

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

DISTRICT ADDRESS AND PHONE NUMBER

4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5200 Fax: (214) 253-5314
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/14/2010 - 10/26/2010*

FBI NUMBER

2000036428

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kenneth A. Sanguist, Jr., Owner

FIRM NAME

Sangar Fresh Cut Produce Co LLC

STREET ADDRESS

1500 S Zarzamora St
Unit 414

CITY STATE ZIP CODE COUNTRY

San Antonio, TX 78207-7210

TYPE ESTABLISHMENT INSPECTED

Fresh Produce Processor/Distributor

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

Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms.

Specifically,

- a.) on 10/18/10, two production employees were observed walking into the facility's main entrance from the outside wearing production attire such as a lab coat, hair net, and apron. Also, throughout the inspection, other production employees were observed wearing or carrying their production aprons and lab coats into the facility from the outside.
- b.) on 10/18/10, several production employees were observed changing into production attire, which included lab coats and aprons, inside the front loading dock area of the facility. During this changing process, employees were observed laying the lab coats and aprons on cardboard boxes stored on pallets inside the loading dock area.
- c.) on the evening of 10/19/10 and morning of 10/20/10, water hoses used for spraying down food processing equipment such as the (b) (4) and the (b) (4) Dicer were observed being stored directly on the floor of the main processing room with the tips of the hoses and attached nozzles contacting the floor. Immediately afterwards, these hoses were observed contacting food (lettuce), food processing equipment ((b) (4) Dicer), and food storage containers in the main processing room.
- d.) on the evening of 10/19/10 and morning of 10/20/10, as part of cleaning practices, an employee was observed using a large knife to pick out remnants of lettuce from the metal floor grate of the (b) (4) processing machine. The knife was then placed into a container of solution afterwards, which contained other knives used for processing.
- e.) on the evening of 10/19/10 and morning of 10/20/10, an employee was observed in the "Specialty Cuts" room washing down the floor area and his apron with a water hose spray nozzle, and then proceed to handle food products and food contact surfaces such as handling bell peppers on the processing table of the same room, without changing gloves or washing his gloved hands.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Rene R. Ramirez, Investigator
Emilio C. Escobar, Investigator
Kathleen Chmura Shaifer, Investigator
Erick G. Marchan, Investigator

DATE ISSUED

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f.) on the evening of 10/19/10 and morning of 10/20/10, a clipboard was observed placed directly on top of chopped cabbage and carrots located on a food processing table inside the main processing room.

g.) on the evening of 10/19/10 and morning of 10/20/10, a large plastic bag of carrots was observed being stored directly on the wet floor of the main processing room. Food debris was also observed on the floor in the immediate area.

h.) on the evening of 10/19/10 and morning of 10/20/10, two employees were observed dismantling the (b) (4) Dicer machine located inside the main processing room at different times and placing food-contact parts of the machine on the floor for cleaning. The employees then reassembled the parts onto the unit. The machine is used to dice processed produce items such as celery, potatoes, carrots, onions, and jalapenos.

i.) on 10/19/10, employees were observed placing plastic cups and trays containing processed produce items such as lettuce, tomatoes, and apples, directly on top of other uncovered cups and trays, which also contained product. The bottoms of the cups and trays were observed coming in direct contact with the product beneath.

j.) on 10/14/10, 10/19/10, and 10/20/10, knives used for cutting lettuce at the portable lettuce-cutting table located in the main processing room were observed to be stored in-between the cutting boards and the space underneath the cutting boards. On the evening of 10/19/10 and the morning of 10/20/10, an employee was observed to take one of these knives and begin to cut lettuce without any washing of the knife prior to cutting.

OBSERVATION 2

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials.

Specifically, on the evening of 10/19/10 and morning of 10/20/10, employees were observed hosing down and cleaning floors and equipment at the same time that food processing was occurring. Water from the hoses was observed splashing off of the floors and onto uncovered food products such as lettuce inside the (b) (4) basket and cabbage and carrots inside a large cardboard box, packaged products such as lettuce, and the cardboard cases used to case the packaged lettuce.

OBSERVATION 3

Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically,

a.) On 10/14/10, 10/15/10, 10/18/10, 10/19/10, and 10/20/10, employees were observed to not wash hands while engaged in food processing operations. Processed products included, but were not limited to, shredded lettuce, celery, carrots, cabbage, potatoes, tomatoes, and celery.

