

## Establishment Inspection Report

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

FEI: 1000115118  
EI Start: 10/16/2003  
EI End: 11/07/2003

### SUMMARY OF FINDINGS

This inspection of Del Rey Tortilleria, Inc. was conducted in response to a request received from FDA Emergency Operations regarding a possible tortilla-related Food Borne Outbreak among school children in Kankakee, IL (St. Anne's School) and in Boston, MA (Framingham Charter School). 33 students who ate chicken fajitas served on flour tortillas at Framingham Charter School on September 24, 2003 and 25 people (21 students, 4 teachers) who consumed a taco meal at St. Anne's Grade School served on October 8, 2003 became sick exhibiting rapid-onset of the following symptoms: vomiting, diarrhea, or abdominal cramping within eight hours of consumption. An epidemiological investigation implicated flour tortillas served at these two schools as the possible vehicle of illness. These flour tortillas were manufactured at Del Rey Tortilleria, Inc. 5201 West Grand Avenue Chicago, IL 60639. An inspection of this firm was conducted in accordance with CP7303.803 (Domestic Food Safety FY'04) and as part of the CHI-DO FY'04 WP.

Del Rey Tortilleria, Inc. is a bakery that manufactures flour tortillas and corn tortilla products (Exhibit #1). The firm has two other manufacturing locations at 1023 W. 18<sup>th</sup> Street Chicago, IL and 2701 S. Trumbell Chicago IL. The manufacturing process of 6, 8 (fajita size), 10 (Burritos #2), and 12 (Burritos #3) inch flour tortillas (manufacturing code: Dec 01 2003) were observed during this inspection. Product label for the various sizes of flour tortillas were obtained and are included in this report as Exhibit # 29.

The previous inspection was conducted by the Illinois Department of Public Health under FDA contract 223-02-4111 on 9/27/02 and indexed [REDACTED]. Objectionable observations included GMP issues (lack of effective pest control).

The current inspection revealed GMP deficiencies and a 12 point FDA-483 was issued to Marcy Toledo, Manager of the firm at the close of the inspection. Objectionable observations noted on the FDA-483 included: condensate dripping directly onto uncovered finished product line, improper storage of toxic compounds, improper raw ingredient storage, broken windows in processing area, and using box fans with dirt build up to cool uncovered finished product.

On 10/16/03, Investigators Kujtim (NMI) Sadiku, Mark I. Kaspar and Nicole J. Clausen displayed credentials and issued a FDA-482 (Notice of Inspection) to Yolanda M. Carreon, Agent-In-Charge at Del Rey Tortilleria, Inc. A second FDA-482 was issued on 10/16/03 to Marcy M. Toledo, Manager, upon her arrival at Del Rey. Another FDA-482 was issued to Marcy M. Toledo on 10/24/03 and 11/7/03. This inspection was conducted in conjunction with The Chicago Department of Public Health (CDPH), Illinois Department of Public Health (IDPH), and Centers For Disease Control (CDC). CDPH and IDPH were present on 10/16/03. The IDPH issued an 11-point Sanitary Inspection Report noting insanitary conditions. This report is attached as Exhibit # 28. CDC participated 10/16 - 20/03.

No rodent, insect or avian-like evidence or refusals were encountered during this inspection. Photos depicting unsanitary conditions at the firm were taken.

Official samples of flour tortillas were collected on 10/17/03 (216795) and 10/20/03 (216799 - 216802, 252378 - 252385). Investigational samples of cleaners and oils used in the flour tortilla processing area were also collected on 10/17/03 (INV 216796 - INV 216798) and 10/20/03 (INV 252386 - 252388). Official Samples of in-process raw ingredients used in manufacturing flour tortillas were collected on 10/24/03 (252389 - 252396). Samples were covered under CHI-DO work plan (PAC 03803D). INV samples were shipped to FCC for chemical / toxicological screening. Samples of flour tortillas and in-process raw ingredients were shipped to FCC and CFSAN as split samples for chemical / toxicological screening.

All sections of this report were written by Investigator Kujtim Sadiku (KS).

