

Food and Non-Food Packaging Materials Audit

for:

Suzhou Linhong Moulding Products Co., Ltd

Audit Date: November 12, 2008

**Auditor Name: Vikki Wang
Silliker, Inc.**

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III. Plant Description

The facility is located in an industrial park.

The facility was built in 2001.

The facility is approximately 28,000 square feet in size.

The process area occupies 13,000 square feet. The storage areas are 10,000 square feet. And the storage areas were dry warehousing. The handling areas are all on the first floor and offices in second floor.

The facility has 80 full time employees. No seasonal or temporary employee was hired.

Operating hours are five days a week. There are three production shifts for molding process and one shift for packaging process. Cleaning/sanitation will take place after production.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

Summary of Audit Findings

I. Critical or Major Areas (Questions scoring a 1 or 2)

| Category | Findings |
|---|--|
| I PRODUCT SAFETY SYSTEMS | <p>I.A.4: Critical control point was not identified on the process flow chart.</p> <p>I.A.6: The records from September to November were reviewed. CCP monitoring record of CCP2 (internal packaging receiving) and CCP4 (final products out bounding) did not meet the requirement in the HACCP plan. CCP3 (swab testing of food contact surface) was not conducted.</p> <p>I.C.2: HACCP training was not conducted.</p> |
| II QUALITY SYSTEMS | <p>II.D.4: Water potability was not tested annually hence the record was unavailable.</p> <p>II.H.2: Mock recall was conducted on 2008-10-13. The products which were exported on 2008-10-16 were the relative products and the code numbers were 2602008068 and 2602008066. The start time and finished time was not record hence there was not evidence to prove that mock recall was finished in 2 hours. Supporting documentations of production were not attached.</p> <p>II.H.3: The relative products were 7inch starch spoons 26022008074. Mock recall was conducted in 2 hours and 100% of the final products were traced. However, the batch number of the raw materials could not been traced correctly.</p> |
| III GROUNDS, BUILDING, AND EQUIPMENT | <p>III.B.5: The lights over the processing area and dressing room were not properly shielded.</p> |
| IV PEST CONTROL | <p>IV.6: Two flies were observed in the container cleaning area.</p> |

II. Positive Observations/Comments

| Category | Findings |
|----------|----------|
| | |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

Food Safety/GMP Rating Analysis

| | Category | #Points Received | # Possible Points | Percentage (%) |
|-------------|---|-----------------------------|------------------------------|---------------------------|
| I | PRODUCT SAFETY SYSTEMS | 60 | 75 | 80.0 |
| II | QUALITY SYSTEMS | 150 | 165 | 90.9 |
| III | GROUNDS, BUILDING, AND EQUIPMENT | 124 | 130 | 95.4 |
| IV | PEST CONTROL | 45 | 50 | 90.0 |
| V | EMPLOYEE PRACTICES | 40 | 40 | 100 |
| VI | RECEIVING, STORAGE, AND SHIPPING | 60 | 60 | 100 |
| VII | PLANT SANITATION | 33 | 35 | 94.3 |
| VIII | MANUFACTURING | 70 | 70 | 100 |
| | OVERALL SCORE | 582 | 625 | 93.1 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

I. Product Safety Systems

(Assessed by observation and review of records)

Hazard and Risk Assessment of Product and Processes (applicable only for food contact packaging materials)

| A. | | Rating |
|----|--|--------|
| 1. | Risk assessments, using HACCP principles, have been completed for the site's processes and products. The assessments should be reviewed at least annually or whenever there are process changes (2 elements) | 5 |
| 2. | A team, comprised of members from across the plant, has been established to conduct the risk assessments and meets on a routine basis. The team includes a person trained in a formal, external HACCP course. (3 Elements) | 5 |
| 3. | A hazard analysis, evaluating each step of the process, has been completed. It has considered biological, chemical and physical hazards for the range of uses of the packaging materials. It has also assessed the likelihood of the hazard's occurrence and the severity of its effect. (3 Elements) | 5 |
| 4. | All critical process points have been identified on the process flow chart. (1 Element) | 1 |
| 5. | Process limits have been established and are documented. (2 Elements) | 5 |
| 6. | Critical process points are monitored at regularly scheduled intervals. Monitoring procedures are documented and monitoring records are maintained. The person monitoring the CCP understands the procedures. (4 Elements) | 1 |
| 7. | Corrective action procedures have been identified and are taken when process limits are not met. Corrective action records are maintained. Product disposition is documented. (4 Elements) | 5 |
| 8. | Appropriate verification procedures have been identified and are documented, including the frequency for each verification step. Calibration tasks are documented and records of the calibration are maintained. (3 Elements) | 3 |
| 9. | The controls identified in the hazard and risk assessment must be verified at least annually through an audit conducted by someone, who is independent from the plan's development. The verification audit must be documented by a report. The verification audit results must be maintained in the site's records. (3 Elements) | 5 |

