

Audit Criteria for Food Contact Packaging Materials, Food-Related Items, and Personal Care (Contact) Products

Company Information	Audit Information
<p>Facility: C0087690 - Bio Products</p> <p>Address: China</p> <p>Contact: Title: Phone: Fax: Email:</p>	<p>Audit# - Visit#: 742111 - 520932</p> <p>Audit Type: PKG - Audit Criteria for Food Contact Packaging Materials, Food-Related Items, and Personal Care (Contact) Products</p> <p>Template Version: 2</p> <p>Audit Category: REGULAR</p> <p>Auditor: Rong Liang</p> <p>Audit Start Time: 10-JUL-2012 09:00:00 AM</p> <p>Audit End Time: 10-JUL-2012 05:00:00 PM</p> <p>Prior Audit Date: 06-JUL-11</p> <p>Prior Audit Score: 90.75%</p>

Audit Result: Needs Improvement

Facility and Operating Profile	
No	Question/Notes
1	Facility and Operations Description:
2	<p>Auditor's Notes: The occupancy area is approximately 2700 square meters in this company. The production building is just one floor including warehouse, injection room and packaging room and the company has 22 injection machines. The manufacturing facility has approximate 80 employees, injection position working with 3 shifts and packaging position working with one shift, 5 days a week.</p> <p>Was the audit Announced or Unannounced?</p> <p>Announced</p>
3	<p>Products made at this facility:</p> <p>See notes</p>
4	<p>Disposable cutlery products made of PLA or PSM</p> <p>The following departments and individuals participated in the audit process:</p> <p>See notes</p>
Section	<p>GM of; GM of ; Quality Manger; Purchase Manager</p> <p>Notes :</p>

Score Summary By Section	
Section Name	Section Score
Section A - Administration and Regulatory Compliance	87.00%
Section B - HACCP Management	87.00%
Section C - Facilities and Equipment	92.00%
Section D - Sanitation, Housekeeping and Hygiene	92.00%
Section E - Rodent and Pest Control Management	92.00%
Section F - Approved Suppliers, Receiving and Inventory Control	89.00%
Section G - Process and Product Evaluation	92.00%
Section H - Packaging and Labeling	84.00%
Section I - Storage and Shipping	95.00%
Section J - Training Requirements	95.00%
Section K - Laboratory Support	N/A
Section L - Product Defense	91.00%
Food Safety, Quality and Food Defense Audit Average Score:	90.55%

Category Scoring Guide

95% - 100% = Meets or Exceeds Audit Expectations

85% - 94.99% = Needs Improvement

75% - 84.99% = Needs Significant Improvement

<75% = Critical

Automatic Audit Failure (Denoted as a "Critical" item in the audit report)

- Product Contamination and/or adulteration
- Significant deviation from identified CCP in the HACCP Plan
- Mislabeled or misbranded product
- Record falsification
- Significant deviation from specification
- Facility is not operating in compliance with stated regulatory requirements

Overview	
No	Question/Notes
	<p>Notes from the auditor:</p> <p>See Notes</p> <p>Documented quality and product safety management system was established in this facility. And the certificate of HACCP has been authorized to this facility since 2009.</p> <p>The main process of products included blending, injecting and packaging. For PLA products, there was additional recrystallization step after injection. The HACCP plans for disposable biodegradable cutlery product was established and the raw material incoming inspection was identified the CCP. The raw material must be accepted from approved suppliers. The suppliers' COAs were available for each lot of raw material.</p> <p>The product specification just defined the appearance requirement. The products shall be free of oil contamination, black point and out of shape. The products would be inspected appearance at injection and packaging step. The oil contaminated products would be cleaned by cotton with alcohol at injection step in this facility. The products were tested for chemical attributes by local CIQ laboratory monthly in 2012. The testing items included methanal, heavy metal and decoloring test.</p> <p>The annual training schedule was available and the training topics included orientation training, related regulations, HACCP, prerequisite program and personal hygiene. The training was conducted monthly and the documentations were maintained properly. The training comprehension was verified by oral question in this facility.</p>
Section Notes :	