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A copy of this EIR should be sent to:  
(As specified per FMD-145)

Ms. Marcy M. Toledo, Plant Manager  
Del Rey Tortilleria, Inc.  
5201 West Grand Avenue  
Chicago, IL 60639

**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 W Grand Ave  
Chicago, IL 60639-3007  
**Dates of inspection:** 10/16/2003, 10/17/2003, 10/18/2003, 10/20/2003, 10/24/2003, 10/29/2003,  
11/7/2003  
**Days in the facility:** 7  
**Participants and dates participated:** Kujtim Sadiku, Investigator (10/16, 10/17, 10/18, 10/20, 10/24, 10/29, 11/7/03)  
Nicole J. Clausen, Investigator (10/16, 10/17, 10/20, 10/24, 10/29/03)  
Mark I. Kaspar, Investigator (10/16, 10/17, 11/7/03)  
William R. Weissinger, Investigator (10/24/03)

**HISTORY**

Del Rey Tortilleria, Inc. is a three-story brick building with the entire manufacturing and packaging operations taking place on the first floor; the second and third floors are vacant. Del Rey has been in business for over 40 years and employees full time employees. The plant is a 58,784 square foot bakery that manufactures tortillas and corn tortilla products. The bakery is located at 5201 W Grand Avenue Chicago, IL and has two other manufacturing locations at 1023 W. 18<sup>th</sup> Street Chicago, IL and 2701 S. Trumbull Chicago IL. The firm office operates 9a-5p Monday through Friday and from 8a-1p on Saturdays. Product is manufactured from 6a-6p Monday through Friday. Ms. Toledo stated a thorough cleaning of the plant is conducted on Saturday. The Del Rey retail store operates 6a-6p, Monday through Sunday. Ms. Toledo informed me that the firm generates annual sales varying between \$ and \$ and that all training is conducted "hands on" at the firm.

**INDIVIDUAL RESPONSIBILITY**

On 10/16/03, Mark I. Kaspar and Nicole J. Clausen and I (KS) showed credentials and issued form FDA-482, Notice of Inspection to Ms. Yolanda M. Carreon, Agent In Charge. A second FDA-482 was issued on 10/16/03 to Marcy M. Toledo, Plant Manager upon her arrival to the firm. A Notice of Inspection, FDA-482, was also issued to Marcy M. Toledo on 10/24/03 and 11/7/03. On 10/24/03, Investigator William R. Weissinger accompanied Investigator Clausen (NJC) and I (KS) on the inspection. Ms. Toledo answered all questions.

*Ms. Marcy M. Toledo, Plant Manager, stated that she was the most responsible individual at the firm at the time of inspection. Ms. 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. 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. Toledo reports to her mother, Jeanette A. Toledo, President, who is the owner of Del Rey Tortilleria, Inc.*

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*Mr. Refligio (NMI) Matinez, Vice-President*, reports to Jeanette Toledo, President of Del Rey Tortilleria, Inc.

*Ms. Yolanda (NMI) Carreon, Plant Manager – 2701 S. Trumbull Avenue*, stated that she was the most responsible individual at the 2701 S. Trumbull facility. Ms. Carreon also stated she is responsible for and has knowledge of all day-to-day operations, safety/quality, development, receiving raw material and facility inspections at the 2701 S. Trumbull facility. Ms. Carreon stated she works at the other two Del Rey facilities, but is currently in charge at the 2701 S. Trumbull Avenue facility. Ms. Carreon reports to *Jeanette A. Toledo, President*, who is the owner of Del Rey Tortilleria, Inc.

*Ms. Jeanette A. Toledo, President*, Del Rey Tortilleria, Inc. Ms. Marcy Toledo stated Ms. Jeanette Toledo is president and owner of all three Del Rey Tortilleria, Inc. facilities located at 5201 West Grand Avenue, 2701 S. Trumbull Avenue and 1023 West 18<sup>th</sup> Street Chicago, IL.

**OPERATIONS, PERSONNEL, AND EQUIPMENT**

Del Rey Tortilleria, Inc. is a manufacturer and distributor of tortillas and corn tortilla products. A list of consignees is attached as Exhibit # 2. The firm's hours of operation are Monday-Friday; 6a-6p. Ms. Toledo stated that Del Rey Tortilleria, Inc. owns [redacted] trucks that distribute locally and [redacted] % of product manufactured at Del Rey is shipped in interstate commerce. Ms. Toledo informed me that the firm generates annual sales varying between \$ [redacted] and \$ [redacted] and that all training is conducted "hands on" at the firm.