B. Product Contamination

| | | |
|----|---|---|
| 1. | NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED. (1 Element) | 5 |
| 2. | No condition or practice exists that may potentially contaminate product. (1 Element) | 5 |
| 3. | A written glass control and brittle plastic program has been established. The program addresses all glass that is to be shielded within the facility, handling of glass and brittle plastic packaging, and clean-up procedures for glass and brittle plastic breakage. (3 Elements) | 5 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

| | | |
|----|--|---|
| | | |
| 4. | A program for the control and use of knives and razor blades has been established. The program addresses how such instruments are to be controlled both in and out of the site, that disposal must be in sealed containers when no longer usable, and that snap-off knives should not be used. | 5 |

C. Employee Training

| | | |
|----|---|---|
| 1. | A program for conducting product safety, facility security, sanitation and GMP training for all employees, including new employees, has been established. Completion of this training is documented as to date(s) given, what topics were covered, and who conducted the training and is a part of the employee's records. The training should be conducted annually. Provisions for temporary employees and contractors are included in the training program. (4 Elements) | 4 |
| 2. | If the plant uses HACCP to control its products safety, employees have been trained in HACCP-related activities in their immediate work areas. This training is documented as to date(s) given and is a part of the employee's records. The training should be conducted annually. Provisions for temporary employees are included in the training program. (3 Elements) | 1 |

D. Miscellaneous

| | | |
|----|---|----|
| 1. | Facility has completed corrective actions from previous third party audits for designated audit defects. Auditor will randomly select 3 corrective actions listed from previous audits and verify that designated audit defects were not observed as being out of compliance in this audit. | No |
|----|---|----|

Possible points **75**

Actual points **60**

Percentage **80.0**

COMMENTS:

I.A.3: The HACCP plan of disposable tableware was reviewed.

I.A.4: Critical control point was not identified on the process flow chart.

I.A.6: The records from September to November were reviewed. CCP monitoring record of CCP2 (internal packaging receiving) and CCP4 (final products out bounding) did not meet the requirement in the HACCP plan. CCP3 (swab testing of food contact surface) was not conducted.

I.A.8: Verification records were not available.

I.A.9: Comment - HACCP system was established on 2008-6-1. Internal audit has not been conducted yet.

I.C.1: Facility security training was not conducted.

I.C.2: HACCP training was not conducted.

I.D.1: From the last Silliker audit, there was some non-conformity which was not corrected. They were, III.B.5: The lights over the processing area and dressing room were not properly shielded. And II.A.1: Trash was on the grass of facility ground. II.D.4: Water potability was not tested annually hence the record was unavailable.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

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II. Quality Systems

(Assessed by review of records)

| A. | QA/QC Program | Rating |
|--|---|--------|
| 1. | A written quality management program, which identifies and defines the policies and procedures for the operation and control of the site's safety and quality programs, is established, organized, and current. There is an approval process for the program and its procedures, including changes. The program identifies an individual whose job description includes responsibility for managing the overall program. (4 Elements) | 5 |
| 2. | There are written standards and specifications for raw materials, intermediate products, finished products and packaging materials. How any rework is used in products must be defined. (4 Elements) | 5 |
| 3. | There is a written record retention program for all quality and safety records, including electronic documents. The program describes what records are included, how long they are maintained and where the records will be kept. There are secure back-up procedures for electronically retained records. (3 Elements) | 5 |
| 4. | Self-audits are performed at least monthly. Copies are maintained for at least 12 months. Self-audits must include physical inspections of all areas and equipment of the facility and grounds, evaluating maintenance, sanitation, and GMP compliance. Personnel from all departments participate. Corrective actions include what is to be done, when, and by whom. (4 Elements) | 5 |
| B. Good Manufacturing Practices | | |
| 1. | A DOCUMENTED GMP PROGRAM HAS BEEN ESTABLISHED. IT COMPLIES WITH ALL APPLICABLE REGULATIONS. (1 Element) | 5 |
| 2. | Signage that identifies applicable employee hygiene requirements in languages appropriate for employees to understand is present at all production entrances. GMPs are posted for employees and visitors and/or they are given a copy of the facility's GMPs. The GMPs or company policy should specify that lack of compliance with the standards might result in disciplinary action. Corrective action procedures must be established for deviations to employee hygiene practices, and records are maintained. (4 Elements) | 5 |
| C. Pest Control | | |
| 1. | A WRITTEN PEST CONTROL PROGRAM HAS BEEN ESTABLISHED. IT MUST INCLUDE A DESIGNATED PEST CONTROL OPERATOR (INTERNAL OR AN OUTSIDE SERVICE), SCHEDULED FREQUENCY OF SERVICE, AND A CURRENT MAP, UPDATED, ANNUALLY, SHOWING THE LOCATION AND TYPE OF ALL PEST CONTROL DEVICES (INTERNAL AND EXTERNAL) (2 Elements) | 5 |
| 2. | The pest control files include documentation of all business licenses, proof of indemnity insurance and certification for all PCOs in accordance with state requirements. The files also include current MSDS and sample labels for products used. All pesticides, chemicals and compounds used meet applicable regulations and approvals (EPA, USDA, OSHA, etc.). The files are accurate, up-to-date and complete. (3 Elements) | 4 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

| | | |
|----|--|---|
| 3. | Service reports, at the frequency described in the contract or in the program, must be up-to-date and available for review. They must show the service performed, types and amounts of chemicals used, EPA or other applicable regulatory registration numbers, the locations treated, targeted pests, signs of activity, and applicable follow-up actions. (4 Elements) | 4 |
|----|--|---|

