AUDIT REPORT

Food and Non-Food Packaging Materials Audit

for:

World Centric Wheat Straw Products factory

Audit Date: August 15, 2017

Auditor Name: Sophy Ge

Mérieux NutriSciences Certification LLC

Audit Summary:

Company: **Parent Company:**	redacted NA	**Audit date:** **Start/End Time:** **# of hrs in Plant/Records:**	2017.08.15 8:30-17:00 3hours/4hours
Plant address:	redacted	**Plant phone & fax numbers:**	redacted
Silliker Auditor: **(name & contact info):**	Sophy Ge, Leo Xu (Shadow) Sophy.ge@mxns.com Leo.xu@mxns.com	**Company Associate(s) accompanying auditor: (name & contact info):**	_____
Products produced by plant:	Paper pulp tableware	**Audit Description:**	Silliker Packaging Audit
		Food Safety Modernization Act:	NA
Audit Score:	95.4	**Rating:**	Generally meet audit expectations
Follow-up audit required:	NA	**Reason for follow-up audit:**	NA
Company associate(s) with whom audit findings were reviewed:	g		

Auditor Signature:	Sophy Ge

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

Plant Description

Redacted - ----------Co., Ltd. which was established in 2008. The main products were paper pulp tableware. The facility has 205,000 square meters for paper pulp tableware processing and storing. There were 2 plants with 14 production lines, and 2 warehouses for raw material and finished product storing. The processes of pulping, molding & shaping, trimming and packing were manufactured in different and segregated workshops. There were 1,100 operators working in 3 shifts and 50 management staffs in 1 shift, 8 hours per day, and 5 working days averaged per week. The cleaning and sanitization of workshop was conducted before and after the shift. The pest control service was provided by professional pest control company named Ecolab.

The company passed the Silliker Packaging Audit last year and also got certificates of HACCP, ISO9001, ISO18001 and BRC with the previous name. And new audits for these certificates were in planning. The quality and product safety management system was running effectively based on the on-site observing and document review. The environment was keeping clean, equipment were well maintained.

Summary of Audit Findings

Major Non-conformances:

I. Product Safety Systems

I.A5. There were 4 UV lamps working in the sterilizer, with the sterilizing capability being verified in 2014. While the inspection, whether all the 4 UV lamps working, was not required in sterilizing process (CCP3). Actually, the UV lamps were inspected weekly by the operator; however, there was no inspection between June 20 and July 4.

VIII. Manufacturing

VIII. A10 The plastic bag inside the basket for containing finished product after inspection or after metal detecting was damaged with part missing.

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Positive Observations/Comments

Staffs were very cooperative during audit.

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Food and Non-Food Packaging Materials Audit Rating Analysis

	Category	#Points Received	# Possible Points	Percentage (%)
I	PRODUCT SAFETY SYSTEMS	84	90	93.3
II	QUALITY SYSTEMS	88	90	97.8
III	GROUNDS, BUILDING, EQUIPMENT AND MAINTENANCE	53	55	94.5
IV	PEST CONTROL	23	25	92.0
V	EMPLOYEE PRACTICES	38	40	95.0
VI	RECEIVING, STORAGE, AND SHIPPING	60	60	100
VII	PLANT SANITATION	43	45	95.6
VIII	MANUFACTURING	64	70	91.4
IX	FACILITY AND PRODUCT DEFENSE	20	20	100.0
	OVERALL SCORE	472	495	95.4

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I.Product Safety Systems

(Assessed by observation and review of records)

