

Food Safety, Quality and Food Defense Audit

Company Information	Audit Information
<p>Facility: T3532 - CEBRO FROZEN FOODS</p> <p>Address: 2100 ORESTIMBA ROAD NEWMAN, CALIFORNIA UNITED STATES , 95360</p> <p>Contact: MR. RICK FALKENBURG</p> <p>Title:</p> <p>Phone: 209-862-4390-20</p> <p>Fax: 209-862-4395</p> <p>Email: falkenberg@sbcglobal.net</p>	<p>Audit#-Visit#: 84917 - 62636</p> <p>Audit Type: BASE1-Food Safety, Quality and Food Defense Audit</p> <p>Template Version: 1.3</p> <p>Audit Category: REGULAR</p> <p>Auditor: BILLY J. LOW</p> <p>Auditor Phone: 559-891-8477</p> <p>Audit Start Time: 02-MAY-2007 08:00:00 AM</p> <p>Audit End Time: 02-MAY-2007 06:00:00 PM</p>
: Rick Falkenburg	

Facility And Operating Profile

No	Question/Notes	Answer
1	<p>Facility and Operations Description:</p> <p>The plant is located in the country as part of a 400 acre farming operation. The farm and plant are privately owned. The existing plant occupies 25,000 sq. ft. General operations are from May to October when fresh vegetables are in season. About 60 employees are used on 2 shifts. The plant works from 5 to 7 days a week depending on harvest and orders.</p>	See Note
2	<p>Regulatory Inspection Type:</p> <p>The plant is under FDA jurisdiction with California State supervision. USDA grade specifications are used for some products.</p>	Other (Explain in Note)
3	<p>Products made at this facility:</p> <p>IQF vegetables and IQF reduced moisture vegetables are produced.</p>	See Note
4	<p>Products made for the client:</p> <p>Varies by client</p>	See Note
5	<p>Did the facility provide proof of Homeland Security registration?</p> <p>Registration letter</p>	Yes
6	<p>What is the average lot size in pounds (coded and identifiable)?</p>	10,000
7	<p>What is the most probable cause of accidental product contamination?</p>	Microbiological contamination
8	<p>The following departments and individuals participated in the audit process:</p> <p>Skip Cerutti, owner; Richard Brown, General Manager; Bertha Cerutti, QA Manager and Dan Wilkinson, VPm sales for White Oak</p>	See Note
Section Notes:		

Score Summary By Section	
Section Name	Section Score
Section A - Administration and Regulatory Compliance	95.00%
Section B - HACCP Management	88.00%
Section C - Facilities and Equipment	92.00%
Section D - Sanitation, Housekeeping and Hygiene	95.00%
Section E - Rodent and Pest Control Management	95.00%
Section F - Receiving and Inventory Control	95.00%
Section G - Process and Product Evaluation	95.00%
Section H - Packaging and Labeling	95.00%
Section I - Storage and Shipping	90.00%
Section J - Analytical Records and Laboratory Support	95.00%
Section K - Food Defense	90.00%
Food Safety, Quality and Food Defense Audit Average Score:	93.18%

Category Scoring Guide

95-100 = Meet or Exceeds Audit Expectations (Acceptable - Excellent)

85-94 = Opportunity For Improvement (Minor)

75-84 = Needs Improvement (Major)

<75 = Immediate Improvement Needed (Critical)

Automatic Audit Failure

Direct Product Contamination.

Adulterated or Misbranded product .

Facility was not operating in sanitary condition.

HACCP System Failure - Plant was producing product that did not meet critical limit(s); appropriate corrective action was not taken; or no HACCP Plan.

Critical Deficiency in any one category.

Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
1	Food Safety, Quality and Food Defense Organization and Responsibilities This is a very small company and the management team has responsibilities occasionally cross lines. The QA Manager reports to the owner but works closely with the GM. Quality has a "release and hold" program.	Acceptable
2	Food Safety, Quality and Food Defense Policies and Procedures Detailed policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product are well organized and available. Testing procedures, sampling programs and accept/reject criteria are defined.	Acceptable
3	Specific Training Goals and Programs for Management and Operating Personnel Management attends outside courses and has a contract technical person on staff that furnishes training and keeps the team current on food safety and quality issues. All employees receive orientation training as well as refresher training yearly.	Acceptable

Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
4	Recall Plan and Procedures A documented plant specific Recall Plan is available that clearly defines a recall coordinator, identifies the recall team members and describes their responsibilities. Office and after-hour telephone contact numbers of all recall team members is available for all team members. The Recall Plan is reassessed and signed at least annually.	Acceptable
5	Regulatory Compliance FDA visited the plant on 8/28/2006. A form 482 was issued to the plant. No deviations were noted.	Acceptable
6	Document and Records Management A document control policy is in place that identifies current revision status, specifies time limit for holding of files and indicates proper disposition of outdated documents and records. Records are indexed and easily retrievable.	Acceptable
7	Change Management The management staff is 4 key members. Meetings are held weekly and changes are discussed and, as necessary, implemented. Changes are communicated to the persons who need to know by Quality or the GM prior to start.	Acceptable
8	Documentation to Track Effectiveness of Policies Third party audits, customer audits and regulatory reviews are sources used to track the effectiveness of policies. Policies and issues are discussed at the weekly management meeting, too.	Acceptable
9	Management Awareness and Commitment to Food Safety, Quality & Food Defense Management is committed to food safety and quality and actively supports it through training programs, auditing for compliance to policies and provision of corrective actions.	Acceptable
10	Crisis and Natural Disaster Management A crisis management plan is in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access. Team members have received specific training in crisis management and team meetings are documented.	Acceptable
11	Customer/Consumer Complaints (Policies, Follow Up and Response) Established March 15, 2002. A written customer complaint program that addresses responsibilities, response time and corrective actions based on the investigation of a complaint is in effect.	Acceptable
Section notes:		

Section B HACCP Management

No	Question/Notes	Answer
1	Prerequisite Programs There are many programs in place, but none have formally been identified as prerequisite programs for the HACCP plan. Suggest prerequisite programs be included in the HACCP opening description.	Minor*
2	Preliminary HACCP Tasks A HACCP team is assembled and team member responsibilities are clearly identified. The team has constructed flow diagrams outlining each step in the process and has performed an on site review to verify its accuracy.	Acceptable
3	Hazard Analysis (HACCP Principle 1) The official hazard analysis for each process step is not included in the plan. A summary of the CCPs is the only document.	Minor*

Section B HACCP Management

No	Question/Notes	Answer
4	Critical Control Points (HACCP Principle 2) Documentation for determining a step or process as a CCP or not, is clearly and thoroughly explained and is scientific based. Meetings are conducted on a regular basis by the HACCP team to review any changes in the process that might affect the CCP determination.	Acceptable
5	Critical Limits (HACCP Principle 3) Control measures identifying operating and critical limits that are measurable, have been established and validated for each CCP. Process capabilities are documented to establish that CCP limits are compatible with the plant process and that limits are attainable.	Acceptable
6	CCP Monitoring (HACCP Principle 4) CCP monitoring procedures are conducted at a frequency sufficient enough to detect any loss of control. Data is evaluated by those empowered to implement corrective actions and is documented on clearly identified HACCP records. A deviation log is kept and records are signed.	Acceptable
7	Corrective Actions (HACCP Principle 5) Corrective actions are developed for each CCP and include instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit is exceeded.	Acceptable
8	Verification and Validation (HACCP Principle 6) Documentation is available confirming the HACCP plan is scientifically and technically sound and that all hazards have been identified and CCPs are effective and valid. Validation of the plan is performed and documented on an annual basis.	Acceptable
9	Documentation and Record Keeping (HACCP Principle 7) HACCP procedures are documented with detailed corrective actions and product dispositions. Final records are in ink, signed by the operator, supervisor and HACCP reviewer and without missing data or blanks. Records are securely stored and easily retrievable.	Acceptable

Section notes:

Section C Facilities and Equipment

No	Question/Notes	Answer
1	Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management Water is tested monthly. All water supply is potable, meets local requirements and is tested at least annually. Water lines and hose drops are fitted with backflow prevention devices that are tested by a trained inspector at least annually. There are no dead ends on potable water lines and no hose nozzles were observed submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water is readily available for production, sanitation and handwashing. There is a documented procedure for handling backed up drains in production and no sewage disposal problems were observed.	Acceptable
2	Plant Construction and Design The facility is constructed in a manner conducive to handling product in a sanitary manner. No observations of overhead contamination or cross contamination were observed. Materials are easily cleanable, floors are well drained and drains have traps and covers. No objectionable odors, fumes or vapors were present. Interior air supplies are screened and filtered and no dust or standing water was observed around the exterior. An essential glass and brittle plastic program is monitored monthly.	Acceptable