D. Cleaning and Sanitation

| | | |
|----|---|---|
| 1. | A written master cleaning/sanitation schedule lists all areas and equipment in the plant that require cleaning (including manufacturing and non-manufacturing areas and equipment) and provides the frequency of cleaning. Documentation of the person responsible for completing these tasks and the verification that they were completed are available for review. (3 Elements) | 5 |
| 2. | Facility maintains current MSDS and labels for all cleaners and sanitizers being used in an organized, accessible and easy-to-use system. Only cleaners and sanitizers authorized for product contact surfaces are used in sites manufacturing food-packaging materials. Written sanitation SOPs are established and implemented for all cleaning tasks that involve chemicals or water. They include responsibility, task to be performed, chemicals and equipment to be used (3 Elements) | 4 |
| 3. | The facility water is from a potable source. (1 element) | 5 |
| 4. | Water potability is checked at least annually. The sample should be taken from a different location in the facility each year. Records are maintained. (2 Elements) | 1 |

E. Processes for Controlling Inbound and Outbound Materials

| | | |
|----|--|---|
| 1. | A documented program has been established for approving and ongoing monitoring suppliers of raw materials, ingredients, and packaging. Facility should have a master list of approved suppliers. (2 Elements) | 5 |
| 2. | An inbound inspection program is required for the delivery all materials. Appropriate procedures or monitoring methods are used to document trailer and load condition including cleanliness. They include the examination of incoming materials for evidence of contamination (pest, microbiological, chemical and physical), damage, quality and condition. Inspection records are documented and filed, including disposition of any rejected product. (3 Elements) | 4 |
| 3. | A written program is established that evaluates incoming materials for compliance to specifications. Letters of guarantee or certificates of analysis can be provided by the supplier, but they should be verified on a routine basis, and the frequency of verification must be identified. (1 Element) | 5 |
| 4. | Food packaging manufacturers must provide documented evidence that the materials, which contact food, are of purity suitable for the intended use. The evidence can be a supplier guarantee or through prior regulatory agency approval. (1 element) | 5 |
| 5. | Food packaging manufacturers must provide documented evidence that manufactured products that contact foods will not cause odor or flavor transfer to the foods being packaged. (1 element) | 5 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

| | | |
|----|---|---|
| 6. | Food packaging manufacturers must provide documented evidence through appropriate testing that manufactured products, which contact foods, are free of pathogenic microorganisms and will not cause transfer of chemicals above the established tolerances into the food during its intended use. (2 elements) | 5 |
| 7. | A documented program has been established for verifying that finished products are ready for shipping and distribution. The procedures meet any applicable regulatory requirements and include trailer inspection and load condition. Outside storage facilities (company or independently owned) are identified, and there are defined procedures for verifying the condition and practices used at these facilities. (3 Elements) | 5 |
| 8. | ALL FINISHED PRODUCTS SHALL BE PROPERLY CODED FOR TRACEABILITY. LOT OR BATCH NUMBER RECORDS OF THE MATERIALS USED CAN BE LINKED TO THE FINISHED PRODUCTS, INCLUDING TRACEABILITY FOR INTERMEDIATE PRODUCT. (1 Element) | 5 |

F. Process Control

| | | |
|----|--|---|
| 1. | Process control points and applicable limits have been identified for all production lines. There are written procedures for monitoring the control points and the corrective actions to be taken when deviations occur. Records of all process control point monitoring and corrective actions are kept. (3 Elements) | 5 |
| 2. | All measurement equipment for monitoring process control points is calibrated according to a defined schedule. The calibration results and any corrective actions are documented. (2 Elements) | 5 |