Timecards from 8/03 were reviewed with the manager to determine whether any hiring, firing, or employee illnesses occurred; none were noted. Ms. Toledo stated 4-5 employees clean the processing areas of the firm from 6a-1p on Saturday. On 10/18/03, I observed 13 employees participating in the Saturday cleaning. CDC used paper pH strips and water from the plant taps to measure pH levels of various chemicals and food contact surfaces within the plant before cleaning. The pH levels of the various surfaces are summarized below:

Product/Location	Pre-cleaning pH	Post-cleaning pH
Magic Green solution	11	NA
Mineral oil	5	NA
Tap water	6	NA
Uncooked dough	7	NA
Mixer #1, internal bin	6	NA
Mixer #2, internal bin	7-7.5	NA
Mixer #2, external metal shelf	6.5	6.5
Line 2, hopper	6	NA
Line 2, balling conveyor	7-7.5	NA
Line 2, post-oven conveyor	7.5-8	NA
Line 3, foam roller post-press	7.5-8	NA
Line 3, box fan #1	7	6
Line 3, bagging area conveyor	5.5-6	6
Line 4, balling conveyor	NA	6.5-7
Line 5, hopper	7-7.5	8-8.5
Line 5, balling conveyor	7	NA
Chutes (dissembled)	NA	8.5

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Rolling metal bed	NA	7-7.5
Balling baskets	NA	6.5

\*N/A - not applicable

Del Rey Tortilleria, Inc. receives shipments of flour on Monday and Wednesday from [REDACTED] which is located in [REDACTED] and [REDACTED] which is located at [REDACTED]. All flour used in production of flour tortillas is a product of [REDACTED] Del Rey uses [REDACTED] flour in manufacturing flour tortillas. Product specification sheets for each type of flour are attached as Exhibit # 14. [REDACTED] flour was used in the production of flour tortillas sampled on 10/17 (lot # [REDACTED]) and 10/20/03 (lot # [REDACTED]). The Invoice (10/23/03) and Bill of Lading (dated 10/10/03) of this shipment received are attached as Exhibit #3, #4.

Flour tortillas implicated in the Framingham outbreak on 9/24/03 had a manufacturing code of 10/6/03. On 10/16/03, Ms. Toledo stated that the flour tortillas with a manufacturing code of 10/6/03 were manufactured on 8/11/03 or 8/12/03. Ms. Toledo also stated that [REDACTED] flour (lot # 0564894) received from [REDACTED] on 8/4/03 (Exhibit #5, 6), [REDACTED] received from [REDACTED] on 8/4/03 (Exhibit # 7, p.1), or [REDACTED] received from [REDACTED] Inc. on 8/6/03 (Exhibit #9) was used in manufacturing the implicated flour tortillas on 8/11/03 or 8/12/03). A shipment of [REDACTED] flour from [REDACTED] received by Del Rey on 8/11/03 (Exhibit #7, p.2) is from the same lot [REDACTED] as the shipment received on 8/4/03 (Exhibit #7 p.1).

Flour tortillas implicated in the Kankakee Outbreak on 10/8/03 had a manufacturing code of 10/14/03. Ms. Toledo stated that the flour tortillas with a manufacturing code of 10/14/03 were manufactured on either 8/25/03 or 8/26/03. Ms. Toledo stated that [REDACTED] flour (lot # [REDACTED]) received from [REDACTED] on 8/20/03 (Exhibit #10, 11) was used in manufacturing the flour tortillas on 8/25/03 or 8/26/03. Ms. Toledo stated that Del Rey does not maintain records to determine the lot of flour used in manufacturing a lot of tortillas.

The flour tortillas implicated in the Framingham, MA Outbreak on 9/24/03 were shipped by [REDACTED]. Invoice dated 8/27/03 is attached as Exhibit # 12. The flour tortillas implicated in the Kankakee, IL Outbreak were shipped by [REDACTED]. Invoice dated 8/13/03 is attached as Exhibit #13.