A.	**Hazard and Risk Assessment of Product and Processes** (applicable only for food contact packaging materials)	**Rating**
1.	A multi disciplinary team lead by at least one person formally trained in HACCP has been established. The team meets on a routine basis and has documented the preliminary plan developmental tasks of product description, intended use and consumer, and method of distribution. (2 elements) • A team is multi-disciplinary and led by one person formally trained in HACCP. • Team meets on a routine basis and has documented the preliminary plan task of product description, method of distribution, intended use and consumer.	5
2.	A flow chart must be prepared for each separate process and include all inputs, such as raw materials, ingredients, packaging, water, steam, etc, and all outputs such as finished product, recycled pathways, and by-products. The charts must be revised when any changes are made to the process and verified by the HACCP Team. (3 elements) • The flow chart identifies each step in the process. • Verification of the accuracy of the flow chart including changes is documented by a date and signature of the verifier. • Auditor on site verification of the flow chart confirms accuracy of site's verified flow chart.	4
3.	A written hazard analysis must be available and identify the significant product safety hazards associated with the process, products, raw materials and ingredients covered by the HACCP plan and reasonably likely to occur. The hazard analysis must be based on scientific and/or technical data and include the specific hazard relevant to the products and processes, including allergen cross contamination when appropriate. (1 element) • A Hazard Analysis focused on product safety hazards reasonably likely to occur has been completed for each step in the process.	5
4.	Critical Control Points are identified on the process flow chart as well as in the documented HACCP plan. Each CCP must have scientifically validated critical limits and monitoring procedures. (2 elements) • Critical control points are identified on the process flow chart and in the HACCP plan. • Critical limits that have been scientifically set and validated are specifically listed for each CCP.	5
5.	Critical control points are monitored at regularly scheduled intervals that ensure control of the process. Monitoring procedures are documented and monitoring records are maintained. The person monitoring the Critical control Points understands the procedures. (2 elements) • Critical Control Points are being monitored per the plan at regular intervals by person(s) that understand the process to ensure controls are being maintained. • Monitoring records are maintained and accurately reflect the findings.	1
6.	Employees who are involved in the HACCP plan have been trained in the 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. (2 elements) • Employees responsible for HACCP have been trained, are aware of basic HACCP elements in their area and undergo annual refresher training. • Records of the training are kept and include the person responsible for the training, the topic covered, who was trained, and evidence that the training was effective.	5
7.	Corrective action procedures have been identified for each Critical control Point, and include all steps needed to identify, quantify and segregate affected product. Records are maintained and include corrective actions, product disposition, root cause analysis, and actions to prevent repeat occurrence. (2 elements) • Corrective action procedures have been identified and include all steps needed to identify, quantify and segregate affected product. • Corrective action records are maintained and include documentation on applicable product disposition, root cause analysis and preventive actions.	5
8.	**CORRECTIVE ACTION PROCEDURES ARE FOLLOWED WHEN CRITICAL LIMITS ARE NOT MET. (1 element)** • **CORRECTIVE ACTION PROCEDURES ARE FOLLOWED WHEN CRITICAL LIMITS ARE NOT MET.**	**5**

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9.	Appropriate verification procedures have been identified and are documented, including the frequency and responsibility for each verification step. Calibration tasks are documented and records of the calibration are maintained. All verification activities are documented. (3 Elements) • The appropriate verification activities and frequencies have been identified and are described in the HACCP plan. • Procedures for the calibration tasks have been developed. • Verification records show compliance with the plan.	4
10.	All records related to performing HACCP tasks and reviewing HACCP records are appropriately signed/initialed and dated. (1 element) • All HACCP records are signed / initialed by the individual performing the task and the individual reviewing the records.	5
11.	At least annually or whenever there have been process, product, raw materials or ingredient changes, the HACCP plan must be re-verified. Verification includes all activities other than monitoring that determine the accuracy and validity of the HACCP plan and PRPs and ensure they are operating in accordance to plan and are controlling the hazards. The reassessment team can be internal or external to the operation and must include at least one person that has been trained in HACCP. Results of the reassessment must be documented by a report that is maintained in the HACCP plan's historical records. (3 elements) • Reassessments of the HACCP plan are conducted at least annually, or when changes occur to ensure plan is still controlling identified hazards. • Re assessment team is internal or external and includes at least one person that has been trained in HACCP. • Results of the reassessment must be documented in a report that is maintained in the HACCP plans historical records.	**5**

B. Product Contamination (Observation)

1.	**NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED. (1 Element)** • **NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED.**	**5**
2.	No condition or practice exists that may potentially contaminate product, or could lead to product contamination. (1 Element) • No condition or practice exists that may potentially contaminate product, or could lead to product contamination.	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. (1 Element) • The glass and brittle plastic program includes all glass that needs to be shielded and for glass and brittle plastic packaging for raw materials and finished products. Clean up procedures clearly describe how breakage in all areas will be managed.	5
4.	A program for the control and use of cutting tools, i.e. 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. (2 Elements) • Cutting tools used in processing equipment or by personnel are controlled. • Snap off style knife blades are not used in the processing areas.	5
5.	Only approved food-grade lubricants are used in product contact zones, and they are appropriately stored and labeled. (1 Element) • Only food grade lubricants that are properly labeled and stored are used in food grade material product zones.	5

