

FINAL
AUDIT SUSPENSE DATE: 01/20/2016

SANITATION AUDIT REPORT

1. VC#/NAME/ADDRESS/PHONE/ESTAB #/EMAIL: VC# 48-0261 Nicho Produce Co., Inc. 925 N 10th Avenue Edinburg, Texas 78541-3129 956-383-5633 Fax 956-380-3281 www.nichoproduce.com	2. UNIT/IRC/ADDRESS/PHONE/AUDITOR/EMAIL: Public Health Command District-Fort Hood ATTN: MCHB-RS-H Building 4297, 80th & Engineer Drive Fort Hood, TX 76544-4752 Phone: (254) 287-7606 FAX: (254) 287-4676 AUDITOR: CPT Drew Price EMAIL: drew.m.price.mil@mail.mil Phone: 361-961-3951 Fax: 361-961-2027
3. NAME & TITLE OF THE ESTABLISHMENT'S POC: Paul Ludden Paul@nichoproduce.com	4. ESTABLISHMENT'S OWNER: Thomas Villarreal
5. DATE OF AUDIT: 22 Jan 2016	6. TYPE OF AUDIT: Routine
7. PRODUCT(S) FOR DIRECTORY LISTING: fruits & vegetables (pre-cut pre-packaged fresh RTE)	8. OTHER PRODUCT(S) PRODUCED OR STORED: Pico de Gallo
9. SAMPLING IS REQUIRED IN CONJUNCTION WITH THIS AUDIT. No	
10. AUDIT RATING: Acceptable	11. DELIVERY STATUS:
12. APPENDICES USED AND ENCLOSURES: Appendix A (General), Appendix P (Fresh-Cut Fruits and Vegetables), and Appendix Y (Food Defense)	
13. OTHER INSPECTION AGENCIES/AUDIT ORGANIZATIONS: Texas Department of Health, last visit 18 Sep 14, no deficiencies. Primus GFS, Global Food Safety Initiative, inspected 20 Nov 15, 94%, valid through 15 Dec 16.	
14. REMARKS: a. CHANGES TO DIRECTORY LISTING: NONE. b. FINDINGS: One observation. c. FREQUENCY: Semi-Annual. d. CURRENT SALES/CONTRACT INFORMATION: Product is provided through Hardie's and Third Coast (GH Foods). Products bearing the H.E.B. company name are not sold to the military. e. AUDIT TEAM MEMBERS: CPT Drew Price f. PHCD/PHCR SPECIFIC COMMENTS: Documents reviewed included: Backflow devices, pest control, HACCP plan, SSOPs, laboratory tests, GMPs, employee training, food defense program, traceability. Conducted walk-through inspection throughout the facility interior and the grounds.	
15. BRAND NAMES AND POINT OF ORIGIN CODE(S)*: BRAND: Nicho Produce; A Cut Above. CODE: All shipping cases are labeled "Nicho Produce." Labels are two by four inches in size and contain the following data: Bar Code which contains the Purchase Order Number and the line number of the product received; Item Description in bold capital letters; Pack Size; Country of Origin; Received Date; Voice Pick code; "Dist. By Nicho Produce Co., Inc. Edinburg, TX"; Inventory Code. LANDMARK: Labels are affixed to all boxes as the product is received.	
EU PLANT CODE*: None * If code is not applicable or not available, enter None.	
16. COMPANY ALIAS: None	
CURRENT FREQUENCY: 6 17. REQUEST FOR REDUCTION: NA	

FINDINGS

ESTABLISHMENT: VC#: 48-0261 - Nicho Produce Co., Inc. 48-0261

AUDIT DATE: 22 Jan 2016

SCORE: O SUBPART PARA: B4

REQUIREMENT: Adequate protection against glass breakage over exposed foods, processing equipment and containers is provided.

(21 CFR 110.20(b)(5), (6) and (7)).

DESCRIPTION: The light fixture in the egg room is cracked, and the bulbs inside the fixture are not shatter-resistant.

