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Summary

This establishment inspection was conducted under Compliance Program 7303.803 (Domestic Food Safety) and as part of the CHI-DO FY '09 work plan. The FACTS The FACTS # for this work is 1004074.

This inspection covered the manufacturing operations of flour tortillas, tostadas, masa and corn chips. The firm was manufacturing all of the above products at the time of the inspection. The inspection revealed continued and repeated significant GMP violations that were noted during the previous inspections. Repeat observations include;

- Holding raw ingredients in unsuitable containers
- Improper storage of maintenance and cleaning compounds
- Failure to properly maintain food contact surfaces
- A dripping pipe in the processing room
- Failure to store raw materials in a manner that protects against contamination.
- Failure to handle equipment, containers and utensils used to convey food in a manner that protects against contamination.
- Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact surfaces.

The previous inspection dated 11/7/07- 2/8/08, was conducted as a result of a food borne outbreaks at three middle schools in Racine, WI and another report of food borne illnesses at a school in Iowa.

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Individuals, who became ill, experienced a rapid onset of gastrointestinal associated symptoms including vomiting, diarrhea, nausea and abdominal cramping. The previous inspection was conducted by FDA on 11/08/07 and resulted in an 8 point FDA 483 (Objectionable Conditions);

- Use of equipment and utensils fails to preclude the adulteration of food with lubricants and contaminants
- Employees with open lesions not excluded from operations where there is reasonable possibility to contaminate food.
- Failure to have smoothly bonded or well maintained seams on Food contact surfaces to minimize the growth of microorganisms.
- Failure to store raw materials in a manner that protects against contamination.
- Plant not constructed to allow floors to be adequately cleaned.
- Effective measures not being taken to protect food against contamination from pests.
- Failure to handle equipment and utensils used to convey food in a manner that protects against contamination.
- Failure to operate fans and other air blowing equipment in a manner that minimizes the potential for contamination.

No avian, insect, or rodent activity was observed.

The firm is B/T registered. Photographs were taken.

No samples were collected. No refusals were encountered.

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: 12/4/2008, 12/18/2008, 1/8/2009

Days in the facility: 3

Participants: Joseph D. Cooper, Investigator
Rosemary A. Sexton, Acting Compliance Officer

HISTORY

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See the previous EIR for the firm's history of business.

INTERSTATE COMMERCE/JURISDICTION

Del Rey Tortilleria, Inc. owns thirteen [REDACTED] trucks that distribute to local customers and ships approximately [REDACTED] of all products manufactured at Del Rey Tortilleria, Inc. in interstate commerce. Del Rey (Grand Ave.) produces flour tortillas, fried chips, tostadas, and masa (sold in their retail store). The firm's does not manufacture corn tortillas at this location. Corn tortillas are manufactured at the 18th St. and Trumbull locations. Since the last inspection, the firm stated that they have ceased direct distribution to any schools.

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 four brand names; Mi Abuelita, La Chica and Del Rey. Since the last inspection, the firm now manufactures a brand name flour tortilla called Las Brazas for a firm in MI. (exhibits 33-36 for product labels).

On 12/4/2008, Ms. Dorothy De La Torre, General Manager informed Investigator Cooper and ACO, Rosemary Sexton that the firm's operations are unchanged since the last inspection. During this inspection the firm advised us that they had annual sales in excess of [REDACTED] dollars in 2008.

Pest control is performed by [REDACTED] on a weekly basis.

The firm employs about [REDACTED] full time employees and operates from 6AM-6PM, Monday through Friday, the office operates 9AM-6PM Monday through Friday and 8AM – 1PM on Saturday, and the retail store is open from 6AM-6PM seven days a week.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 12/4/08, Investigator Joseph D. Cooper and Acting Compliance Officer Rosemary Sexton displayed credentials and issued FDA482, Notice of Inspection to Mr. Barry A. Laub, Accountant for Del Rey Tortilleria. During a brief discussion Mr. Laub identified Ms. Dorothy De La Torre as the most responsible individual at the firm. An additional FDA482, Notice of Inspection to Ms. De La Torre who was identified as the most responsible individual of the firm by herself and Mr. Laub. On 12/18/08 and 1/8/09, additional FDA482, Notice of Inspections were issued to the firm.