C. Allergen/Non Food Contact Material Management (applicable only for food contact packaging materials)

1.	**THE FACILITY HAS DEVELOPED A PROGRAM TO PREVENT CROSS-CONTACT OF ALLERGENS and/or non food grade materials. (1 Element)** • **THE FACILITY HAS DEVELOPED AN ALLERGEN/NON FOOD GRADE MATERIAL PROGRAM TO CONTROL CROSS CONTAMINATION RISKS.**	**5**

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

2.	A master listing of raw materials used by the plant has been developed and is documented. (2 elements) • There is a master list of allergens and non food grade materials used in the facility. • Production records have allergen and non food grade materials properly identified.	**N/A**
3.	The program includes documented control procedures for allergen and non food grade materials in all areas of the facility including,: separation in storage, clean up procedures for spills, controls for utensils and storage containers, which include proper labeling when ingredients or products are not in original containers. (1 element) • The allergen and non food contact material program includes documented control procedures for all areas/processes of the facility.	**N/A**
4.	Production scheduling is done to ensure allergens or non food contact materials are run prior to change-over and that specific change-over procedures are developed for allergen and non food grade materials. Verification of change-over activity is conducted. Records of change-over and verification activities are maintained. (2 elements) • Allergens or non food grade materials are observed to be controlled through production schedules and detailed SSOPs. • There are records of changeover including verification that allergen or non food contact removal practices took place.	**N/A**
5.	Facility has a written procedure on handling the rework of allergens and non food contact materials. It includes proper labeling of rework and control of rework back into process and/or product. (1 element) • Rework or work in process that contains allergens or non food grade materials must be labeled to ensure the allergen or non food grade ingredient is identified and only used in like containing product.	**N/A**
6.	Facility has validated the cleaning procedures that directly affect the cross contamination points of allergens and non food contact materials. (1 element) • Facility has validated equipment and area cleaning procedures to ensure the removal of allergens or non food grade materials.	**N/A**

D. Employee Training

1.	A program for conducting product safety, facility and product security, GMP and sanitation 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. (3 Elements) • Orientation training occurs for all new employees and temporary employees. • Annual training exists for all employees, and temporary employees are included. • Records of the training are kept and include the person responsible for the training, the topic covered, who was trained, and evidence that the training was effective.	5

E. 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 non-conformities were not observed as being out of compliance in this audit. (1 Element) • Facility has made progress in completing corrective actions identified in previous third party audits.	Yes

Possible points	**90**

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Actual points	**84**
Percentage	**93.3**

COMMENTS:

I.A.1- Comment: A multi-disciplinary HACCP team was established, HACCP Plan TH/JH-2007 updated on 2017.3.20. HACCP team leader Liwei was trained on 2015.12.7-8 by Zhonganxin Certificate , other members were trained on 2017.04.09.

I. A2. HACCP plan was updated on March 1, 2017, while the flow chart was verified by the HACCP team on March 20, 2017, and CCP was not identified on the flow chart in the HACCP plan.

I.A.4- Comment: There was 2 CCPs identified in HACCP plan. CCP1 was UV sterilizing for control micro, operator will check the sterilizing time more than 8 seconds each hour. CCP2 was metal detecting for preventing metal hazard; the operator inspected the metal detector with the test card (Fe >= 0.8mm) every 1 hour during production.

I. A5. There were 4 UV lamps working in the sterilizer, with the sterilizing capability being verified in 2014. While the inspection, whether all the 4 UV lamps working, was not required in sterilizing process (CCP3). Actually, the UV lamps were inspected weekly by the operator; however, there was no inspection between June 20 and July 4.

I.A9. There was no calibration requirement for time-meter in sanitizing process (CCP2).

I.A.11- Comment: The CCPs monitoring records were reviewed during audit, and all records were signed by monitor and reviewed by Workshop Manager.

I.C.2-6 -Comment: There was no food allergen and non-food contact product manufactured in the plant.

I.E1 - Comment: The last SILLIKER GMP audit was conducted on August 22, 2016, and all the corrective actions were closed.

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II.Quality Systems

(Program and 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. The program includes a procedure for approval and communication of changes to policies and procedures. The program includes an organization chart and identifies an individual whose job description includes responsibility for managing the overall program. Records showing compliance to programs are easily located during the audit. (3 elements) • A current defined quality program is in place and includes an approval process for changes. • The quality program includes a current organization chart and identifies the individual whose job description includes responsibility for overall program management. • The program is well organized and records can be easily located during the audit.	5
2.	There are written standards and specifications for raw materials, intermediate products, finished products including finished products' packaging. How any rework is used in products must be defined. (2 elements) • There are written standards and specifications for raw materials, intermediate products, finished product and finished products' packaging. • Procedures for how rework is used in the process and finished products, including allowable amounts, is clearly defined in finished product specifications or other documents.	5
3.	There is a written record retention program for all quality and food 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. (2 elements) • There is a written record retention program for all quality and food safety records that describes records to be included, how long they are maintained and where the records will be kept. • There are secure back-up procedures for electronically retained records.	5
4.	Facility 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. (2 elements) • Audits of the entire facility and equipment are completed at least monthly with copies maintained for at least 12 months and evidence of corrective action resolutions. • The audits are done by a team to ensure cross functional participation and ownership of the program	5