Non-Compliance Summary		
No	Question/Notes	Answer
Section A /4	<p>Product Identification, Traceability and Recall Plans and Procedures</p> <p><i>Raw material used into finished products can not be traced accurately in this facility. Although product traceability sheet was available to show which lot of raw material used into, there was no operational documentation to demonstrate it in this audit. It is recommended that incoming material tracking program must be in place to trace raw materials from receipt through use into finished product.</i></p>	Needs Improvement*
Section A /8	<p>Documentation to Track Effectiveness of Policies</p> <p><i>Management review shall be conducted annually per the procedure. However the management review and internal audit were not conducted in 2011 in this facility. It is recommended that management review must be conducted annually at least.</i></p>	Needs Improvement*
Section B /2	<p>Hazard Analysis (HACCP Principle 1)</p> <p><i>HACCP plan for disposable cutlery products was established in 2008. PSM or PLA material products were produced in this facility in this audit. However the HACCP plan was just for the PSM material products. The company stated that the PLA material products started the production since 2010. However the HACCP plan was not updated to cover PLA material product. Although the process of PSM and PLA products were similar, it is recommended there must be a detailed Hazard Analysis document for each type of product.</i></p>	Needs Improvement*
Section B /7	<p>Verification and Validation (HACCP Principle 6)</p> <p><i>The verification of HACCP plan was not conducted in 2011. It is recommended that verification of the HACCP plan must be conducted to confirm that the products are achieving the level of safety required and that the HACCP plan is operating effectively.</i></p>	Needs Improvement*
Section C /7	<p>Plant Lighting and Protection</p> <p><i>All glass lights were not protected properly in this facility. It is recommended that all glass lights must be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product.</i></p>	Needs Improvement*

Section D /7	Personal Hygiene and Good Manufacturing Practices <i>Employees' hair was not covered fully in this audit. It is recommended that employees' hair must be covered fully to prevent foreign material contamination of product.</i>	Needs Improvement*
Section E /4	Pest Tight Doors and Entrance Closures <i>The gap was present between the floor and doorjamb in raw material warehouse and finished product warehouse. It is recommended that all doors must be tight closing with no visible light observed between the floor and doorjamb.</i>	Needs Improvement*
Section F /4	Storage and Handling Policies and Practices <i>When visit in raw material warehouse, it was found that PSM material packaging bags were used for storing PLA materials. However the bags were not identified clearly to show its content. It is recommended that all materials must be identified clearly to avoid misuse.</i>	Needs Improvement*
Section F /6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds <i>One bucket of liquid was stored in the blending room in this audit. The facility stated it was equipment lubricant, however it was not identified. It is recommended that chemical container used in production area must be labeled its content.</i>	Needs Improvement*
Section G /1	Process Control and Documentation Procedures <i>In-process products were stored in the finished product warehouse in this audit, however it was not labeled with date and lot number. It is recommended that in-process ingredients and products must be properly labeled with date and lot number.</i>	Needs Improvement*
Section H /3	Clear Manufacturing Codes on Individual and Cased Product <i>One pallet of EP-S003 spoon products were not printed manufacturing date in finished product warehouse. It is recommended that all products must have a code date that is of such size, color and contrast to afford easy legibility at a reasonable distance.</i>	Major Nonconformance*
Section L /1	Management <i>Security program was in place in this facility. However the product defense risk assessment was not conducted in this facility. It is recommended that risk assessment must be conducted to develop the product defense program.</i>	Needs Improvement*