Samples of in-process raw ingredient used in the production of flour tortillas on 10/24/03 were collected aseptically. Approximately [REDACTED] grams of the following ingredients were collected on 10/24/03: [REDACTED] received from [REDACTED] on 10/20/03 (Invoice and loading order are attached as Exhibit # #15, 16); [REDACTED] manufactured by [REDACTED] and received from [REDACTED] on 10/7/03 (Invoice and Bill of Lading are attached as Exhibit # 17, 18); Vegetable Shortening (lot # [REDACTED]) manufactured by [REDACTED] and received from [REDACTED] on 10/1/03 (Invoice and Bill of Lading are attached as Exhibit #19, 20); Baking Powder (lot # [REDACTED]) manufactured by [REDACTED] and received from [REDACTED] on 10/22/03 (Invoice is attached as Exhibit #21); Calcium Propionate (lot # [REDACTED]) manufactured by [REDACTED] and received from [REDACTED] on 10/13/03 (Invoice, Packing List and Bill of lading are attached as Exhibit #22, 23, 24); Salt [REDACTED] manufactured by [REDACTED] and received from [REDACTED] on 10/15/03 and 10/22/03 (Invoices are attached as Exhibit #25); Beta-Tabs (metabisulfite tablets) manufactured by [REDACTED] and received from [REDACTED] on 9/29/03 (Invoice and Bill of Lading are attached as Exhibit # 26, 27).

Investigational samples of cleaning compounds and lubricating oils used in the processing areas were also collected. Approximately 2 ounces of the following compounds were collected in 2 ounce wide mouth amber [REDACTED] lined capped glass bottles on 10/17/03: [REDACTED] yellow granulated floor soap (INV 216796), manufactured by [REDACTED]

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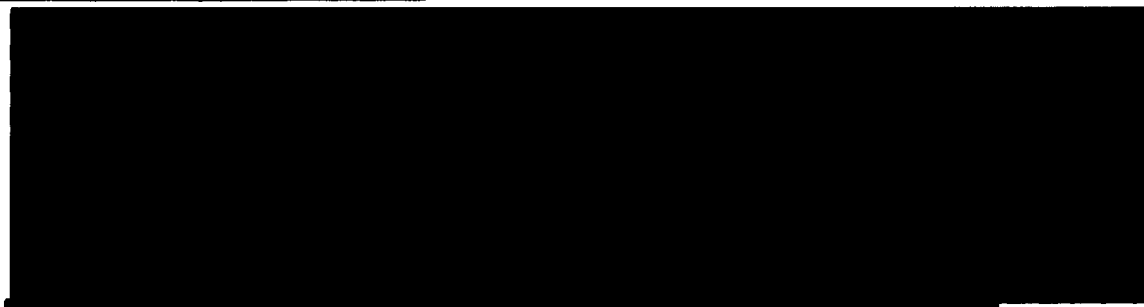
EI End: 11/07/2003

[REDACTED] (INV 216797)  
 sold by [REDACTED] (INV 216798) Oil  
 The following Investigational samples of cleaning compounds and oils were collected in the same manner described above on 10/20/03: [REDACTED] (INV 252386) distributed by [REDACTED] distributed by [REDACTED]. An empty 2 ounce wide mouth amber lined capped glass bottle was submitted as a control to FCC (INV 252388). Material Safety Data Sheets (MSDS) of the compounds listed above are attached as Exhibits #31-35. Note: Ms. Toledo provided MSDS for [REDACTED] manufactured by [REDACTED] in place of for [REDACTED] (INV 216798) and MSDS for [REDACTED] synthetic Oven Chain Lubricant, manufactured by [REDACTED] in place of [REDACTED] (INV 252386). No MSDS available for [REDACTED] Information sheet obtained from internet (Exhibit #35).

The manufacturing process of 6, 8 (fajita size), 10 (Burritos #2), and 12 (Burritos #3) inch flour tortillas (manufacturing code: Dec 01 2003) were observed during this inspection. The process is conducted in the following manner:

**Flour tortillas (Manufacturing Code: Dec 01 2003)**

1.



The packages are heat sealed and placed on conveyor to date-stamping machine. The finished product is boxed, placed onto pallets and stored in an unrefrigerated storage room. Ms. Toledo stated that tortillas are shipped within two days.