B.	Processes for Controlling Inbound and Outbound Materials	
1.	A documented program has been established for approving of domestic and international suppliers of raw materials, intermediate products, and finished product packaging. It must meet all applicable, current regulatory requirements. Facility should have a master list of approved suppliers. (1 element) • Facility has a master list of suppliers and procedures for the approval of all suppliers.	5
2.	An inbound delivery inspection program is required for the ongoing monitoring of all raw materials, intermediate products, finished products' packaging at receipt. Appropriate procedures or monitoring methods are used to document load conditions, including cleanliness of the delivery containers or trailers. 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. (2 elements) • There is an inspection program for ongoing monitoring of inbound deliveries of materials that includes all appropriate questions, such as those listed in the audit question. • Inspection records for the monitoring programs are documented, filed, and include actions and disposition of rejected products.	5

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3.	A written, ongoing monitoring QA program is established to evaluate raw materials, ingredients and packaging for compliance to specification. Packaging includes product labels. When letters of guarantee are used to assure compliance, the plant has identified the frequency for their renewal and verification. Raw and packaging materials and ingredients that are monitored via a certificate of analysis upon receipt must be identified on a master list, and the site must have a predefined system for verifying the accuracy of the COA results against the specification. (2 elements) • Facility has a documented ongoing monitoring QA program to evaluate ingredient, raw materials, and packaging compliance to specification. • The frequencies for renewal and verification for letters of guarantee must be identified. • There must be a predefined system to verify accuracy of the COAs for materials accepted based on COA reports.	5
4.	Food packaging manufacturers must provide documented evidence that the materials, which contact food, are of a purity suitable for the intended use. The evidence can be a supplier guarantee or through prior regulatory agency approval. (1 Element) • The raw materials, ingredients and materials used to produce food contact packaging must be of a purity such that the food contact packaging produced has no adverse effect on the food it contains. Documented evidence can include a continuing letter of guarantee, certificate of conformance to the packaging specification, certificate of compliance with the regulatory requirements (if applicable) or reference to a regulatory approval statement, listing or register.	5
5.	Packaging manufacturers must provide documented evidence through appropriate testing that manufactured products, which contact foods, are free of pathogenic microorganisms and will not permit the migration of chemicals, resulting in a transfer of odors or flavors above the established tolerances into the food during its intended use. (1 Element) • Validated studies and/or test results must be documented to ensure that food contact packaging is not a source of potential pathogenic contamination and to ensure that odor or flavor migration from packaging to food is within the customer defined and regulatory (if applicable) limits.	5
6.	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. (2 elements) • The procedure for verifying that finished products are ready for distribution is established and being practiced to ensure specification compliance and load condition, including product rotation and shelf life. • There are procedures for use of outside storage locations with current records specification compliance and load condition, including product rotation and shelf life.	5
7.	**FINISHED PRODUCTS CAN BE TRACED TO THE LOT NUMBERS OR CODE DATES OF ANY INGREDIENTS, RAW MATERIALS AND REWORK USED. (1 element)** • **FINISHED PRODUCTS CAN BE TRACED BACK THROUGH THE MANUFACTURING PROCESS TO THE INGREDIENTS, RAW MATERIALS AND ANY REWORK USED.**	**5**
8.	Finished products can be traced to the food contact/primary packaging materials used. (1 element) • Finished products can be traced back through the manufacturing process to the product contact/primary packaging used.	5

C. 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. (2 elements) • Facility has identified process control points with appropriate criteria controls. • Written procedures and records for monitoring process control points. Corrective actions are identified and taken when process step is out of control and for corrective actions.	3
2.	All measurement equipment for monitoring process control points (e.g., thermometers, scales, pH meters, refractometers) is calibrated according to a defined schedule. The calibration results and any corrective actions are documented. (1 element) • There is a set schedule for calibrating equipment and records of the calibration results and corrective actions are maintained.	5

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D. Product Recall Procedures and Customer Communications