AUDITOR'S TYPED NAME & SIGNATURE	DISTRICT COMMANDER'S TYPED NAME & SIGNATURE
DIGITALLY SIGNED BY: CPT Drew Price ON 01/25/2016 12:29:37 PM	DIGITALLY SIGNED BY: Brian Sullivan ON 01/28/2016 09:55:50 AM

REGION COMMANDER'S TYPED NAME & SIGNATURE

DIGITALLY SIGNED BY: LTC Julio Montero ON 02/01/2016 12:39:49 PM

* DEFECT: C-Critical, M-Major, O-Observation

METHODOLOGY**ESTABLISHMENT:** VC#: 48-0261 - Nicho Produce Co., Inc. 48-0261**PERSONNEL/ADMINISTRATION:**

Tomas (Tommy) Villarreal, Treasurer, email: tommy@nichoproduce.com or tvillar487@aol.com, phone: (956) 239-5633

Paul T. Ludden, Production Manager, email: paul@nichoproduce.com, (956) 383-5633

Tammy Garza, Food Safety Specialist, email: hacpp@nichoproduce.com, (956) 383-5633

GENERAL:**OPERATING HOURS:** Administration hours are Monday through Friday, 0700 to 1700 and Saturday 0700 to 1200. Closed on Sunday. Production Monday through Saturday 0700 to 1700.**NUMBER OF EMPLOYEES:** There are 58 full-time employees (4 management, 6 administration, 16 production, 10 processing, 2 sanitation/maintenance, and 20 drivers). There are no part-time employees. Temporary employees are only used for the administrative office.**CODE DATING/ PRODUCT SIZES:** "Nicho Produce" and "A Cut Above" (used only for processed products). Labels are two by four inches in size and contain the following data: Bar Code which contains the Purchase Order Number and the line number of the product received; Item Description in bold capital letters; Pack Size; Country of Origin; Received Date; Voice Pick code; "Dist. By Nicho Produce Co., Inc. Edinburg, TX"; Inventory Code. Package sizes are 2.5 lb. bag, 5 lb. bag, and 5 lb. trays.**RECALL/ TRACEABILITY:** When a product is purchased by a member of Nicho Produce, a Purchase Order is generated in Edible Software. When the product arrives at the warehouse, it is inspected for quality, temperature and the count is verified. Labels are then generated and affixed to all boxes. The product is then received into the system and the Bill of Lading is taken to the office to be checked and filed. A recalled product is identified by its Shipping Product Code and Edible Software is used to identify its recipients. Customers are identified and contacted via phone, fax, and email. Local FDA, USDA, Texas Health Department and Legal Counsel are all contacted as well. The recall team consists of Tommy Villarreal, Paul Ludden, Joe Maldonado, Manuel Rivera, Robert Rutiaga, Eii Reyes and Lorenzo Esquivel. The last mock recall performed was 20 Oct 15 on red seedless grapes. The time taken to discover where the affected product might have been sent was 12 minutes, and the mock recall was completed in 15 minutes.**SHELF LIFE:** Recommended shelf-life on processed products is a time span of 7 to 10 days depending on product. The recommended consumer storage temperature to achieve shelf-life is 35°F to 42°F. Shelf-life studies are derived from in-house studies.**FACILITIES:**

The facility is located in Edinburg, Texas, at the north end of the residential area and the down town district. It is at the corner of West Chevez Street and North 10th Ave. The original facility was built in 1955. Various additions took place in the 1980's and 90's. Total square footage is 26,219. The building is constructed primarily of cinder block and steel on a slab foundation. The roof is made of metal with appropriate roofing covering. Interior walls in production and storage areas are made of nonporous fiberglass reinforced plastic and nonporous vinyl. The facility consists of 1 Processing Room, 1 Shipping and Receiving area, and 17 Storage areas for different products. Cooler 10 and the rear west dock has been enclosed.