G. Maintenance

| | | |
|----|---|---|
| 1. | A written program exists for the proper preventive maintenance of all equipment and appropriate areas of the facility. There is an established schedule and a system for verifying that the PM tasks have been completed. (2 Elements) | 5 |
| 2. | A documented program exists for employees to identify items in the facility needing maintenance. A system for reconciliation that maintenance has been completed is in place. (2 Elements) | 5 |
| 3. | Only approved food-grade lubricants are used in product contact zones, and they are appropriately stored and labeled. (2 Elements) | 5 |
| 4. | There is a written program to address that equipment, which has undergone repairs, maintenance or re-assembly, is clean and free from contamination hazards before being used in manufacturing of packaging materials. Responsibility for monitoring and verifying completion of this process is assigned. Documentation of this sanitation is required. (3 Elements) | 5 |
| 5. | Written guidelines are in place to insure food-packaging materials are protected during all maintenance activities. The guidelines must specify the actions required to protect exposed and non-exposed products and to take if contamination occurs. (2 Elements) | 5 |
| 6. | Written guidelines are established to ensure tool and parts control when repairs are taking place during production. The guidelines should include proper placement of tools and parts and should address tools used in raw areas versus finished product areas. (2 Elements) | 5 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

H. Customer Complaint and Recall Procedures

| | | |
|----|--|---|
| 1. | A documented, product recovery program that can trace the distribution of specific production lots and the source of all materials used therein has been established and is maintained. The program must comply with FDA/USDA or equivalent guidelines for conducting a product recovery. The program must define procedures for contacting customers. Contact lists for responsible employees and customers are current. Responsibility for managing the recovery program is assigned. (3 Elements) | 5 |
| 2. | Mock recalls are conducted at least every 12 months to assess the effectiveness of the program. The results of the mock recall are on file, available for review, and must include a summary page and copies of all supporting documents. The mock recall should account for 100% of the materials tested. Auditor will list the date of the last mock recall, the item tested, and the percentage of product recovered in the comments. (3 Elements) | 2 |
| 3. | Auditor is to conduct a mock recall on one item during the audit to verify that the facility can identify, track and locate 100% of finished product lots to first external customer or the raw materials or packaging to finished product lots and onto first external customer. Auditor will list the item tested and summarize results in the comments. (1 Element) | 1 |
| 4. | A documented program on how to collect and evaluate customer complaints, especially those related to product safety and quality, has been established. There is a system for notifying QA personnel of applicable customer complaints and for investigation to identify a probable cause and resolution. Customer complaints are summarized on a routine basis to identify areas for continuous improvement. (3 Elements) | 5 |

Possible points **165**

Actual points **150**

Percentage **90.0**

COMMENTS:

II.B.1: Comment –GMP program was not specially documented. However, the requirement of personal hygiene, uniform management was mentioned in other documents.

II.C.2: MSDS and approvals for the pesticide were not maintained. Comment - The facility take responsible for the pest control by itself

II.C.3: Types and amounts of pesticide used were not recorded.

II.D.2: The concentration of sanitizer which was used to sanitize the container was not documented.

II.D.4: Water potability was not tested annually hence the record was unavailable.

II.E.2: The cleaning condition of incoming products was not recorded.

II.E.8: Comment - The code reviewed was 2602008075. 260 is the code of the facility. 2008 mean Year 2008. 075 mean the 75th lot of the year.

II.H.2: Mock recall was conducted on 2008-10-13. The products which were exported on 2008-10-16 were the relative products and the code numbers were 2602008068 and 2602008066. The start time and finished time was not record hence there was not evidence to prove that mock recall was finished in 2 hours. Supporting documentations of production were not attached.

II.H.3: The relative products were 7inch starch spoons 26022008074. Mock recall was conducted in 2 hours and 100% of the final products were traced. However, the batch number of the raw materials could not been traced correctly.

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III. Grounds, Building and Equipment

(Assessed by observation and review of records)

| A. | Plant Grounds | Rating |
|----------------------------|--|---------------|
| 1. | Roads, yards, grounds, and parking lots are maintained in neat and good condition, and free of trash and litter. Grass and weeds are cut to minimize harborage areas for pests and are not within 20 feet of the building. Ornamental landscaping must not provide harborage next to the building. (3 Elements) | 4 |
| 2. | Plant grounds have adequate drainage to prevent pooling water that can serve as a source of contamination by seepage, foot-borne filth, or provide a breeding place for pests. There should be no evidence of pooled water and no standing water should be observed. (2 Elements) | 5 |
| 3. | Equipment and pipes stored on plant grounds are at least 20 feet away from the buildings or at least 6 inches above the ground and in an organized manner to prevent breeding areas and harborage for pests. Any pipes within 20 feet of the building must have closed ends. (2 Elements) | 5 |
| 4. | Litter and waste are properly stored in enclosed containers. All waste is removed from the premises at appropriate intervals and in such a manner to prevent spillage and litter. The dumpster and the dumpster areas are cleaned on a regularly scheduled basis and are clear of debris and spilled product. (3 Elements) | 5 |
| 5. | The loading dock areas are clear of debris and spilled products. Equipment or items stored on the dock should be clean and organized. All bumpers, levelers and shelters are in good repair and clean. (3 Elements) | 5 |
| B. Plant Facilities | | |
| 1. | Plant buildings and roofs are suitable in construction and designed to facilitate maintenance and sanitary operations. There are no roof leaks. (2 Elements) | 5 |
| 2. | Interior floors, walls, and ceilings are constructed of materials that can be adequately cleaned and maintained in good repair. (3 Elements) | 5 |
| 3. | Adequate screening or other protection is provided for defense against pests. Doors and windows should be closed or screened with no gaps greater than 0.25 inch. Cracks and crevices have been sealed to prevent entrance or harborage of pests. Drains protruding from outer building walls must be screened. (3 Elements) | 4 |
| 4. | Aisles and workspaces between processing equipment and walls are unobstructed and of adequate width to permit employees to perform their duties and protect against contamination. (1 Element) | 5 |
| 5. | All glass and brittle plastic in receiving, shipping, production, and storage areas of the facility are shielded or protected against breakage. (1 Element) | 1 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