**MANUFACTURING CODES**

The manufacturing code of the products observed during manufacturing on 10/16/03 was:

Dec 04 2003

Ms. Toledo stated packages are marked with a 45-day expiration date if the tortillas were made between August 1st and approximately April 1st, and a 30-day expiration date during the summer (April 1<sup>st</sup> – August 1st). However, this scheme was not followed consistently; Ms. Toledo also stated that if a purchaser requested, the company would also apply a 60-day expiration date at any time of the year and without a change in recipe or packaging, as long as the boxes are stamped, "keep refrigerated." The plant produces approximately [REDACTED] cases of tortillas per day and approximately [REDACTED] cases per week.

**OBJECTIONABLE CONDITIONS**

Observations listed on form FDA 483

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**OBSERVATION 1**

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

Specifically,

On 10/20/03, condensate was spraying from the air vent above the flour tortilla processing line # 6 and dripping directly onto the cooling rack carrying flour tortillas.

Reference: 21 CFR 110.20(b)(4)

**Relevance:** Condensate was spraying from the air vent above line #6 was dripping directly on finished flour tortillas. Flour tortillas should be manufactured in a manner to avoid adulteration of finished product. See Exhibit #30, p.1 photographs.

**Management's Response:** Ms. Toledo stated the problem was corrected on 10/20/03. I observed the air vent on 10/20/03 and concluded the condensate was not dripping from the air vent on 10/20/03. This observation should be re-evaluated at the next inspection.

**Related Exhibits:** Exhibit #30, photographs.

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**OBSERVATION 2**

Failure to manufacture foods under conditions and controls necessary to minimize contamination.

Specifically,

A. On 10/16/03, 2 - 55 gallon drums of [redacted] hydraulic oil were stored 10 feet from in process raw ingredients and the [redacted] mixer located along the south wall in the flour tortilla processing area.

B. On 10/16/03, an uncovered 5-gallon bucket of [redacted] containing red epoxy residue and water was stored 1 foot away from the [redacted] mixer and 5 feet from uncovered in-process raw ingredients located along the south wall of flour tortilla processing area.

Reference: 21 CFR 110.80(b)(2)

**Relevance:** Toxic chemicals should be stored in an area of the firm to avoid contamination of food products.

**Management's Response:** Ms. Toledo stated that the bucket containing the epoxy red was removed from the flour tortilla processing area and chemicals will be stored in the storage area of the firm. This observation should be re-evaluated at the next inspection. The 2, 55-gallon drums of [redacted] oil were removed from the processing area prior to our return to the firm on 10/17/03.

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**OBSERVATION 3**

Failure to store raw materials in a manner that protects against contamination.

Specifically,

A. On 10/16/03, in-process raw ingredients (baking powder, salt, calcium propionate) stored along the south wall of flour tortilla processing area were stored in uncovered plastic containers.

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B. On 10/16/03, an unlabeled and uncovered 5 gallon bucket of [REDACTED] was stored along south wall of flour tortilla processing area.

C. On 10/16/03, unlabeled plastic spray bottles containing mineral oil were stored between the hopper and dough former directly above in-process raw dough on lines 3 and 5 in the flour tortilla processing area.

D. On 10/18/03, a 40 pound block of vegetable shortening was stored uncovered overnight on a cutting table located east of lines 5 and 6 in the flour tortilla processing area.

**Reference:** 21 CFR 110.80(a)(1)

**Relevance:** In-process raw ingredients should be maintained in a manner in which to assure food product safety and avoid contamination.

**Management's Response:** Ms. Toledo stated she will remind employees to keep raw ingredients covered to maintain food safety and quality.

**Related sample:** Sample # 252390

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**OBSERVATION 4**

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

Specifically,

On 10/18/03, unlabeled spray bottles of [REDACTED] Cleaner were stored approximately 2 feet from flour tortilla processing lines.

**Reference:** 21 CFR 110.35(b)(2)

**Relevance:** Cleaning products should be stored in an area of the firm to avoid contamination of food products.

**Management's Response:** Ms. Toledo informed employees to remove cleaners from the flour tortilla processing area and all chemicals and cleaners will be stored in the storage area of the firm. This observation should be re-evaluated at the next inspection.