Section A. Administration and Regulatory Compliance		
No	Question/Notes	Answer
1	<p>Organization and Responsibilities <i>The current plant management organization chart was dated and signed by top management. It shows the reporting structure of the plant operating departments. Quality manager is responsible to top management in this plant. A clear documentation of the responsibilities and authorities of the Quality department was available. The control and release of withheld and retained product was designated as the responsibility of the Quality Manager.</i></p>	Acceptable
2	<p>Policies and Procedures Manual <i>Documented quality and safety management system was established in this plant. Documented policies, procedures and pre-requisite programs that address relevant product safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product were available. These policies and procedures were current, dated and signed and they look applicable and complete.</i></p>	Acceptable
3	<p>Management Awareness and Commitment <i>Management commitment and active support was showed through training program and financial resources for product quality and safety system in this plant. Equipments and facilities were in proper condition in this plant. One member of top management was in attendance during the opening and closing meetings during the audit.</i></p>	Acceptable
4	<p>Product Identification, Traceability and Recall Plans and Procedures <i>Raw material used into finished products can not be traced accurately in this facility. Although product traceability sheet was available to show which lot of raw material used into, there was no operational documentation to demonstrate it in this audit. It is recommended that incoming material tracking program must be in place to trace raw materials from receipt through use into finished product.</i></p>	Needs Improvement*
5	<p>Regulatory Compliance <i>The file of regulatory actions, visits, reports or other notifications received from any regulatory agency was maintained in this plant. Written responses with appropriate corrective actions were documented. A log of samples submitted for pathogen, antibiotic or environmental testing was maintained.</i></p>	Acceptable
6	<p>Document and Records Management <i>The document and records management procedures were established and it addresses document creating process, the control of document issue and revise, document filing, specific time limits for holding files and proper disposition of outdated documents and records. All documented procedures were identified the current revision status. Locations for the storage of documents and records were designated. Records were indexed and easily retrievable in this plant.</i></p>	Acceptable
7	<p>Change Management <i>Change management procedure was established and it described the process of communication, approval and training for changes in key management personnel, specifications, policies and procedures.</i></p>	Acceptable
8	<p>Documentation to Track Effectiveness of Policies <i>Management review shall be conducted annually per the procedure. However the management review and internal audit were not conducted in 2011 in this facility. It is recommended that management review must be conducted annually at least.</i></p>	Needs Improvement*
9	<p>Crisis and Natural Disaster Management <i>A crisis management team was assembled and included a sufficient number of members representing the necessary department to handle and resolve critical situations such as recall, product defense issue and emergency situations. A list to outline the responsibility of each member with 24/7 telephone number was available. Quality Assurance was responsible for evaluating the status of ingredients, in-process materials and finished product involved in an emergency and making sure they were acceptable prior to the start of production or shipping.</i></p>	Acceptable
10	<p>Customer/Consumer Complaints (Policies, Follow Up and Response) <i>Customer complaint management procedure was established in this plant. It addressed department responsibility, the handling process for a complaint including investigation of complaint, response to customer, taking corrective actions and tracing the effectiveness. The company stated that customer complaint did not happen in this facility.</i></p>	Acceptable
Section Notes :		

Section B. HACCP Management		
No	Question/Notes	Answer
1	Preliminary HACCP Tasks <i>Preliminary HACCP tasks were accomplished in this facility. HACCP team was assembled and team member responsibilities were clearly identified. The flow diagram outlining each step involved in the process of PSM material product was available and CCP was identified on it.</i>	Acceptable
2	Hazard Analysis (HACCP Principle 1) <i>HACCP plan for disposable cutlery products was established in 2008. PSM or PLA material products were produced in this facility in this audit. However the HACCP plan was just for the PSM material products. The company stated that the PLA material products started the production since 2010. However the HACCP plan was not updated to cover PLA material product. Although the process of PSM and PLA products were similar, it is recommended there must be a detailed Hazard Analysis document for each type of product.</i>	Needs Improvement*
3	Critical Control Points (HACCP Principle 2) <i>Documentation for determining a step or process as a CCP or not was clear and thoroughly explained, defining the hazards and the specific controls that eliminate or reduce the hazard.</i>	Acceptable
4	Critical Limits (HACCP Principle 3) <i>The critical limits were established, specified and validated for each CCP. Critical limits were measurable. Process capabilities were documented to demonstrate that established CCP limits were compatible with the plant process and that limits were attainable.</i>	Acceptable
5	CCP Monitoring (HACCP Principle 4) <i>Monitoring procedure for each CCP was established and the frequency of monitoring was sufficient to assure the CCPs in control. Monitoring data were documented on the HACCP records and evaluated by a designated person with knowledge and authority to carry out corrective actions with indicated.</i>	Acceptable
6	Corrective Actions (HACCP Principle 5) <i>Corrective actions were developed for each CCP and included instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit was exceeded.</i>	Acceptable
7	Verification and Validation (HACCP Principle 6) <i>The verification of HACCP plan was not conducted in 2011. It is recommended that verification of the HACCP plan must be conducted to confirm that the products are achieving the level of safety required and that the HACCP plan is operating effectively.</i>	Needs Improvement*
8	Documentation and Record Keeping (HACCP Principle 7) <i>HACCP procedures were documented with detailed corrective actions and product dispositions. Documentations and records including hazard analysis, CCP determination, CCP monitoring etc were kept properly. Deviations from the HACCP plan were thoroughly documented with detailed corrective actions and product dispositions. Final records were in ink, signed by the operator, supervisor and HACCP reviewer and without missing data or blanks. Records were securely stored and easily retrievable.</i>	Acceptable
Section Notes :		