Section C Facilities and Equipment

No	Question/Notes	Answer
3	<p>Plant Condition (Walls, Ceilings, Floors, etc.) The plant, overall, is well maintained. Ceilings and walls are tight and clean with no apparent leaks or holes. The floor in some areas has exposed aggregate and some cracking. This is an ongoing problem due to the interaction of the product and concrete. The floors were clean. Management maintains an ongoing program for reviewing and determining which floors need repairs.</p>	Acceptable
4	<p>Ready To Eat (RTE) Operational Areas Not applicable.</p>	N/A
5	<p>Employee Support Facilities The restrooms and lunchroom open directly into a processing room. A new area is being developed outside of production to accommodate the welfare facilities.</p>	Minor*
6	<p>Handwashing Facilities Hand washing facilities are provided in locker rooms, toilet facilities and at entrances to work areas. They are adequate in size, quickly deliver tempered water and are maintained with hand soap, hand sanitizer and single service towels. Hands-free activated faucets are available in and adjacent to processing areas.</p>	Acceptable
7	<p>Equipment Layout, Design and Conditions Equipment is designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Where equipment may make direct product contact, it is constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts.</p>	Acceptable
8	<p>Plant Lighting and Protection Adequate illumination is provided and lighting is protected from breakage and possible contamination. Light fixtures are maintained clean, free of cracks, dust or other materials that could cause contamination.</p>	Acceptable
9	<p>Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) There is a documented preventative maintenance program that covers the equipment and facilities. Permanent repairs are made promptly. Food-grade and non-food grade lubricants are not stored together.</p>	Acceptable
Section notes:		

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
1	<p>Master Sanitation List and Monitoring There is a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, locker rooms, cafeterias, break areas and toilet facilities with scheduled tasks that are monitored for completion and documented on a regular basis.</p>	Acceptable
2	<p>Standard Sanitation Operating Procedures and Monitoring There is a documented Standard Sanitation Operation Procedure that defines and specifies standard cleaning methods for equipment and facility structures. The procedure includes the frequency of cleaning, the chemicals used and the water temperatures where applicable. Records are kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a reoccurrence.</p>	Acceptable
3	<p>Cleaning Chemical and Sanitizer Control There are procedures that specify the proper dilution of chemicals and/or sanitizers and all containers of cleaning chemicals and sanitizers are properly labeled. Chemical containers are used for their intended purpose only. Chemicals are securely stored during periods of non-use.</p>	Acceptable

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
4	Pre Op Monitoring and Corrective Action A Quality Control Technician is responsible for pre-op sanitation inspections. There is a check sheet used and deficiencies and corrective actions are documented.	Acceptable
5	Verification of Cleaning Effectiveness Micro swabs for TPC and environmental swabs are used to verify cleaning effectiveness.	Acceptable
6	Operational Housekeeping and Monitoring All areas of the plant are kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials are accumulated in identified containers and properly disposed of. No evidence of mold, mildew or slime on walls, floors, ceilings or equipment was observed. Floor drains are kept clean, odor free and covered. No tool storage or materials were observed on top of equipment, electrical boxes or window ledges.	Acceptable
7	Personal Hygiene and Good Manufacturing Practices Employee training is provided that covers plant specific Good Manufacturing Practices, Personal Hygiene, Plant Sanitation, HACCP and Product Tampering Awareness. All sanitation employees receive training in basic food handling. Continuing refresher training is provided at least quarterly and records are kept of individual training programs and topics covered for each employee. Training is presented in an appropriate language to be clearly understood by all employees. Detailed dress codes and personal hygiene requirements are provided.	Acceptable
8	RTE Sanitation and Corrective Action For further processing	N/A
9	GMP Self Inspections and Corrective Actions Internal GMP self-inspections are conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities are conducted to record the effectiveness of corrective actions for deficiencies and repeat items.	Acceptable

Section notes:

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
1	Documented and Specific Pest Control Program Clark is the contract PCO. There is a current pest management policy and program that outlines the responsibilities of the Pest Control Operator (PCO), the proper use of internal trapping devices, outside bait stations and the documentation of service and activity reports. Site maps for all traps and bait stations were current, Material Safety Data Sheet (MSDS) and the PCO applicator's license and letter of insurance were current and on file.	Acceptable
2	Outside Premises Management (Grounds, Waste Disposal Areas) The buildings exterior and grounds were well maintained and no pest harborages were observed. Adequate trash and waste disposal facilities are available and no standing water on the premises that could attract pests was observed.	Acceptable
3	Inside Premises Management Interior conditions were orderly and clean throughout and allowed for easy access and evaluation along walls. Control measures are used at distances from food or food contact surfaces to avoid any potential for contamination. Trapping devices were in proper working condition and no bait stations were observed being used inside the plant or warehouse.	Acceptable