**Related sample:** Sample #252387

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**OBSERVATION 5**

Lack of backflow protection from piping systems that discharge waste water.

Specifically,

On 10/16/03, a water supply hose and its nozzle connected to a water pipe hanging overhead in the garage area were submerged in a vat of green soap and water.

**Reference:** 21 CFR 110.37(b)(5)

**Relevance:** Lack of backflow prevention may contribute to cross contamination of water used to manufacture flour tortillas.

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**Management's Response:** The water supply hose and nozzle were detached from the water pipes hanging overhead and the taken out of the vat of soap and water as soon as it was pointed out to the firm. Ms. Toledo stated she will inform employees not to let this happen again. This observation should be re-evaluated at the next inspection.

**Related samples and exhibits:** Exhibit #30 p.2, photographs.

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**OBSERVATION 6**

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

Specifically,

A. On 10/17/03, a broken pane of glass on the south wall of the mechanical storage room located in the northeast corner of the flour tortilla processing area was located approximately 6 feet from the [REDACTED] flour dough cutter / former on line # 1.

B. On 10/17/03, a broken pane of glass located along the north east wall in the flour tortilla production area was approximately 4 feet from the hopper containing raw flour tortilla dough and approximately 3 feet from the uncovered conveyor belt carrying raw flour tortilla dough on line # 1.

**Reference:** 21 CFR 110.35(a)

**Relevance:** Building and facility should be maintained to avoid the adulteration of food products with extraneous material.

**Management's Response:** Ms. Toledo stated that the two panes on glass were repaired. I (KS) observed the panes of glass repaired on 10/17/03.

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**OBSERVATION 7**

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

Specifically,

A. On 10/17/03, cooling box fans with build up of oil-like substance and debris on fan blades and the box portion of fan were located approximately 6 inches directly above conveyor carrying uncovered cooked hard shell tortillas in corn tortilla processing room.

B. On 10/18/03, cooling box fans with build up of dirt-like substance and debris on fan blades and box portion of fan were located approximately 2 feet directly above cooling conveyor carrying uncovered cooked flour tortillas to packaging area on lines 1, 2, and 3 in flour tortilla processing area.

**Reference:** 21 CFR 110.20(b)(6)

**Relevance:** Cooling fans should be maintained and kept clean to assure food quality and safety and to eliminate adulteration of food products.

**Management's Response:** Ms. Toledo stated the fans were removed and cleaned. I (KS) observed employees remove the fans and clean them in the garage area of the firm. This observation should be re-evaluated at the next inspection.

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**OBSERVATION 8**

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

Specifically,

On 10/18/03, the conveyor belt on line 5 in flour tortilla processing area that carries cooked flour tortillas from cooling racks to packaging area has 2 tears approximately 2 inches long located at each end of the metal seam.

**Reference:** 21 CFR 110.40(b)

**Relevance:** Equipment used in the manufacturing of food products should be maintained to assure food quality and safety and to eliminate adulteration of food products.

**Management's Response:** Ms. Toledo stated the conveyor belt will be repaired. This observation should be re-evaluated at the next inspection.

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**OBSERVATION 9**

Failure to take effective measures to protect finished food from contamination by refuse.

Specifically,

On 10/18/03, the floor drain located 2 feet from line 5 in the flour tortillas processing area was filled with trash such as plastic wrappers, empty [REDACTED] cups, raw tortilla dough, empty plastic cups and straws.

**Reference:** 21 CFR 110.80(b)(6)

**Relevance:** Building and facilities in the manufacturing area of food products should be maintained to assure food quality and safety and to eliminate adulteration of food products.

**Management's Response:** Ms. Toledo stated the drain had been cleaned out and covered. I (KS) observed employees cleaning the drain and cover the drain on 10/18/03.

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**OBSERVATION 10**

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

Specifically,

A. On 10/16/03, [REDACTED] cups of coffee and plastic bottled drinks were observed in the packaging area of the flour tortilla processing area.

B. On 10/18/03, a floor drain approximately 6 inches in diameter between line 1 and 2 in the flour tortilla processing area was uncovered. This drain was filled with water and was located one foot from the cooling conveyor of line #6.