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 updated annually. Responsibility for managing the recovery program is assigned. (2 elements) • The site has an established and documented product recovery program, including assigned responsibility for managing the program. Program is in compliance with governmental guidelines and includes details on how customers affected by the recovery are to be contacted. • The contact lists are updated annually, or as necessary, and include 24/7 contact information for all internal and external contacts necessary to conduct the recovery.	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 raw materials, ingredients, primary packaging or product tested within 2 hours. Auditor will list the date of the last mock recall, the item tested, and the percentage of product recovered in the comments. (2 elements) • A mock recall has been conducted within the last 12 months with all supporting documentation maintained and available for review. • The mock recall recovered 100% of product within 2 hours.	5
3.	Auditor is to conduct a traceability exercise on one raw material, ingredient or packaging item during the audit to verify that the facility can identify, track and locate 100% of raw materials or packaging to finished product and onto first external customer or first level of external distribution within 2 hours. Auditor will list the item tested and summarize results in the comments. (1 Element) • Results of the auditor-initiated mock recall meet the program guidelines.	5
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) • There is a mechanism for the collection and evaluation of complaints. • Each valid complaint is investigated to determine a cause and resolution. • Complaints are summarized to conduct trend analysis and identify areas for improvement.	5

Possible points	**90**
Actual points	**88**
Percentage	**97.8**

COMMENTS:

II.B1- Comment: Master list of all the suppliers was used to ensure the materials were from the approved supplier.

II.B4- Comment: The raw material was inspected during each batch raw material receiving, and checked third party test report once a year.

II.B5- Comment: The end-product was tested by Jinan Institute of Product Quality Inspection on 2017.05.18 include flourescent rightener<0.20mg/kg, PBBs, Pb, Cd, Hg and etc.

II. C1. The barrels for water-proofing additive and oil-proofing additive were not covered in the formulating room.

II.D2- Comment: The Mock recall was conducted on February 16, 2017, for the final product 7' Paper Plate (code P011), lot number of 20170201, and quantity of 200 cartons. All products could be traced within 2 hours.

II.D3- Comment: The onsite traceability exercise was conducted for the final product Paper Plate (code PL-SC-U9), lot number of 20170718, and quantity of 120 cartons. All the raw materials and packaging materials information could be traced within 2 hours.

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III. Grounds, Building, Equipment and Maintenance(Observation)

A.	**Plant Grounds**	**Rating**
1.	Facility roads, yards, grounds and parking lots are maintained in good condition and free of trash and litter. There is adequate drainage and equipment on perimeter of facility is properly stored. Litter and waste are properly stored, dumpster areas are clean with timely removal of waste. The loading dock areas are organized, with bumpers, levelers and shelters in good repair. (8 elements) Guidance: • Grass, weeds and ornamental landscaping are cut or designed to minimize harborage areas for pests. • Grading and conditions around the exterior perimeter prevent standing water. • No evidence of poor drainage. • Equipment within 20 feet of the building does not create a source of potential harborage • Pipes within 20 feet of building are capped • All trash containers are covered with no waste build up • Dumpster and surrounding area is cleanable and maintained clean • Loading dock areas are clear of clutter, debris and spilled products.	Fully Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		

B.	**Plant Facilities**(Observation)	
1.	Plant facility is designed to facilitate production. Floors, walls and ceilings are smooth and easily cleanable and well maintained. Exterior of building is in good repair and does not inhibit sanitary operations. Outer openings of doors and windows are designed to control ingress of pests. Roofs are in good condition with no leaks. (7 Elements) Guidance: • Roofs are in good condition, troughs, gutters and down spouts well maintained (no leaks) • Interior floors, walls and ceilings are in good condition and made of materials that can be easily cleaned • Outer openings, doors, and windows are protected from pest entry • There are no cracks in walls to the exterior of the facility • Drains protruding on exterior of the building are protected if their design can lead to pest entry. • Aisles and workspaces are unobstructed and have adequate width • The lighting is adequate in all areas of the facility to suit purpose	Generally Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		