MAJOR EQUIPMENT:

Equipment used are the cutting machine, open flume wash, spin dryer, packing table and bag sealing machine. The new metal detector has been calibrated and deployed for use in production.

FOOD PROTECTION AND SANITATION:**HACCP/ FOOD SAFETY PROCEDURES:**

The company has a written HACCP plan with two CCPs (sanitizer concentration level and metal detection). The Owner, Production Manager, Compliance Officer, and Food Safety Specialist comprise the HACCP team. The Production Manager Compliance Officer and Safety Manager are currently HACCP certified. Records of the concentrations, cleaning and deep cleaning visits were reviewed at the time of audit. The HACCP plan was last reviewed in March 2015.

CCP 1- Processing and Wash.**Critical Limit:** Produce wash in Chlorine Dioxide IAW 21 CFR 173-300, which requires "...not to exceed 3 ppm residual chlorine dioxide... followed by a potable water rinse..." The wash system is computer controlled and is provided, maintained, and monitored by AquaPulse Systems. The system monitors both the ppm and the Oxygen Reduction Potential (ORP).**Corrective Action:** If correct concentration is not met, an alarm sounds and text messages are sent to the Owner, Production Manager, and Safety Manager. All data is continuously recorded in 5 minutes increments and is stored digitally. When alarm sounds, production stops until cause and corrective action with equipment is taken. Product is then either sent back through the wash cycle or discarded.**CCP 2- Metal Detection.****Critical Limit:** The metal detector is verified at each change in product and every 60 minutes for 2.5 non-ferrous, 3.8 ferrous, and 4.0 stainless steel.**Corrective Action:** All finished product passes through the metal detector before being case packed. If metal is detected, the conveyor

belt stops and an audible alarm is sounded. The production workers must then notify Quality Assurance in order to have the metal detector reset and the conveyor restarted via key. Any product that triggers the alarm is discarded. Results are logged. Logs reviewed.

CP 1 - Production room and equipment cleaning. Critical Limit: Cleaning and sanitizing is done twice per day (before start-up, between products and after production). Additionally, a third party (Cintas) performs "Deep Clean" services monthly.
Corrective Action: Sanitation records are maintained and reviewed for compliance.

RAW MATERIALS:

Water is provided by the City Of Edinburg. Source water potability records are provided by the city annually. Raw products are supplied by various wholesaler/shipper/packers and brokers and consist of lettuce, carrots, celery, green cabbage, red cabbage, bell pepper, onions, romaine, broccoli, cauliflower, bananas, apples, and citrus. Raw product is transported by independent third party carriers whose temperatures and truck numbers are logged. Product is inspected upon arrival, labeled with a UPC, and distributed to the appropriate area within the facility for storage. Receipt inspection includes culling of any spoiled (rotten or molded) product to prevent the spread to good product which maximizes longevity of products.

ALLERGENS:

This facility processes peanuts, eggs, wheat, and tree nuts. All allergens are kept in designated areas with warning signage of allergen potential. Separate cleaning materials and equipment are used in these areas. Employees are trained in allergen handling, including washing their hands thoroughly between handling of allergens and non-allergens.

LABORATORY TESTING:

The city of Edinburg provides water to Nicho Produce Co. Potability testing on source water was performed by Texas Plants and Soil Lab on 23 Nov 15 and resulted in Fecal Coliform none detected, E. coli none detected, and Total Coliform none detected. The facility uses Quanta/PSL Analytical laboratory to analyze water and ice. IEH-Quanta/PSL Analytical provides environmental, water, and finished product testing. The water is tested weekly and the ice is tested monthly. The ice and water are tested for Generic E. coli, Coliforms, and Listeria and was last performed 13 Jan 16 and found less than 1 CFU/100 mL for Coliform and E. coli. This laboratory meets ISO 17025 requirements IAW DODVSA Policy B-002. Environmental swabs are taken from rotated surfaces are swabbed and a random finished product is tested weekly for Listeria Species (spp). If results show positive for Listeria spp, the subject areas are re-cleaned and retested for Listeria spp. If the second test returns positive results for any food contact surfaces, product is placed on hold status and the area is re-cleaned and samples are drawn for Listeria monocytogenes testing. If results come back as negative, no further action is needed. If results come back positive, the product is destroyed and production is suspended until the root cause and corrective actions can be taken. Once production resumes, all products will be placed in hold status and tested for Listeria monocytogenes. All products will continue to be held and tested until both products and contact surfaces show negative results for Listeria monocytogenes. Non-food contact surfaces, meaning the floors and drains, are re-cleaned and tested until correct results are achieved. The company has a written environmental testing policy that is in accordance with 9 CFR 430.4 and FDA Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance, 2008. No in-house testing is done. Nicho Produce GFSI audit included 140 various water, product, and environmental lab tests.