| | | |
|-----|--|---|
| 6. | There is adequate lighting in all areas of the facility, including processing, storage, receiving, shipping, locker rooms, restrooms, and break areas. (1 Element) | 5 |
| 7. | Adequate ventilation or control equipment is in place to minimize odors and vapors. Fans and other air-blowing equipment are operated and maintained to minimize the potential for contaminating packaging materials. (2 Elements) | 5 |
| 8. | Water lines and hoses are protected against backflow or cross-connections between potable and waste water systems in areas where potential backflow conditions exist. (1 Element) | 5 |
| 9. | Hand wash stations are appropriately located near the production areas. Hand washing stations are provided with antibacterial soaps, warm water and single use towels or a suitable drying device at all times. Signs in the appropriate languages direct employees to wash and sanitize their hands before they start work, after each absence from their workstation and at any time their hands may become soiled or contaminated. (3 Elements) | 5 |
| 10. | Break areas, locker rooms, and restrooms are maintained in a clean, sanitary condition. They are equipped with proper ventilation and self-closing doors. Drains function properly and are free of standing water. Break areas are separated from the production areas and are free of plant garments, aprons, etc. Ladies' restrooms must have covered trash receptacles. Hand washing signage is posted in all of these areas. (3 Elements) | 5 |
| 11. | Ladders and walkways over exposed product lines are protected to prevent potential contamination. Appropriate kick plates are installed as necessary. (1 Element) | 5 |

C. Equipment

| | | |
|----|--|---|
| 1. | All plant equipment is designed and constructed to prevent contamination of products. Contact surfaces and seams in plants manufacturing food-packaging materials are smoothly bonded. Wooden equipment and / or wooden surfaces are not used in food-packaging production areas. (2 Elements) | 5 |
| 2. | Equipment is maintained in good repair and is being used for the task for which it was intended. Contact surfaces are corrosion resistant and able to withstand the processing environment. No mold or rust is observed on equipment. (2 Elements) | 5 |
| 3. | Temporary repairs of equipment will not inhibit proper sanitation or be made with materials that contribute in any way to the contamination of the product or environment. (2 Elements) | 5 |
| 4. | Soiled or broken pallets are not used. (1 Element) | 5 |
| 5. | Vehicles and equipment used for moving raw materials and finished packaging throughout the facility are cleaned and maintained in good condition. Fork truck or hand truck batteries are stored segregated from packaging materials. (2 Elements) | 5 |

D. Facility and Product Defense/Security

| | | |
|----|---|---|
| 1. | The facility has a program to restrict areas of the plant to authorized personnel only. The facility has systems in place on how to alert personnel about the restricted areas. All access points are secured or monitored according to the program. (3 Elements) | 5 |
|----|---|---|

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| | | |
|----|---|---|
| 2. | All visitors must be in compliance with the facility's program for food defense. The visitor policy is posted or provided to all visitors and non-employees. (2 Elements) | 5 |
| 3. | All incoming trailers are observed to be properly secured. Receiving records document the delivery driver identification. Records document that less than full loads are managed according to the facility policy. (3 Elements) | 5 |
| 4. | Records and observations confirm outbound trailers are properly secured and LTL controls are being followed. Driver identification is documented on shipping records. (2 Elements) | 5 |
| 5. | Facility has developed a standard procedure for screening all potential employees. This procedure could include checking references, drug testing, or criminal background checks. | 5 |

| | |
|------------------------|-------------|
| Possible points | 130 |
| Actual points | 124 |
| Percentage | 95.4 |

COMMENTS:

III.A.1: On day of audit, no waste bins were available on the plant ground; garbage (empty milk and bread container) were left directly on the floor.

III.B.3: Gate of the production area was not properly closed.