Ms. Jeanette A. Toledo, the President and Owner of Del Rey Tortilleria. Ms. J. Toledo was identified by both Mr. Laub and Ms. De La Torre as the most responsible individual of the firm. Ms. J. Toledo was vacationing in Mexico at the time of the inspection. Ms, J. Toledo declined to be present for the issuance of the FDA483.

Ms. Dorothy L. De La Torre, Manager of Del Rey has knowledge of and is responsible for day-to-day operations, receiving/shipping, sanitation, and the hiring and firing of employees. Investigator

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Cooper and ACO Sexton observed Ms. De La Torre delegating tasks and supplying copies of requested documents for FDA. We (JDC/RAS) observed Ms. De La Torre demand corrections are instituted by production employees during this inspection. Ms. De La Torre stated that she hired the new sanitation company for the firm. Ms. De La Torre was present during the inspections and for the issuance of the FDA483. Ms. De La Torre answered questions and made copies of requested documents by FDA during this inspection. De La Torre stated that she does seek approval for all major decisions regarding Del Rey and does report directly to Ms. J. Toledo.

Mr. Barry A. Laub, Account for Del Rey has knowledge of and is responsible for the firm's finances. Mr. Laub also has knowledge of daily operations and FDA findings made during prior inspections. During this inspection, we (JDC/RAS) observed Mr. Laub making corrective actions and delegating tasks to production employees. Mr. Laub also has knowledge of manufacturing and sanitation procedures and operations. Mr. Laub answered questions and supplied copies of documentation to FDA during this inspection. Mr. Laub was present for the inspections and issuance of the FDA483. Mr. Laub reports to Ms. Dorothy De La Torre and will also consult with Ms. Janette Toledo on financial matters concerning Del Rey.

Manufacturing Operations

On 12/4/08, Ms. Dorothy De La Torre, General Manager informed Investigator Cooper and ACO, Rosemary Sexton the changes that have been made since the last inspection. Ms. De La Torre is now at the "Grand Ave." location General Manager only and Ms. M. Toledo is the General Manager for the 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.

Management advised us that they have implemented some additional safeguards for their operations such as having dedicated mixer operators and using pre-measured amounts of ingredients. When mixing the dough all dry ingredients are mixed together first, then liquids are added and mixed. Previously everything was mixed together. Management feels that this will keep the dough from clumping and to potentially have a more consistent tortilla.

On 12/4/2008, Ms. Dorothy De La Torre, General Manager informed Investigator Cooper and ACO, Rosemary Sexton that the firm's operations are unchanged since the last inspection with the exception of using a pre-made and measured pre-mix for the flour tortillas.

The firm is now using a flour tortilla pre-mix for all flour tortillas. The pre-mix is pre-made by [REDACTED] and packaged into a 50lb poly lined bag. The product consists of [REDACTED] and [REDACTED] and [REDACTED]. Employees of the firm have been trained by [REDACTED] in the use of the pre-mix in production. The procedure for mixing is in the production area of the facility. The [REDACTED] product does not have a label that bears the ingredients and Del Rey finished product labels do NOT

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bear a complete list of ingredients. Investigators communicated with the firm during the last inspection, that the finished product label should have a complete list of ingredients.

The firm has also contracted [REDACTED] to audit various programs at Del Rey, such as; customer support, budget and savings, employee work safety, cutting edge technology, and solving current issues at the facility. [REDACTED] monitors the firm sanitation procedures and the dispensing of all the sanitizers used in the plant (exhibit 11).