EMPLOYEE HYGIENE AND TRAINING:

Employees do not receive a medical examination prior to employment. Employee training is provided approximately quarterly by Paul Ludden or Tammy Garza on GMPs, personal hygiene, sanitation, HACCP, visitor handling, food defense and shipping procedures. The facility has also implemented weekly safety meetings. All training is documented and employees are tested quarterly after passing all the exams during their initial training. Management utilizes a Food Safety training DVD and conducts food safety testing of employees using the JJ Keller Food Safety Handbook, 3rd Edition, and is provided in English and Spanish. Employees are required to achieve 90% or better to pass. If requirement is not met, employees are restricted from work, retrained and retested until criteria are met. Training logs and sign in sheets were reviewed. All signage is posted in English and Spanish.

PLANT SANITATION:

There is a Master Sanitation Schedule in place. The Sanitation Team (aka QA Team) Leader is Paul Ludden with Lorenzo Esquivel, Tammy Garza, and Lupe Ocanas serving as alternates. Sanitation is performed by company employees both before production start-up and after production using chlorine dioxide, "not to exceed 3 ppm" IAW 21 CFR 173.300, Zep Amine Z (Quat) at 200 to 400 ppm, ZEP FS Amine A at 200 to 400ppm, and Zep Provisions at 200 to 400 ppm. Records were reviewed. Sani Step ammonia chloride crystals, a time release floor sanitizer, is sprinkled on the walkway from the front offices through the storage area that leads to the outside offices and continues onto the outside loading dock and staff break room. Ster Bac Quat foam is used as a foot bath and is sprayed every 7 minutes for 10 seconds. The foam foot bath is sprayed at the entrance to the production room at 400 to 800ppm and the base of the spinner in the production room in a direction to allow the foam to coat the legs of the spinner and the drain next to it at 800 to 1000ppm. Listex P100 and Zep Biofilm Drain Purge are used on the drains in the production room. A third party (Cintas) performs "Deep Clean" services monthly using KaiBosh (MAQuat 64 PD) at 703 ppm in accordance with manufacturer's instructions. Chemical suppliers used are Zep Manufacturing and JAEL Janitorial. Chemicals used are Quaternary Ammonium, Chlorine Dioxide, and Ammonia. MSDSs are provided by chemical suppliers and are kept on file. New MSDSs are updated as needed by suppliers. Master sanitation tasks are performed quarterly or sooner if needed. Chemicals are stored in a secure area under lock and key with access limited to Paul Ludden and the office manager. Chemical concentration levels are used per the manufacturer's instructions and are verified by test strip or titration. A dry steam cleaner reaching 240°F at 180 psi is used for equipment and facility locations deemed necessary. Pre-operational checklists are utilized daily IAW SSOPs. Record logs of sanitizer levels, cleaning, and maintenance were reviewed. Chemicals are labeled and divided into either "Kitchen" or "Warehouse" use and stored appropriately. The facility also uses an ozone generator after sanitizing the processing room. The ozone generator is placed in the processing room at night for eight hours and requires aeration before entry for processing the next morning. Buckets, shovels, and other plastic wear are color coded with only blue being permitted in the production area and red for non-production areas. Chemicals used in the mechanic area (separate bldg) are diesel, oil, lubricants, gas refrigerant, and ethylene gas liquid.