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	Emilio O. Escobar, Investigator <i>E. Escobar</i>	
	Kathleen Chmura Shaffer, Investigator <i>KCS</i>	
	Erick G. Marchan, Investigator <i>ERM</i>	

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Kenneth A. Sanquist, Jr., Owner		FEI NUMBER 2000036428
FIRM NAME Sangar Fresh Cut Produce Co LLC	STREET ADDRESS 1500 S Zarzamora St Unit 414	
CITY STATE ZIP CODE, COUNTRY San Antonio, TX 78207-7210	TYPE ESTABLISHMENT INSPECTED Fresh Produce Processor/Distributor	

b.) on 10/19/10, the employce handwash sink located inside the main processing room was observed to be obstructed by a pallet containing cases of raw food products (bulk romaine lettuce). The pallet did not allow employees full access to the handwash sink.

OBSERVATION 4

Personnel with adverse health conditions are not instructed to report to their supervisors.

Specifically, on the morning of 10/20/10, an employee was observed to have cut his finger while cleaning the (b) (4) Dicer located inside the main processing room. The employee then proceeded to walk to the "Specialty Cuts" room, where he rinsed the cut finger in the sink, wrapped a paper towel around it while still bleeding, grabbed a pair of gloves, and was about to work on other food-related tasks without reporting the incident to a supervisor. After we reported the incident to the designated supervisor, the employee was sent to get his finger bandaged and was re-assigned to assist with cleaning operations.

OBSERVATION 5

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

Specifically,

a.) throughout the current inspection on 10/14,15,18,19,20/10, constant food processing was observed to be occurring, with infrequent cleaning of food processing equipment and utensils taking place in-between product runs.

b.) there is no dedicated utensil-washing sink available to wash and sanitize utensils and equipment used during the processing of produce, such as knives and plastic containers. The utensils and equipment are currently being washed inside the "Specialty Cuts" room's employee handwash sink, or inside the first compartment of the three compartment sink in the same room used for soaking processed food products in (b) (4)

OBSERVATION 6

Failure to take apart equipment as necessary to ensure thorough cleaning.

Specifically, on the evening of 10/19/10 and morning of 10/20/10, during the observation of the equipment washing procedures, an employee was not completely disassembling the (b) (4) slicer located inside the main processing room for adequate cleaning and sanitizing. It was not until after the employee cut his finger while cleaning the slicer that a second employee completely disassembled the slicer and began to clean and sanitize the unit.

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OBSERVATION 7

Failure to take effective measures to protect finished food from contamination by raw materials and refuse .
Specifically,

- a.) raw produce products are received inside the front receiving/processing room in cardboard boxes, where they are then unloaded and transferred to the walk-in coolers via forklifts, or the "Specialty Cuts" room via the main processing room by dolly. These raw products enter these three food processing areas during food processing.
- b.) on 10/21/10, approximately 3 large boxes containing trash and produce waste were observed being stored in a rear unrefrigerated room of the additional storage location at unit # (b) (4). The refuse was observed to be emitting rancid odors. The warehouse was being used for storage of refrigerated storage of raw food products such as onions, cabbage, cauliflower, and jalapenos, as well as raw eggs and packaged spices.

OBSERVATION 8

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

- a) on 10/18/10, 2 pallets containing unopened cardboard cases of raw celery were observed being stored on the wet concrete floor directly below the cooling unit inside walk-in cooler # (b) (4). Condensation droplets were observed to be dripping onto the floor directly beside the product.
- b) on 10/18/10, numerous pallets containing unopened cardboard cases of raw celery and other raw produce items were observed being stored directly against the concrete and metal walls inside walk-in cooler # (b) (4). One case of celery located at the bottom rear of the pallet was observed to be crushed.

OBSERVATION 9

The design, construction, and use of equipment and utensils fails to preclude the adulteration of food with contaminants.
Specifically,

- a) on 10/19/10, employees were observed cutting bell peppers inside walk-in cooler # (b) (4) using plastic-lined wooden pallets as the cutting surface. The pallets were being supported by tall food containers.
- b) the two white lexan cutting boards located on the portable lettuce-cutting table located inside the main processing room

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were observed to be in disrepair and in need of cleaning. The boards, one of which contained a hole in it, contained score marks stained with dirt.

OBSERVATION 10

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

Specifically, on 10/18/10, one plastic basket and two plastic containers containing processed tomatoes, grapes, and other processed produce items were observed to be cracked along the corners and top edges. These containers are used to store the processed food products prior to packaging in their final containers.

OBSERVATION 11

Lack of adequate drainage of areas which may contribute to contamination of food by seepage, foot-borne filth, and providing a breeding place for pests.