III.B.5: The light in the processing area and locker were not properly guarded.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

IV. Pest Control

(Assessed by observation)

| | | Rating |
|-----|---|---------------|
| 1. | There are an adequate number of interior pest control devices, spaced at consistent intervals (typically 20-40 ft.) around the interior perimeter of the facility, including mechanical stations within 10 ft. of both sides of doors leading to the exterior, including dock doors. Pest control devices must also be used in dry storage areas, coolers, locker rooms, and break areas. These devices must be located so that they do not contaminate product, packaging or equipment. A number and/or color code must correspond with the master identification map. Bait is not used inside the facility. (3 Elements) | 4 |
| 2. | There are an adequate number of tamper-resistant exterior pest control stations spaced at appropriate intervals (usually 25-50 ft.) around the building's exterior perimeter. Stations are secured in place next to the building, closed, and a key or a tool (e.g., Allen wrench) is required to open. Bait must be anchored inside the stations to avoid being removed by a rodent or floating away during heavy rains. These devices must be located so that they do not contaminate product, packaging or equipment. The number and location code must correspond with the master identification map. (4 Elements) | 5 |
| 3. | Live catch devices and glue boards are checked at least twice monthly. Exterior bait stations are checked at least monthly. The PCO must sign and date the labels on all devices. These labels should be on the inside of the devices, unless they are mechanical devices with a clear window. (4 Elements) | 5 |
| 4. | All pest control devices must be appropriately positioned and located so that they do not contaminate product, packaging or equipment. Bait must not be used in interior areas. All pest control devices are clean and functioning properly. Bait in the stations has a fresh appearance. (4 Elements) | 5 |
| 5. | There is no evidence of external pest activity. (2 Elements) | 5 |
| 6. | There is no evidence of internal pest activity. (1 Element) | 1 |
| 7. | THERE IS NO EVIDENCE OF DECOMPOSED PESTS ANYWHERE IN THE INTERIOR OF THE FACILITY, INCLUDING IN PEST CONTROL DEVICES. (1 Element) | 5 |
| 8. | THERE IS NO EVIDENCE OF INSECTS, SPIDERS, RODENTS OR BIRDS ON OR IN ANY FOOD PACKAGING MATERIALS (1 Element) | 5 |
| 9. | Insect light traps (ILTs) and flying insect traps may be used. Placement must be according to manufacturer instructions and comply with applicable regulatory processes. If instructions are not available, ILTs must be more than 4 feet off the ground, at least 10 ft. from exposed product, packaging, or equipment. They must be located to avoid interference with plant operations. They must be cleaned and maintained on a scheduled basis. Bulbs must be changed at least annually, and shatter protection must be in place. There must be a schedule for replacing the sticky boards in sticky-type ILTs. (4 Elements) | 5 |
| 10. | Avicides are prohibited inside the facility. If used on the exterior, avicides must be used according to program and label requirements. (1 Element) | N/A |

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|-----|--|---|
| | | |
| 11. | All pesticides, chemicals and other compounds stored on site for pest control are properly labeled and kept in locked, secured areas away from any food storage or processing areas. (1 Element) | 5 |

Possible points 50

Actual points 45

Percentage 90

COMMENTS:

IV.1: Code on the pest control device was not corresponding with the code on the map.

IV.6: Two flies were observed in the container cleaning area.

IV.10: Comment - Avicides were not used in the facility.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

V. Employee Practices

(Assessed by observation)

| | | Rating |
|----|---|--------|
| 1. | Employees follow written programs on employee hygiene practices, maintain personal cleanliness, and use hygienic practices at all times. (2 Elements) | 5 |
| 2. | Exposed jewelry, except for a plain wedding band, and other objects that might contaminate products like artificial nails and body piercings, are not worn. Objects, such as pens, thermometers, etc. that could fall into food, equipment or containers, are not carried in above-the-waist pockets. (2 Elements) | 5 |
| 3. | Hairnets or other appropriate restraints are properly worn in food packaging production areas, as designated by facility's employee hygiene practices. All employees with facial hair, who work in production areas, should wear beard covers. The facility's employee hygiene policy must address moustaches, including definition for acceptable appearance and when coverage of the moustache is required. (3 Elements) | 5 |
| 4. | Garments worn in the facility (uniforms, aprons, frocks, lab coats, etc.) are clean and appropriate for the operation and do not contribute to potential product contamination. All garments should have snaps not buttons. Outer garments like frocks and aprons are not worn in restrooms, break areas or outside of the facility. (2 Elements) | 5 |
| 5. | Eating, chewing gum, drinking and use of tobacco are confined to designated areas outside of the processing and storage areas. (3 Elements) | 5 |
| 6. | No personal items are noted in food handling areas. Employees have a separate area away from the processing and storage areas for storing their personal items. This area is kept in a neat, clean, and well maintained. Food must not be stored in lockers or consumed in locker rooms (3 Elements) | 5 |
| 7. | EMPLOYEES WITH OBVIOUS SORES, INFECTED WOUNDS, OR OTHER INFECTIOUS ILLNESSES SHALL NOT BE ALLOWED TO HAVE DIRECT CONTACT WITH EXPOSED FOOD PRODUCTS OR PRODUCTION / STORAGE AREAS. (1 Element) | 5 |
| 8. | Employees are observed washing their hands after activities that may have contaminated them. Activities can include but are not limited to: using the restrooms; after breaks; prior to entering production areas; prior to handling product; prior to touching product contact; after handling garbage. When disposable gloves are being used they must be changed when they are damaged, after any absence from the workstation, or when potential contaminates are handled. Non-disposable rubber gloves must be washed and sanitized frequently, after breaks, and/or handling potential contaminates. (2 Elements) | 5 |

| | |
|------------------------|------------|
| Possible points | 40 |
| Actual points | 40 |
| Percentage | 100 |