PEST CONTROL:

Pest Control is provided by Orkin twice per month by technician Mauro Silva. His license expires 31 Jan 16. Target pests include rodents, crawling and flying insects. Last visit was 21 Jan 16. Copies of the company license and technician license are kept on file. Orkin provides service to outside bait stations (bait block inside), perimeter spray, and inside tunnel glue traps. Service logs and

licensing were reviewed. The pest control diagram is attached. No pest control supplies are stored at the facility.

WASTE DISPOSAL:

Waste management is provided by municipal services weekly or more frequent if needed. Daily visual inspection is conducted of the refuse area to determine this need. Product trim is removed from premises daily by local farmers and used for pig feed. The farmers provide their own containers which are not allowed in the building and they sign in and out at each visit. Nicho Produce workers bring the product trim to the outside in a bucket that is rinsed with chlorine dioxide provided by an outside hose before the bucket can return to inside the facility.

PROCESS:

GENERAL

Processing of all fruits and vegetables is very similar, with only small step differences for: (1) Leafy Vegetables, and (2) Fruits and Non-Leafy Vegetables. All fruits and vegetables are received raw fresh in bulk through the receiving docks in the front of the building. All produce is inspected and culled to prevent spread of deteriorative conditions and is then moved to storage. Storage temperatures and humidity vary by type of product but follow the USDA recommended storage guidelines. Temperatures are monitored and logged, records reviewed. After processing, as indicated below, all finished products are sent through the metal detector (CCP 2) and then packed in cardboard boxes with Nicho Produce labels, palletized, and stored pending shipment. The only additive is an anti-browning agent used on peeled and diced potatoes and apples.

LEAFY VEGETABLES

Leafy vegetables are purchased and received with a pre-wash. After removing from the storage cooler, leafy products are manually dumped onto a large stainless steel processing table where they are sorted and prepared by employees manually. Preparation involves removing the stems and wrapper leaves. The product is then loaded into the shredder that feeds directly into the flume wash. The flume wash (CCP 1) contains chlorine dioxide that is automatically dispensed by a Pulse Instruments mixer maintained and monitored by AquaPulse Systems. Chlorine dioxide is used IAW 21 CFR 173.300. The chlorine dioxide concentration is maintained at no more than 3 ppm and an ORP of 550 to 800, and is verified by indicator paper (ClO₂ specific), and titration. Proper ORP and ppm are verified before production begins. During the wash, product appears to be adequately submerged and agitated (approximately 15 to 30 seconds) to ensure full contact with vegetable surfaces. The flume wash is a one-step wash with overflow of water and fresh new chlorine dioxide water intake, in addition to the recirculated wash water. Wash water is replaced after product changes, every couple of hours of work, or when visually identified as needing change. ORP readings that do not fall within the acceptable range of 550 to 800 triggers the alarm as stated above under "Food Protection and Sanitation." At the end of the flume, product is carried up by conveyor belt through a potable spray rinse and through the "shaker" before it is dropped into the spin dry canister. Spin dried product is then dumped onto a holding stainless steel table with the bag filling chute in one front corner. Product is manually culled and sent through the chute into the packaging (5 lb. bag) which is sitting on the scale. Once the bag is properly filled, it is vacuum packaged and heat sealed. Before being placed into shipping case the bags are sent through metal detection (CCP 2) and then the UPC label is placed on the bag.

FRUITS AND NON-LEAFY VEGETABLES

Fruits and non-leafy vegetables are manually washed in the stainless steel sink (same chlorine dioxide mixture system as flume) or large white food designated barrels (CCP 1). All faucets in the processing room receive the same wash water as the partially covered flume wash which contains the computer mixed and monitored chlorine dioxide. Once the outer skin is washed, fruits are either cut to portion size by hand with knives or by use of several lever action corers, peelers, and cutters that are sanitarily maintained as described above with chlorine dioxide and/or quat sanitizers. Products are then bagged, weighed, packaged, and labeled as described above using the same coding system. Some fruits are placed into trays that have a snap lid secured with a tape strip placed over the top.