On 12/4/08, the manufacturing operations for tortillas were observed in the production area of the firm. The firm currently uses a pre-mix formula from an outside company for the manufacturing of flour tortillas. The procedure for manufacturing flour tortillas is posted in the firm's production area. The procedure is as follows;

1. [REDACTED] flour
2. [REDACTED] (premix ingredients documented in this report).
3. Mix [REDACTED] for [REDACTED]
4. [REDACTED] mix.
5. [REDACTED] while mixing [REDACTED]
6. Mix on [REDACTED] for [REDACTED] Dough should have smooth and soft texture and should be between [REDACTED] degrees F.
7. Proof for [REDACTED]

[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.

MANUFACTURING CODES

Del Rey tortillas have an expiration date of 30 days. The case and individual packages are stamped with a "USE THRU" date. The products they were produced on 12/04/08 were stamped with a "use thru" date of 01/04/09.

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COMPLAINTS

No complaints made since the last FDA inspection.

RECALL PROCEDURES

The firm does have a formal recall procedure in place.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

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 12/04/08 a heavy duty cleanser [REDACTED] being stored in the room where tostadas are cooked and prepared tamales dough is mixed.

On 01/08/09, [REDACTED] Cleaner was being stored and accessible for use in the tortilla production area approximately 15' from where flour tortillas were being manufactured.

Reference: 21 CFR 110.35(b) (2)

Supporting Evidence and Relevance: The firm is storing caustic chemicals in production areas of the firm where cleaning compounds should not be stored. Toxic cleaning compounds should be monitored and maintained in a manner to protect food products from contamination. The cleaning chemicals were accessible by all employees of the firm and maintained in the tostadas production area and the tortilla packaging area. Cleaning compounds should be maintained in a separate non-food, limited access area of the firm to protect food products from the possibility of contamination and/or adulteration.

There is no assurance that caustic sanitation agents are being used, stored, and maintained properly by employees of the firm. The firm's management stated that only two sanitation employees have access to the cleaning agents. On 12/4/08, FDA observed the firm re-using an empty caustic cleaning drum to hold paint, when the MSDS sheet instructs the user NOT to reuse the drum in any manner. On 1/8/09, the firm was storing a caustic cleaning agent open with direct access by any employee while tortillas were being manufactured. There is no assurance that ALL employees have not used various cleaning agents on various pieces of equipment in the facility without knowledge on how or when to the various sanitation products. (See exhibit 37 pg. 44)

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Discussion with Management: Management moved both chemicals to a locked area of the facility where only authorized employees can have access to it.

OBSERVATION 2

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

Specifically,

On 12/4/08, condensate like liquid was directly over stainless steel cooking tubs used to hold and store cooked and in process masa in the masa production area of the facility.

Reference: 21 CFR 110.20(b) (4)

Supporting Evidence and Relevance: Finished and in-process food products should be maintained in a manner to protect it from contamination. Condensate-like liquid dripping into and/or near in-process food products may contribute to cross-contamination (exhibit 37, page 45)

Discussion with Management:

Management stated that a "sleeve" or covering for the pipes will be purchased and added to the pipes. This corrective action was not completed by the close of the inspection on 1/8/09.

OBSERVATION 3

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

Specifically,

On 12/04/08, a medical inhaler was stored on the production table approximately 5' from the tortilla mixer in the production area of the firm.

On 12/04/08, a hose used in the production of flour tortillas was on the floor in a pool of standing water just prior to being used to clean and sanitize the flour tortilla mixer in the production area.

On 12/4/08, an open drum labeled "██████████ Cleaner" containing paint was stored in the firm's storage area directly next to the production area where the firm was manufacturing flour tortilla products. The drum was approximately 100' from tortilla production.

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On 12/4/08, 2 large stainless steel spatulas were being stored directly on the floor. One spatula was being used in prepared dough for tamales in the Tostada room. The second spatula was on the floor just outside the door from where the masa production.

On 12/04/08, a plastic scoop used in masa production was laying directly on the equipment used to grind cleaned corn into masa. A similar scoop was in the chip manufacturing room being stored on top of a piece of cardboard and under several floor tiles.

On 12/4/08, an empty [REDACTED] detergent bucket filled with hot water was used as an employee hand dip during masa production in the masa production room.