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
4	Pest Tight Doors and Entrance Closures All doors were tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., provided easy access to pests.	Acceptable
5	Secure Storage and Documentation of Pest Related Chemicals No pest related chemicals are stored on site.	Acceptable
6	Activity Reports Detailed with Corrective Actions Activity reports were available, indicating specific sites of activity, type of activity, recommended corrective action, specific chemicals used, quantities used, locations where used, the date used and for what purpose. Activity reports were signed by the PCO and by a designated plant representative. Deficiencies are addressed with corrective action documentation.	Acceptable
Section notes:		

Section F Receiving and Inventory Control

No	Question/Notes	Answer
1	Incoming Vehicle Review and Documentation A written inspection program describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers are inspected for food safety, quality and security related concerns at the time of receiving.	Acceptable
2	Specific Receiving Policies with Inspection and Acceptance Plans All vegetables come from approved suppliers with proof of liability insurance, letters of guarantee and usage of pesticide reports.	Acceptable
3	Release Criteria for Ingredients All ingredients are maintained in a secure fashion and released for use against a defined approval program. An inventory management system is in place to assure proper rotation.	Acceptable
4	Storage and Handling Policies and Practices Overflow production is stored in an off site cold storage facility. Procedures for the storage and handling practices of ingredients and supplies have been established to assure they do not become a source of contamination. Receiving areas and storage locations are maintained in a clean and sanitary manner and ingredients and supplies are held under conditions necessary to maintain product integrity.	Acceptable
5	Bulk Receiving Systems Sanitation and Monitoring Not applicable.	N/A
6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds Only food grade lubricants used in processing areas and cleaning chemicals are stored in a secure location. No allergen ingredients are used.	Acceptable
Section notes:		

Section G Process and Product Evaluation

No	Question/Notes	Answer
1	Process Control and Documentation Procedures Process control procedures are established, monitored and documented to assure product is manufactured to meet all food safety requirements. In-process ingredients and products are adequately protected and properly labeled with date and lot number.	Acceptable

Section G Process and Product Evaluation

No	Question/Notes	Answer
2	Specification and Formulation Control and Accuracy Records are available that demonstrate compliance to product formulations and finished product specifications. Test protocols and frequencies are followed as identified in the specification and production records are maintained for twelve months beyond product shelf life.	Acceptable
3	Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.) Scales are calibrated quarterly and there is a certified thermometer used for calibrating hand held and the incubators.	Acceptable
4	Foreign Material Control Metal detection is used and the device is positioned at the end of the belt prior to filling the cases or bins. Ferrous, nonferrous and stainless steel test spheres are used for calibration.	Acceptable
5	Application of Statistical Control Not applicable.	N/A
6	Allergen and Sensitive Ingredient Controls No allergens used.	N/A
7	Documentation Showing Product Meets Specifications Records are maintained to document that product is manufactured according to specification. Finished products are inspected and tested. Product is not shipped until all parameters meet specification and approved by management.	Acceptable
8	Rework and Carryover Products No rework or carryover is used. Processing is completed daily.	Acceptable
9	Analytical Records Management Established systems are utilized to properly store and retrieve analytical information, documents, reports, records, etc.	Acceptable
Section notes:		

Section H Packaging and Labeling

No	Question/Notes	Answer
1	Label Accuracy and Regulatory Compliance Procedures and policies are in place to assure proper labeling of products and that labels meet regulatory requirements.	Acceptable
2	Documented Net Weight or Count Compliance Policy and Performance A documented policy for net quantity compliance requires the calibration of quantity measuring devices. Calibration checks are conducted at the beginning and end of production and are documented on production records.	Acceptable
3	Clear Manufacturing Codes on Individual and Cased Product The code format used includes the year, Julian date and production period; i.e. 071271.	Acceptable
4	Package Integrity and Function for Distribution All packaging is designed and assembled to provide protection for the product from environmental and shipping conditions. Verification of proper sealing and closure of the packaging is conducted.	Acceptable
5	Label Security and Obsolete Label Controls No obsolete labeling. Printed at time of use.	Acceptable

Section H Packaging and Labeling

No	Question/Notes	Answer
6	Tamper Evident Packaging None used.	N/A
Section notes:		