Specifically,

a.) on the evening of 10/19/10 and morning of 10/20/10, accumulations of (b) (4) solution were observed on the floor of the main processing room, at the end of the (b) (4) unit. The liquid was pooling under and around the perforated metal basket filled with shredded lettuce, which is placed into the (b) (4) after it is filled, then packaged.

b.) on 10/14/10 and 10/18/10, water from an unknown source was observed to be pooling on the floor of walk-in cooler # (b) (4) near the center floor drains. This is a high employee, pallet jack, dolly, and forklift traffic area of the cooler, which is used for storage of raw and processed produce items.

OBSERVATION 12

Failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents the food from becoming adulterated.

Specifically, on 10/21/10, we observed approximately forty (40) cases of shell eggs, 15 dozen/case, located inside the walk-in cooler located at the firm's additional warehouse storage location, located in unit # (b) (4) being stored at a temperature of 55° F. The labeling for the shells eggs reads in part, "**** (b) (4) EGGS LOOSE GRADE AA EX-LARGE****". Other boxed food items such as potatoes, onions, cabbage, cauliflower, spices, and eggs were also being stored inside this walk-in cooler, as well as uncovered plastic containers containing tomatoes, bell peppers, cucumbers, jalapenos, and lemons.

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OBSERVATION 13

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

Specifically,

- a.) an approximately 8 ft. by 8 ft. section of floor located inside the front receiving/processing room, near the door which leads to the front loading area, was observed to contain various cracks. Debris could be seen in the larger cracks, which were approximately 1/2" - 1" wide, and approximately 6 ft. long.
- b.) the floor area located inside the main processing room, at the end of the "(b) (4)" unit, facing the wall, was observed to be pitted and in disrepair.
- c.) the floor of walk-in cooler # (b) (4) was observed to be uneven and in disrepair.
- d.) the section of wall located behind the (b) (4) Dicer inside the main processing room, below and beside the dicer blade storage area, was observed to be rusted. Produce items such as celery, carrots, potatoes, onions, and jalapenos are diced on this unit on a regular basis.
- e.) an electrical plate was observed to be loose and shifted at the rear wall of the "Specialty Cuts" room, directly behind a processing table. This resulted in there being a small opening in the wall. Produce items are processed on this table on a regular basis.

OBSERVATION 14

Plumbing constitutes a source of contamination to food, water supplies, equipment, and utensils.

Specifically, the water hose faucet located inside the "Specialty Cuts" room, behind the (b) (4) was observed to not have a backflow prevention device installed. A water hose was attached to the faucet at the time, which was being used to hose down the floors near the (b) (4)

OBSERVATION 15

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

Specifically, on 10/18/10, a roof drain pipe leading from the roof of the facility down into the front entrance door area of the facility was observed to be leaking water from an elbow bend, as well as from the point where the pipe enters the floor. The leaking water was observed to form a puddle on the floor at the inside front of the main entrance of the facility. Employees

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were observed walking through this wet area to enter and leave the facility.

OBSERVATION 16

Lack of a sanitary towel service or suitable hand drying devices.

Specifically, on 10/14,15,18,19,20/10, the employee handwash sink located inside the main processing room was observed to be without paper towels or any other type of hand-drying devices.

OBSERVATION 17

Hand-washing facilities lack running water of a suitable temperature.

Specifically, the employee handwash sink located inside the main processing room does not have cold water available for employees to wash hands. The cold water knob was turned, and no water came out. Also, hot water was only available after it took approximately one minute to reach the faucet.

OBSERVATION 18

Failure to provide adequate screening or other protection against pests.

Specifically,

a.) an approximately 1/2" gap was observed along the top of receiving door # (b) (4) located inside the front receiving/processing room. This door leads to the outside front of the facility.

b.) an approximately 1/2" gap was observed along the bottom of the west rolling door located inside the "Specialty Cuts" room. This door leads to the outside rear of the facility.

OBSERVATION 19

Appropriate training in food handling techniques and food protection principles has not been provided to food handlers

Specifically, according to the processing manager, employees receive GMP training when they are first hired, which includes training on personal hygiene and illness. MSDS (Material Safety Data Sheets) training was also provided to employees by a (b) (4) representative for the chemicals used by the plant, but has since been discontinued according to the processing manager. There is no other documentation which demonstrates that employees have received training in food handling techniques and food protection principles.

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*** DATES OF INSPECTION:**

10/14/2010(Thu), 10/15/2010(Fri), 10/18/2010(Mon), 10/19/2010(Tue), 10/20/2010(Wed), 10/21/2010(Thu), 10/26/2010(Tue)

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