Section C. Facilities and Equipment		
No	Question/Notes	Answer
1	Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management <i>Potable water was from municipal water system. It was sampled in plant and tested by a certified laboratory annually and the test report showed that potable water conformed to GB 5749 (China potable water specification).</i>	Acceptable
2	Plant Construction and Design <i>The construction of the facility is such that it facilitated the manufacture of quality products and that it meets the GMP requirements. Exterior of plant and grounds are covered with cement pavement and lawn to minimize dust. There was no evident standing water in this plant. Walls and floors were constructed with hard, smooth and easy cleaning material. Floors were well drained and drains were equipped with traps and covers. A glass and brittle plastic program was in place.</i>	Acceptable
3	Plant Condition (Walls, Ceilings, Floors, etc.) <i>Plant facilities including walls, ceilings, floors etc. were properly maintained in orderly and clean conditions. The ceiling surfaces and overhead structures such as piping were clean, in good repair and free of flaking paint. Ceiling panels, framework and supports were properly secured with no missing or damaged parts.</i>	Acceptable

Section C. Facilities and Equipment		
No	Question/Notes	Answer
4	Employee Facilities <i>Locker room for personnel was adequate, convenient and physically separated from production areas in this plant. Toilet facilities were available and it was well lit, clean and properly ventilated.</i>	Acceptable
5	Handwashing Facilities <i>Hand washing facilities were provided at entrances to work areas and in toilet facilities. They were adequate in size, quickly deliver tempered water and maintained with hand soap and single service towels. Hands-free activated faucets were available in and adjacent to processing areas. Sign in graphics for hand washing was clearly posted.</i>	Acceptable
6	Equipment Layout, Design and Conditions <i>Processing equipments were installed in such a manner as to permit proper operation and access for clean and inspection. Equipments were made of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material where it had direct product contact and were free of flaking paint, rust and cracks.</i>	Acceptable
7	Plant Lighting and Protection <i>All glass lights were not protected properly in this facility. It is recommended that all glass lights must be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product.</i>	Needs Improvement*
8	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) <i>Documented preventative maintenance program that cover all food contact production equipment and facilities was in place in this plant. Equipments and facilities were maintained per the preventative maintenance schedule and documented. Temporary repairs were not observed in this plant.</i>	Acceptable
Section Notes :		

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Answer
1	Master Sanitation Schedule and Monitoring <i>Master sanitation schedule was established in this plant. It covered operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. Monitoring documentations for completion of scheduled cleaning tasks were available during this audit.</i>	Acceptable
2	Standard Sanitation Operating Procedures and Monitoring <i>SSOP for equipment and facility structure was established in this plant and it defined standard cleaning methods, frequency etc. Cleaning was monitored and documented in this plant. Records were kept of all deficiencies found and the corrective action that was taken to bring the equipment into a sanitary condition and prevent a reoccurrence.</i>	Acceptable
3	Cleaning Chemical and Sanitizer Control <i>All containers for cleaning chemicals and sanitizers were properly labeled and they were securely stored during periods of non-use in this plant. There was a separated area from production areas for storage cleaning chemical and sanitizer. The entrance was locked and MSDS for chemical was available on site.</i>	Acceptable
4	Pre Operational Monitoring and Corrective Action <i>A pre-operational checklist was used to check plant and equipment were clean and sanitary prior to daily operation. Deficiencies were noted and corrective actions taken.</i>	Acceptable
5	Verification of Cleaning Effectiveness <i>Sanitation effectiveness was monitored visually prior to production in this plant.</i>	Acceptable
6	Operational Housekeeping and Monitoring <i>During this audit, it was observed all areas of the plant were kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials were accumulated in identified containers and disposed of properly. Floor drains were kept clean, odor free and covered. Tool or materials was not stored on top of equipment, electrical boxes or window ledges.</i>	Acceptable
7	Personal Hygiene and Good Manufacturing Practices <i>Employees' hair was not covered fully in this audit. It is recommended that employees' hair must be covered fully to prevent foreign material contamination of product.</i>	Needs Improvement*
8	Internal Audits and Corrective Actions <i>Routine internal GMP self-inspections was conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities were conducted to record the effectiveness of corrective actions for deficiencies and repeat items.</i>	Acceptable

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Answer
Section Notes :		