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2.	Processing and food handling areas are designed and maintained to minimize the potential for contamination and manage food safety risks. (17 Elements) Guidance: • All glass and brittle plastic are protected from shattering and breakage • Ventilation is adequate and fans or other air –blowing equipment are clean and well maintained, no odors • Water lines and hoses are protected against back flow or cross connections to prevent contamination of potable water • Wash down hoses are not stored on the floor • Hand wash sinks are convenient to processing areas. • All processing areas have hand wash sinks with hands free operations for warm water, anti bacterial soap, single use towels or suitable hand drying devices. • Hand wash signs are present at each sink in a language appropriate for employees of the facility. • Break areas are away from product processing areas and where appropriate separate break areas for low and high risk production area employees. Employee lunches should not be stored in lockers • All break areas, locker rooms and restrooms are maintained clean and in good condition • Restroom drains, toilets, and ventilation are in good condition and functioning properly • Women's and unisex restrooms have covered waste containers • Signs for washing and sanitizing hands are present in break areas, locker areas and restrooms as appropriate and in the language (s) of the facility. • Ladders and walkways over exposed product lines are protected to prevent potential contamination, with kick plates installed as necessary. • Soiled or broken pallets are not used in the facility • Multiple pallets or excess pallets are not stored near raw material, in product processing or product storage areas. • Transport vehicles are in good repair and not a potential source of contamination. • Vehicles and batteries are charged and stored in areas separated from processing and packaging products.	Fully Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 15 pts, Generally Meets = 13 pts, Partially Meets = 12 pts, Minimally Meets Rating = 0 pts, N/A		

C. **Equipment and Maintenance**(Observation)

1.	There is a planned system for the continuing preventive and corrective maintenance of all equipment in the facility. (3 Elements) Guidance: • There is a preventive maintenance schedule that includes all equipment in the facility • There is a system in place that allows employees to inform maintenance about work requests • All preventive and corrective task completions are verified as complete in a timely manner.	Fully Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		

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2.	Equipment in the facility is properly designed and maintained.(10 Elements) Guidance: • Equipment is designed to be easily cleaned and used for intended purpose • There are no equipment design issues that would prevent proper cleaning • There are no non industry accepted product contact surfaces that are made of wood. • There is no mold or rust on equipment • Product contact surfaces of equipment do not contain rough welds • Painted surfaces are in good condition with no flaking present. • Conveyor belts are intact and do not contain chips, or loose fragments. • Welds on the insides of product contact piping to not contain any unsanitary welds. • There is no excess lubricant on grease zerks or gear boxes. • Temporary repairs will not inhibit sanitation and are completed with materials that will not cause contamination to the product or the environment.	Generally Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 10 pts, Generally Meets = 8 pts, Partially Meets = 6 pts, Minimally Meets Rating = 0 pts, N/A		
3.	There is a written program to address how products will be protected during maintenance activities and the cleaning and sanitizing of equipment that has undergone repairs, maintenance or re-assembly.(5 Elements) Guidance: Program includes the following : • Procedures that address how the facility will protect product when breakdowns occur and/or repairs are made in product zones • Procedures for product disposition when affected by maintenance activities • Procedures that describe how maintenance will handle tools during maintenance activities, including provisions for prevention of cross contamination in low and high risk production areas. • Procedures that describe the sanitation activities that are to occur after equipment has undergone repairs • Responsibility and training required for those responsible for completing and verifying the effectiveness of completion of sanitation activities after maintenance.	Fully Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		
4.	Equipment is cleaned and sanitized after under- going repairs. Product affected by maintenance activities is properly evaluated and managed. Tools are not observed to be a source of contamination. (7 Elements) Guidance: • Records are maintained that show sanitation was completed, as required by procedure and observations by auditor confirm procedure is followed. • Product affected by maintenance activities has been safely dispositioned • Tools and parts have been removed from the work area on repair is completed • Tools and parts are not stored in a work area or on food contact surfaces • Tools are not stored or carried in the pockets of maintenance staff or line employee responsible for maintenance. • There is no potential for cross contamination from tools in low and high risk production areas or dedicated tools are in use. • Tools are sanitized before use in high risk production areas.	Fully Meets
All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 10 pts, Generally Meets = 8 pts, Partially Meets = 6 pts, Minimally Meets Rating = 0 pts, N/A		

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

Possible points	**55**
Actual points	**52**
Percentage	**94.5**

COMMENTS:

III. B1. One drain in pulping room was dirty with strong odor. Some standing water was observed in forming floor.

III. C2. The pithead and inside wall of paper pulping pool was made by ceramic tile and part of them were damaged. There was no inspection was required after cleaning the pool, and the inspection result was not provided.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

IV. Pest Control

(Assessed by observation and review of records)

