees that if they are sick they cannot work.

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**OBSERVATION 4**

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

Specifically, on 12/16/2005 we observed dirty box fans used to cool tortilla chips in the chip processing area. These fans have a build up of a grease -like material on the blades and grill of the fans.

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Reference: 21 CFR 110.20(b)(6)

**Supporting Evidence and Relevance:**

Cooling fans should be maintained and kept clean to assure food quality, safety, and to eliminate possible adulteration of food products. **This is a repeat violation.**

Exhibit 5

**Discussion with Management:**

Ms. Toledo stated the fans would be replaced in about 1 week.

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**OBSERVATION 5**

Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of food particles and the opportunity for growth of microorganisms.

Specifically, on 12/16/05 the tortilla press conveyer belt had a tear in it on the newly installed line 7.

Reference: 21 CFR 110.40(b)

**Supporting Evidence and Relevance:**

Tears in seams can trap foods and provide the opportunity for microbial growth.

Exhibit 6

**Discussion with Management:**

This conveyer belt on Line 7 was replaced as of 1/11/06.

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**OBSERVATION 6**

Plumbing constitutes a source of contamination to food.

Specifically,

On 12/16/05, an intermittent drip was observed from a hot water pipe in the production room on to a bag of [REDACTED] flour, lot [REDACTED], on the West mixer raw ingredient staging platform.

Reference: 21 CFR 110.37(b)(3)

Supporting Evidence and Relevance:

Water dripping on raw ingredient can contribute to toxin growth.

Exhibit 7

Discussion with Management:

This flour product is stored on the staging platform next to the West mixer and therefore does not stay in this location for a long time. This dripping pipe has been insulated and will be taped. No dripping was observed when verifying this correction.

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**OBSERVATION 7**

Failure to perform packaging in a manner that protects food from becoming contaminated.

Specifically, on 12/19/05 I observed an employee packaging tortillas into plastic bags on line # 2. He then went over to the wall where boxes are lined up and grabbed one to place packaged tortillas into. After filling the box he began to package tortillas again without washing his hands first.