Section E. Rodent and Pest Control Management		
No	Question/Notes	Answer
1	Documented and Specific Pest Control Program <i>Documented pest management plan was established in this plant. Qualified PCO was responsible for pest control and management. Outside bait stations and internal trapping devices were properly equipped and the documentation of service and activity reports was available. 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.</i>	Acceptable
2	Outside Premises Management (Grounds, Waste Disposal Areas) <i>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.</i>	Acceptable
3	Inside Premises Management <i>Interior conditions were orderly and clean throughout and allowed for easy access and evaluation along walls. Control measures are used at distances from product or product 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.</i>	Acceptable
4	Pest Tight Doors and Entrance Closures <i>The gap was present between the floor and doorjamb in raw material warehouse and finished product warehouse. It is recommended that all doors must be tight closing with no visible light observed between the floor and doorjamb.</i>	Needs Improvement*
5	Secure Storage and Documentation of Pest Related Chemicals <i>Pesticide was not used in this facility.</i>	Acceptable
6	Detailed Activity Reports with Corrective Actions <i>The inspection documentations for pest control devices were available in this audit. It included the pest type and numbers trapped in devices.</i>	Acceptable
Section Notes :		

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Answer
1	Supplier Approval Policies and Procedures <i>Supplier approval procedure that identifies criteria for approving suppliers was established in this plant. Approved supplier list was available and all ingredients and packaging materials were purchased from approved supplier. Certificate of Analysis (COA) or Continuing Letters of Guarantee was current and available for all ingredients and packaging materials.</i>	Acceptable
2	Incoming Vehicle Inspection and Documentation <i>Written inspection program describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers were inspected for product safety, quality and security related concerns at the time of receiving.</i>	Acceptable
3	Release Criteria for Ingredients <i>All materials were maintained in a secure fashion and released for use against defined program. Inventory management system was in place to ensure ingredients and goods were used in proper rotation.</i>	Acceptable
4	Storage and Handling Policies and Practices <i>When visit in raw material warehouse, it was found that PSM material packaging bags were used for storing PLA materials. However the bags were not identified clearly to show its content. It is recommended that all materials must be identified clearly to avoid misuse.</i>	Needs Improvement*
5	Bulk Receiving Systems Sanitation and Monitoring <i>There was no bulk material in this facility.</i>	N/A

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Answer
6	<p>Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds <i>One bucket of liquid was stored in the blending room in this audit. The facility stated it was equipment lubricant, however it was not identified. It is recommended that chemical container used in production area must be labeled its content.</i></p>	Needs Improvement*
Section Notes :		

Section G. Process and Product Evaluation		
No	Question/Notes	Answer
1	<p>Process Control and Documentation Procedures <i>In-process products were stored in the finished product warehouse in this audit, however it was not labeled with date and lot number. It is recommended that in-process ingredients and products must be properly labeled with date and lot number.</i></p>	Needs Improvement*
2	<p>Specification and Formulation Control and Accuracy <i>Specifications that define acceptable product attributes were established in this plant. Test protocols and frequencies were followed as identified in the specification. Records were available that demonstrate compliance to product formulations and finished product specifications.</i></p>	Acceptable
3	<p>Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.) <i>Key process control devices were calibrated by outside contractor annually in this plant. The program to evaluate the performance of measuring devices to assure accuracy on daily basis was in place. Thermometers used for product evaluations are calibrated on a daily basis, documented and traceable. All weighing scales are checked and documented daily to verify accuracy. Standard weight in the range the weights being produced were used for verification checks.</i></p>	Acceptable
4	<p>Foreign Material Control <i>PSM or PLA granule was extruded into products in this plant. Metal foreign material was not likely to exist in products.</i></p>	Acceptable
5	<p>Application of Statistical Control <i>Statistical control is used to determine the capability of the process equipment and the setting of critical limits for critical control points.</i></p>	Acceptable
6	<p>Allergen and Sensitive Ingredient Controls <i>Allergen or sensitive materials were not used in this plant.</i></p>	Acceptable
7	<p>Specification Compliance Documentation <i>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.</i></p>	Acceptable
8	<p>Rework and Carryover Products <i>There is a documented procedure for managing rework and carry over products. Rework is traceable to its original production and to finished product. Production dates and original lot numbers are carried forward in production documents. Rework and carry-over is kept to a minimum and used promptly at the first opportunity. There is a routine and documented "clean break" in the rework/carryover cycle.</i></p>	Acceptable
9	<p>Analytical Records Management <i>Records management procedure was established and analytical documents, reports and records were properly stored and retrieved.</i></p>	Acceptable
Section Notes :		