STORAGE:

RAW PRODUCTS

Raw products are inspected and culled in the receiving area to prevent the spread of deteriorative conditions. After receipt, product is moved into storage areas. Each of the 17 storage areas has the temperature and humidity controlled for specific commodities stored therein. Storage coolers are equipped with ultraviolet sanitizing air scrubbers to eliminate/prevent airborne microorganisms from being circulated. Catalytic generators are used to distribute ethylene for ripening and produce is subsequently moved to the amplified air circulation (windy) room to slow ripening back down. Commodities that have ice are stored in what is called the "wet room" because of the ice melt. Wet room pallets have been changed to all plastic. No wooden pallets are used in the wet-room storage. Allergens are stored in specific areas and are properly marked.

FINISHED PRODUCTS

After packing, product is moved to designated storage area for finished products only, held and maintained at 38°F to 40°F on plastic pallets until shipped. Humidity is not controlled but typically varies from 30% to 50%.

DISTRIBUTION:

Finished product is staged, loaded, and transported by 28 company owned trucks to customers. Trucks are swept out and inspected daily by supervisor and washed weekly by the chlorine dioxide hose provided regardless of condition. Trucks found to not meet standards are washed and rinsed immediately IAW SOPs. Trucks are parked in a fenced in and camera monitored area with a locking gate and also in the front of the building where there are cameras. Truck cleaning logs are maintained and reviewed at the time of the audit.

FOOD DEFENSE:

The Food Defense program was discussed and reinforced with facility management IAW MIL-STD 3006C, Appendix A, Table VII, Subpart J, Appendix Y, and the Food Defense Questionnaire. A copy of the food defense questionnaire and Appendix Y were provided to the company representative and discussed. During the pre-audit and audit walk-through, the six components of the food defense program were discussed with management. The status of each component is as follows:

Food Defense Policy/program in place (MIL-STD-3006C Table Y-I): Satisfactory. Last Reviewed: 08 Jun 15

Outside Grounds and Roof Areas (MIL-STD-3006C Table Y-II): Satisfactory.

Employee and Visitor Programs (MIL-STD-3006C Table Y-III): Satisfactory.

Material Receiving (MIL-STD-3006C Table Y-IV): Satisfactory.

Facility Operations (MIL-STD-3006C Table Y-V): Satisfactory.

Finished Goods Storage/Shipping (MIL-STD-3006C Table Y-VI): Satisfactory.

PRODUCT FLOW			
ESTABLISHMENT: VC#: 48-0261 - Nicho Produce Co., Inc. 48-0261			AUDIT DATE: 22 Jan 2016
DESCRIPTION: (please use the attachment section below for graphical representation)			
ATTACHMENTS			
TYPE	FILE NAME	SIZE(KB)	LAST REV
Backflow Certification	Backflow Certificate.pdf	192905	2/1/2016 1:00:00 AM
Business Card	Nicho Business Card.pdf	40337	2/1/2016 1:00:00 AM
Flow Chart	Nicho Produce Flow Chart Jul 14.pdf	264912	2/1/2016 1:00:00 AM
HACCP	Nicho Produce HACCP Risk Matrix.pdf	102709	2/1/2016 1:00:00 AM
Lab Results - Vendor	Lab Results.pdf	100336	2/1/2016 1:00:00 AM
Other	Mock Recall.pdf	79528	2/1/2016 1:00:00 AM
Other	Primus Certificate.pdf	202925	2/1/2016 1:00:00 AM
Plant Diagram	ATT4PRBO.pdf	264224	2/1/2016 1:00:00 AM
Product Code Sheet	Nicho Produce Label example JAN14.pdf	215142	2/1/2016 1:00:00 AM
Water Potability	Water Potability.pdf	172849	2/1/2016 1:00:00 AM

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