On 12/4/08, an empty [REDACTED] detergent bucket was used as a corn strainer for masa production in the masa production area of the firm.

On 12/4/08, the firm's waste separator was leaking onto the floor in the storage area. Employees were observed walking to and from different storage and production areas of the firm conducting different tasks throughout the facility including in the production area.

Reference: 21 CFR 110.80(b) (2)

Supporting Evidence and Relevance: A medical inhaler was observed on a food contact surface table used to mix products in the production area. A medical inhaler should be maintained in non-production area of the facility, the inhaler left in the production area where tortilla products may contribute to product adulteration. (See exhibit # 37 pg. 11)

An employee of the firm was observed cleaning a mixer in the tortilla room with a hose, laying the hose on the floor in a pool of water, cleaning the mixer again, and laying the hose in water. The hose was not maintained in a manner to protect food products from contamination. (See exhibit # 37, pg. 47)

The firm uses empty cleaning agent drums for food production and/or maintenance use in the firm. On 12/4/08, an empty drum that used to hold toxic cleaning agents was being used for paint and paint thinner used inside the plant. The paint filled drum was observed open in the firm's storage area approximately 50' from where tortilla products were being packaged. (See exhibit # 37, pgs. 25 & 26)

Stainless steel spatulas were observed directly touching the floor and were not cleaned and sanitized before being used in production of food products. Storing in-process equipment used in the manufacturing of tortilla or masa production directly on the floor may contribute to the possibility of adulteration or cross-contamination. (See exhibit # 37, pgs. 24 & 40)

All food contact surfaces including utensils should be properly maintained and/or stored to prevent potential cross contamination (exhibit 37, pgs. 33 & 37).

The firm uses empty cleaning agent drums for food production and/or maintenance in the firm. The equipment is not adequately maintained for its intended use. Sanitation containers should NOT be used for holding food or used as a food

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contact surface. Storing food in a non-food grade container may contribute to adulteration or contamination. (see exhibit 37, pgs. 5, 6, 7, & 8)

The firm was using a used, empty sanitizer bucket as a hand dip in the masa production area. An employee was dipping hands in warm water and then using exposed hands to manufacture masa. The employee handled different equipment in the masa production area and did not wash and sanitize hands after equipment handling or hand dipping. (see exhibit 37, pgs. 27 & 28)

The firm filters the solid waste from masa manufacturing in the storage area of the firm. On 12/4/08, the waste separator was in disrepair and leaking onto the floor in the storage area. Employees were observed moving from different areas of the firm including production. Walking through the wet area in the storage room where the leak was observed into different areas of the firm may contribute to product contamination. (See exhibit 37 pgs. 21, 22, & 23)

An employee of the firm was observed cleaning a mixer in the tortilla room with a hose, laying the hose on the floor in a pool of water, cleaning the mixer again, and laying the hose in water. The hose was not maintained in a manner to protect food products from contamination. This observation was made on the same production day that the waste separator was observed with a leak. Employees were observed walking to and from the storage area and production area of the firm. (See exhibit 37, pg. 47)

Walking through waste water and then into the production area where the hose was observed on the floor in a pool of water while being used in the sanitizing of the tortilla mixer, may contribute to the possibility of cross-contamination.

Discussion with Management:

The medical inhaler was immediately removed by the employee. The waste separator pipe was corrected and verified by FDA on 12/18/08.

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 12/04/08, three (3) dirty box fans used to cool, hot Tostadas was along the tostada cooling line. These fans had a build up of grease and dirt like substance on the blades of the fan and the cover of the fans and were blowing directly on to the tostadas.

THIS IS A REPEAT OBSERVATION

Reference: 21 CFR 110.20(b)(6)

Supporting Evidence and Relevance: Box fans used in the cooling of tostadas were covered in dirt-like residue. The box fan is not maintained in a manner to protect food products form cross contamination and was not manufactured for the intended use of cooling off food products.(see exhibit # 37 pg. 41)