COMMENTS:

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

VI. Receiving, Storage and Shipping

(Assessed by observation and review of records)

| A. Receiving and Shipping | | Rating |
|----------------------------------|---|---------------|
| 1. | All materials should be properly identified and labeled. They should include the date of receipt or a verifiable system for first in/first out (FIFO) or first expired/first out (FEFO) product rotation. Materials in storage must be traceable into the production system by the vendor's lot number or the processing facility's assigned system. (2 Elements) | 5 |
| 2. | Shipping and receiving areas are clean, organized, and free of debris and spilled products. Equipment stored on the dock (load bars, bulkheads, etc.) should be organized and in good repair. (2 Elements) | 5 |
| 3. | Transport vehicles used (incoming or shipping) are clean and free of any pest contamination. They are in sound condition and capable of preventing any product contamination. (2 Elements) | 5 |
| 4. | If ingredients are received in bulk (tanker, rail, etc.), transfer procedures must protect the product from contamination. Hoses must be clean, capped and stored off the ground, and connection ports into the building must be capped and locked when not in use. (3 Elements) | 5 |

| B. Storage | | |
|-------------------|---|---|
| 1. | Storage practices must be appropriate for the items being stored. Sufficient space (typically 18 inches) is maintained along all walls to permit proper cleaning and inspection for pest activity. No materials should be stored within this space. All materials are stored at an adequate height (6 inches or pallet height) above the floor, except for roll stocks of paper, paperboard, or plastic. Easy access to all areas around the walls for cleaning and inspections is provided. (2 Elements) | 5 |
| 2. | (FIFO) and or (FEFO) rotation practices are used and documented for all raw materials, in-process materials, and finished packaging. (3 Elements) | 5 |
| 3. | All stored materials are clean, dry, intact, in good condition, and free from contamination or spoilage. They are properly packaged or covered to prevent contamination of other products. . They are stored under appropriate conditions. (3 Elements) | 5 |
| 4. | Any damaged materials are immediately segregated and repackaged or properly discarded. All materials rejected or on hold are properly identified, adequately segregated, and protected from contamination. Hold storage areas are clearly identified. (3 Elements) | 5 |
| 5. | Storage or transfer containers for materials, which were removed from their originally labeled packages, must be clearly labeled. Food and packaging containers manufactured by the facility should not be used to store items. (2 Elements) | 5 |
| 6. | Inks, sealants, adhesives, and waxes are stored covered in areas having adequate ventilation. All containers must be properly labeled. (2 Elements) | 5 |
| 7. | Materials received from another plant for further manufacturing or printing must be labeled, stored in their original containers and sealed until use. Partially used containers of materials must be resealed, when placed back into storage. | 5 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

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| | | |
|----|---|---|
| 8. | Dry storage areas are maintained in a clean and sanitary manner. All spills are immediately cleaned up, and there is no evidence of spills, trash or other litter within the facility. (2 Elements) | 5 |
|----|---|---|

Possible points **60**

Actual points **60**

Percentage **100**

COMMENTS:

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

VII. Plant Sanitation

(Assessed by observation and review of records)

A. Cleaning Equipment and Chemicals

Rating

| | | |
|----|--|---|
| 1. | Only cleaners and sanitizers authorized for use with product contact surfaces must be used in plants manufacturing food-packaging materials. They are used for their intended purposes and stored in secure, locked areas away from any manufacturing or storage. Chemicals that are connected to dilution devices do not have to be in a locked area, if their location does not pose a contamination risk to packaging, or equipment. (2 Elements) | 3 |
| 2. | Containers, brushes and applicators used for cleaning and sanitizing product contact surfaces in plants manufacturing food-packaging materials are color coded or labeled to properly identify them for their intended use and distinguish them from tools used for structural cleaning. If a color-coding system is used, appropriate signage describing the system in languages appropriate for employees to understand is posted. (2 Elements) | 5 |
| 3. | Cleaning equipment is properly stored (when not in use) and is not stored in manufacturing areas. The equipment is non-porous and in good repair. (2 Elements) | 5 |

B. Cleaning, Sanitation and Housekeeping Procedures

| | | |
|----|---|---|
| 1. | Cleanliness is maintained in all non-processing and non-product contact areas. The cleanup of spills and accumulation of materials is conducted on a continuing basis during production. (2 Elements) | 5 |
| 2. | Cleanliness is maintained on all product contact surfaces. Significant accumulations of product build-up are not observed during production. (2 Elements) | 5 |
| 3. | Knives, saws, trimmers, and other tools used in manufacturing and packaging are adequately cleaned and sanitized as necessary throughout the production and at the end of the production period. (1 Element) | 5 |
| 4. | Proper cleaning and sanitizing procedures are followed and are accessible to employees needing them. Equipment is disassembled as necessary to insure thorough cleaning. Results are being documented to verify cleaning and sanitation was completed per procedure. (3 Elements) | 5 |