Section I Storage and Shipping

No	Question/Notes	Answer
1	Warehouse and Finished Product Management Overflow is stored at an off site refrigerated warehouse. Warehouse conditions are maintained and controlled in a manner to assure product integrity. Finished product and packaging materials are held separated and away from chemicals. Product not "cleared" for shipment is clearly identified and stored in a location where it is not likely to be shipped in error.	Acceptable
2	Retained and Returned Products Only reference samples are held. All products are segregated by grade.	Acceptable
3	Storage Facility and Dock Maintenance Warehouse storage areas are clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items are stored off the floor, floors and walls are in good condition and emergency doors are tight fitting. Shipping docks, dock plates and levelers are clean and kept orderly.	Acceptable
4	Transport Condition Written procedures for acceptable carrier conditions are available to shipping personnel. Outbound trailers are inspected and results are documented. No product is loaded into unacceptable carriers. When non-dedicated carriers are used, trailer logs are assessed to determine if unacceptable materials had been present.	Acceptable
5	Release Authorization to Ship Product Quality is the release authority. Release authorization is required before any product is shipped.	Acceptable
6	Product Traceability A mock recall was reviewed, dated 12/11/2006. A fictitious narrative described the product and possible cause. No summary was completed and the time for the recall extended over several days. Documents identifying the production quantity and customers were on file. Suggest the exercise be simplified to meet the expectations of 4 hours or less and identify the percent of recovery and the actual time used to complete the exercise.	Minor*
Section notes:		

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
1	Laboratory Facility and Staffing Laboratories are adequately equipped and staffed to provide the essential technical support. Lab staff qualifications are documented, toxic supplies are securely stored and properly labeled and the laboratory is clean, orderly and well lit.	Acceptable
2	Laboratory Procedures and Documentation Laboratory procedures are documented, authorized and dated. Testing procedures are based on recognized and approved procedures and documentation of all testing is available.	Acceptable

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
3	Laboratory Equipment Calibration Records of laboratory balances and test equipment calibrated by a certifying company are documented. Calibrations checks conducted internally are documented with specific instrument identification, date of calibration and the individual performing the calibration check.	Acceptable
4	Analytical Accuracy Verification Detailed test procedures, work instructions, training records and record keeping are established to verify that monitoring and test results meet finished product specifications. Tests performed are documented and meet accepted standards of a recognized authority. Documented evidence is available that demonstrates laboratory test results are accurate and reliable.	Acceptable
Section notes:		

Section K Food Defense

No	Question/Notes	Answer
1	Management No official program has been established and an ORM has not been performed. Suggest the information found at www.fsis.usda.gov , product security be used as a guideline as well as other resources found in the FDA and Homeland Security web sites.	Minor*
2	Human Element All individuals entering the facility must show proof of identification. Temporary employees are fully supervised at all times. Contractors and visitors are required to show identification and sign in and out. Visitors are accompanied while in the facility. A current roster of employees and work assignments is maintained and employees are prohibited from bringing personal items such as purses, cases, containers, lunch boxes, etc. into processing areas. A screening program is in place for all employees and a program to train Food Defense rules at the facility has been implemented. Training is documented for each individual at the facility.	Acceptable
3	Facility A schematic of the facility and outside grounds is available that identifies all entrances into the building, accesses to the roof and sensitive areas. Access to sensitive areas and utilities is restricted. When not in use, non-traffic doors, dock doors and utility access is secured. Emergency doors are alarmed. A process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas is documented.	Acceptable
4	Operations A program for inbound and outbound trucks is in place. The program includes inspections and monitoring the drivers while on site.	Acceptable
Section notes:		

Section 3 Ingredients of Concern

No	Question/Notes	Answer
1	Does the plant use or store Peanuts or Peanut Products?	No
2	Does the plant use or store Tree Nuts?	No
3	Does the plant use or store Crustacea?	No
4	Does the plant use or store Fish?	No
5	Does the plant use or store Egg or Egg Products?	No

Section 3 Ingredients of Concern

No	Question/Notes	Answer
6	Does the plant use or store Milk or Milk Products?	No
7	Does the plant use or store Soybean or Soy Products?	No
8	Does the plant use or store Wheat, Corn (Maize) or Related Grains?	No
9	Does the plant use or store Mollusks?	No
10	Does the plant use or store Seeds?	No
11	Does the plant use or store Cottonseed Products?	No
12	Does the plant use or store Legumes?	No
13	Does the plant use or store Sulfites?	No
14	Does the plant use or store FD&C Yellow #5 or #6?	No
15	Does the plant use or store Monosodium Glutamate, Autolyzed yeast, Hydrolyzed protein?	No
16	Does the plant use or store Meat?	No
17	Does the plant use or store Poultry?	No
Section notes:		

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* Represents Non Compliances.

If you have any questions about this report, please contact your NSF Project Manager, Melanie Fisher, at 734-913-5720 or mfisher@nsf.org.