Section H. Packaging and Labeling		
No	Question/Notes	Answer
1	<p>Label Accuracy and Regulatory Compliance <i>Procedures and policies are in place to assure proper labeling of products and that labels meet regulatory requirements.</i></p>	Acceptable
2	<p>Documented Net Weight or Count Compliance Policy and Performance <i>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.</i></p>	Acceptable

Section H. Packaging and Labeling		
No	Question/Notes	Answer
3	<p>Clear Manufacturing Codes on Individual and Cased Product <i>One pallet of EP-S003 spoon products were not printed manufacturing date in finished product warehouse. It is recommended that all products must have a code date that is of such size, color and contrast to afford easy legibility at a reasonable distance.</i></p>	Major Nonconformance*
4	<p>Package Integrity and Function <i>Product cartons were proper function for distribution in this plant.</i></p>	Acceptable
5	<p>Label Security and Obsolete Label Controls <i>Written label security control procedure was established and it described the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.</i></p>	Acceptable
Section Notes :		

Section I. Storage and Shipping		
No	Question/Notes	Answer
1	<p>Warehouse and Finished Product Management <i>Warehouse conditions were maintained in a manner to assure product integrity. Finished product and packaging materials were stored in separated warehouse. There were no chemical, cleaning products or damaged products observed in warehouse during audit.</i></p>	Acceptable
2	<p>Retained and Returned Products <i>The documented procedure for non-conformity product control was established in this company. It defined identification, secured segregation, documentation and evaluation for non-conforming retained and returned products. Designated areas are established for retained and returned products and an inventory log is maintained showing current product on hold and the disposition of all released product with proper authorization.</i></p>	Acceptable
3	<p>Storage Facility and Dock Maintenance <i>Storage facility was maintained clean and orderly and had adequate space around the periphery for access, inspection and cleaning in this company. Pallets were used and kept in good repair in warehouse.</i></p>	Acceptable
4	<p>Transport Condition <i>Outbound trailer inspection program was established and the inspection was documented in this plant.</i></p>	Acceptable
5	<p>Release Authorization to Ship Product <i>Release authorization documentations were available before product shipment in this plant.</i></p>	Acceptable
Section Notes :		

Section J. Training Requirements		
No	Question/Notes	Answer
1	<p>New Hire Training (GMP, Food Defense, HACCP) <i>Employee training program was established in this plant. Annual training plan including new hire training was available. New operating personnel received the training in GMP, personal hygiene etc.</i></p>	Acceptable
2	<p>Training Language <i>Training was provided in the language and presentation format that can be easily and clearly understood by the trainee.</i></p>	Acceptable
3	<p>Prerequisite Program Training <i>The program included training for pre-requisite training for basic food handling sanitation and for specific critical jobs. There were documented training for all sanitation employees.</i></p>	Acceptable
4	<p>Refresher Training <i>Employee refresh training in GMP was conducted annually and documented in this plant. Quarterly training session covering topics on GMP, pre-requisite training was take place.</i></p>	Acceptable
5	<p>Proof of Knowledge <i>Training records showed that training comprehension was verified through oral question.</i></p>	Acceptable
6	<p>Training Records <i>All employee training records including date, training provider, training agenda and trainees' signature were maintained in this plant.</i></p>	Acceptable

Section J. Training Requirements		
No	Question/Notes	Answer
7	Training Program Review <i>The training program was reviewed annually in this plant.</i>	Acceptable
Section Notes :		

Section K. Laboratory Support		
No	Question/Notes	Answer
N/A		
Section Notes : There was no laboratory in this facility.		

Section L. Product Defense		
No	Question/Notes	Answer
1	Management <i>Security program was in place in this facility. However the product defense risk assessment was not conducted in this facility. It is recommended that risk assessment must be conducted to develop the product defense program.</i>	Needs Improvement*
2	Human Element <i>A screening program was in place for all employees in this plant. A positive identification and recognition system was in place. All individuals entering the facility showed identification badge with the individual's name.</i>	Acceptable
3	Facility <i>Access to sensitive areas was restricted and locked and video monitoring system was used for security in this plant.</i>	Acceptable
4	Operations <i>Documented policies and procedures were established to address areas of concern. Non-employee drivers and delivery personnel had designated waiting areas in this company. Trucks and/or trailers were inspected before unloading. Vehicles were secured after loading was completed and seal numbers were recorded.</i>	Acceptable
Section Notes :		

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* Represents Non-Conformances.

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