Possible points 35

Actual points 33

Percentage 94.3

COMMENTS:

VII.A.1: A pack of washing powder was observed in the processing area and was not locked.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

VIII. Manufacturing

(Assessed by observation and review of records)

| A. | Manufacturing | Rating |
|-----------|---|---------------|
| 1. | If roll stocks of material are stored on the floor, the ends of the rolls are trimmed and several turns of the material are discarded prior to use to prevent contamination. Staged packaging materials are kept clean, dry and free from contamination during manufacturing. (2 Elements) | 5 |
| 2. | Regrinding of plastic or shredding, packaging or baling of paper trim are done away from manufacturing areas, and efforts are in place to control excess dust and spillage. (2 Elements) | 5 |
| 3. | Single service containers must not be reused. They must be discarded when empty. (2 Elements) | 5 |
| 4. | Rolls, dies, and support equipment must be stored at an adequate height above the floor to prevent contamination. (1 Element) | 5 |
| 5. | Temperature sensitive operations are monitored to insure proper temperature controls are maintained. (1 Element) | 5 |
| 6. | Food packaging materials must not be manufactured on equipment used for non-food materials, unless the equipment has been adequately purged and cleaned of the non-food materials. Documentation of the cleaning must be maintained. (2 Elements) | 5 |
| 7. | Appropriate process control points and limits are observed being monitored on a regular basis. The monitoring results are being recorded, Employees questioned during the audit are aware of and understand how to monitor their control points. Auditor will comment on what was asked and the worker's response. (2 Elements) | 5 |
| 8. | Corrective actions are being taken as required and documented, whenever a process control point is outside of the established criteria or limits. Auditor will review random online monitoring and corrective action records and comment on compliance. (1 Element) | 5 |
| 9. | All manufacturing operations are performed to protect against contamination, including adequate physical protection from contaminants that could drip, drain, or fall into the products. (1 Element) | 5 |
| 10. | No equipment used is observed to have the potential to contribute to the contamination and/or adulteration of product with physical, chemical or microbial contaminants. (1 Element) | 5 |
| 11. | Glass and brittle plastic packaging must be controlled in manufacturing areas. Controls are in place, when glass or brittle plastic containers are used for the storage of raw materials. (2 elements) | 5 |
| 12. | When magnets, screens, sieves, etc. are used in the manufacturing lines, they must be inspected on a scheduled basis to insure proper performance. Inspection records must be documented and maintained. (2 Elements) | 5 |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.

| | | |
|-----|--|---|
| 13. | Any compressed air used in manufacturing is filtered to prevent contamination. There is a schedule for inspecting the filters, and the filters are not located over the product contact surfaces. (3 Elements) | 5 |
| 14. | Maintenance tools, gloves, rags and other miscellaneous materials are not found on or near manufacturing equipment. Tools used for equipment adjustment must be clean and in good repair (no rust, etc.). (2 Elements) | 5 |

Possible points 70

Actual points 70

Percentage 100

Comments:

VIII.A.7: Comment - The temperature of molding was asked and the responsible person could answer the question correctly.

VIII.A.8: Comment - Non-conformity was not observed during the audit.

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.



Food Safety and GMP Assessment Rating System

This rating system describes a food plant's level of compliance with recognized food safety and Good Manufacturing Practices. The point system and definitions are objective guidelines for evaluating the plant's compliance with the assessed standards and are intended to assure consistency in rating. **Comments are provided for any standard rated lower than 5.**

| Number of elements in question | >3 elements missed | 3 elements missed | 2 elements missed | 1 element missed | All elements fulfilled | |
|--------------------------------|--------------------|-------------------|-------------------|------------------|------------------------|--|
| >3 | 1 | 2 | 3 | 4 | 5 | Score Given To Question |
| 3 | NA | 1 | 2 | 4 | 5 | |
| 2 | NA | NA | 1 | 3 | 5 | |
| 1 | NA | NA | NA | 1 | 5 | |

This rating system is an objective guideline. Auditors may use their discretion regarding scoring, considering the severity of food safety issues and numbers of observations of an issue noted.

Each plant will receive a total overall score based on the ratings of the individual standards in the audit form. The minimum acceptable numerical score may vary depending upon the company requiring the audit.

| Rating | Numerical Score |
|-----------|-----------------|
| Excellent | 95% or higher |
| Good | 90 – 94 % |
| Fair | 85 – 89 % |
| Poor | < 85% |

Items in CAPS and bold are automatic failure questions if a "1" is scored by auditor.