A.	Pest Control	Rating
1.	**A WRITTEN PREVENTIVE PEST CONTROL PROGRAM HAS BEEN ESTABLISHED. THE PROGRAM IS RISK BASED AND ADDRESSES ALL IDENTIFIED POTENTIAL PESTS RELATED TO THE FACILITY'S PROCESS AND SITE ENVIRONMENT. (6 Elements)** Guidance: • Pest control program is established based on risk. • Program is in the form of a contract or written internal program • There is an identified Pest Control Operator internal or external to the facility. • There is an up to date schematic map that includes all pest control devices in use. • There is an established frequency of service. • Trend analysis for all pest control devices is conducted.	**Fully Meets**
If there is no written program or contract at all this is considered a critical non conformance and the score will be minimally with a critical non conformance. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		
2.	Pests are effectively controlled and managed inside and outside the facility through implementation of the comprehensive pest control program that meets industry best practices, local and federal regulations. Auditor observations and review of service records and trending results show program is effective.(18 Elements) Guidance: • Service records meet the established requirements of the written program • Records are complete and show corrective actions being taken for identified pest activity, identified preventive measures needed and additional monitoring opportunities. • Current copy of certification for the Pest Control Operator • Current copy of the pest management company license to operate • Proof of the PCO's current liability insurance • Evidence of review and accuracy of the pest control device map. • A current list of pesticides approved for use at the site by corporate or on-site management • MSDSs and specimen labels for all pesticides in use showing regulatory approval for use in a food handling facility. • Chemical usage records showing chemical name, quantity or concentration used, target pest and location of application, • The site has an adequate number of interior pest control devices along all walls in food handling areas (production, packaging, storage and cooler areas), as well as Lunch rooms, break rooms and locker rooms. • The site has an effective number of exterior pest control devices (rodent and otherwise as applicable) which meet regulatory requirements spaced at effective intervals around the building's exterior perimeter. • All live catch devices (including glue boards) are checked at least twice-a-month. Exterior bait stations are checked at least monthly. • Record of service verification such as stickers, cards, or bar codes shall be on the inside of the station. • PCO must initial and date labels, or s, scan the barcode or use punch cards in all interior and exterior devices. • The positioning of all pest control devices must be effective for the intended purpose and to exclude potential contamination to food products, equipment and packaging. Bait is not used inside the facility. • All pest control devices are clean, functioning and bait where used has a fresh appearance. • The placement of flying insect control devices, insect light traps (ILTs) and insect-o-cutors (low and high voltage units) and other traps, when used, must be according to manufacturer instructions and comply with applicable regulations. • All flying insect control devices must be cleaned and maintained on an effective schedule. Bulbs must be shatter resistant and must be changed at least.	Generally Meets

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

All scoring in this question is based on the risk to food safety and the severity of the finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program will be scored lower than guidance suggests. Fully Meets = 15 pts, Generally Meets = 13 pts, Partially Meets = 12 pts, Minimally Meets Rating = 0 pts, N/A		
3.	**THERE IS NO EVIDENCE OF DECOMPOSED PESTS ANYWHERE IN THE INTERIOR OF THE FACILITY, INCLUDING IN PEST CONTROL DEVICES. THERE IS NO EVIDENCE OF INSECTS, SPIDERS, RODENTS OR BIRDS ON OR IN ANY FOOD INGREDIENTS, PRODUCTS OR PACKAGING MATERIALS. (1 Element)** Guidance: • **NO DECOMPOSED PESTS ARE FOUND ANYWHERE IN INTERIOR OF THE FACILITY. NO PEST INFESTATION IS FOUND IN OR ON ANY INGREDIENTS, FOOD PRODUCTS OR PACKAGING MATERIALS.**	Fully Meets
This is a one element question scored based on risk to food safety and number of instances observed. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		
4.	Avicides are prohibited inside the facility. If used on the exterior, avicides must be used in accordance to label requirements and must meet the pest control program. (1 element) Guidance: • Avicides are prohibited inside the plant's facilities and are used appropriately.	NA
This is a one element question scored based on risk to food safety and number of instances observed. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		
5.	Pesticides, chemicals and other compounds stored on site for pest control must be properly labeled and kept in locked, secured areas away from any product storage or processing areas. (1 element) Guidance: • If facility is storing pesticides on site, the chemicals must be segregated from product handling areas and must be secured. Glue boards and traps, not in use, do not need to be segregated and secured.	NA
This is a one element question scored based on risk to food safety and number of instances observed. Fully Meets = 5 pts, Generally Meets = 4 pts, Partially Meets = 2 pts, Minimally Meets Rating = 0 pts, N/A		

Possible points	**25**
Actual points	**23**
Percentage	**92.0**

COMMENTS:
IV.A2: Some dead insects, such as crawler, spider and flies, were observed in the fished product warehouse. Flying insect control device (1#C-M-01), was set on the wall near the entrance with the height of more than 2 meters, which would reduce the effectiveness of insect catching.
IV.A4-Comment-: Avicides were not used in the plants.
IV.A5- Comment: Pesticides were controlled by Ecolab, who provided pest control service, and were taken from the plant after each service.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

V. Employee Practices

(Observation)

A.	Employee Practices	Rating
1.	**A DOCUMENTED GMP PROGRAM HAS BEEN ESTABLISHED. IT COMPLIES WITH ALL APPLICABLE REGULATIONS. (1 Element)** • **FACILITY HAS DEVELOPED BASIC GMP REQUIREMENTS FOR EMPLOYEE HYGIENE, PEST CONTROL, SANITATION, AND FACILITY MANAGEMENT.**	**5**
2.	Signage that identifies applicable employee hygiene requirements in languages appropriate for employees to understand is present at all entrances to GMP zones. 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. (3 elements) • Employee hygiene rules are posted or given to visitors. • All entrances to production areas (GMP zones) have appropriate signage in languages appropriate for employees to understand about the hygiene practices. • Corrective action procedures must be established for deviations to employee hygiene practices, including use of a discipline policy for infractions to the GMPs as applicable.	5
3.	Employees follow written programs on employee hygiene practices, store personal items appropriately, maintain personal cleanliness, and use hygienic practices at all times. (2 Elements) • Employees follow written programs on employee hygiene practices and store personal items appropriately. • Employees maintain personal cleanliness and use hygienic practices at all times.	3
4.	Exposed jewelry, other than a plain wedding band, and other objects that might contaminate products, such as artificial nails and body piercings, are not worn. Objects, such as pens, thermometers, etc. that could fall into materials, equipment or containers, are not carried in above the waist pockets. (2 Elements) • Exposed jewelry is not worn. • Objects are not carried in above-the-waist pockets.	5
5.	Hairnets or other appropriate restraints are properly worn in processing production areas and in other areas of the facility as designated by facility's employee hygiene practices. The facility's employee hygiene policy must address all facial hair, including definition for acceptable appearance and when coverage of facial hair such as moustaches is required. (2 Elements) • Hairnets or other appropriate restraints are properly worn in food processing and other designated areas. • Facial hair is covered with beard covers. The facility's employee hygiene policy must address all facial hair, including definition for acceptable appearance and when coverage of the moustache is required.	5
6.	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. Employees adhere to traffic flows when moving through the facility by changing frocks, aprons or uniforms to minimize cross-contamination. (3 Elements) • Garments are clean, appropriate for the operation and do not have snaps not buttons. • Outer garments are not worn in restrooms, lunchrooms or outside the facility. • Employees change frocks or uniforms as necessary to minimize cross-contamination.	5
7.	Gloves worn in the processing areas are maintained in intact, clean and good condition. Procedures for the proper handling and usage of gloves are established, implemented, and verified where required. (2 elements) • Gloves worn in processing areas are maintained intact, clean & in good condition. • Procedures for the proper handling & usage of gloves are established, implemented, and verified, where required.	5

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

8.	Eating, chewing gum, drinking and use of tobacco are confined to designated areas outside of the processing and storage areas. (3 Elements) • Eating and chewing gum are confined to designated areas outside of the processing areas. • Drinking is confined to designated areas outside of the processing areas. • Use of tobacco is confined to designated areas outside of the processing areas.	5

Possible points	**40**
Actual points	**38**
Percentage	**95.0**

COMMENTS:
V.A3: The finger nails of the employee who put the product into the UV light machine were too long.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

VI. Receiving, Storage and Shipping

(Observation)

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) • All materials are labeled with date of receipt or there is a verifiable product rotation system. • Packaging can be identified by lot number or code date, either assigned by the supplier or the site.	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) • Shipping and receiving docks are clean, organized, and free of debris and spilled products. • Equipment stored on the docks should be organized and in good repair.	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) • Transport vehicles are clean, free of pest contamination and in sound condition. • Conditions in the trailers should be able to be maintained at product temperatures and not be a potential source of contamination.	5
4.	If raw materials or 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 when not in use. (3 Elements) • Transfer procedures must protect the product from contamination. • Hoses must be clean, capped and stored off the ground. • Connection ports into the building must be capped and locked when not in use.	5

B.	Storage	
1.	Sufficient space 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 scheduled cleaning and inspections is provided. (2 Elements) • Sufficient space is maintained along all walls for scheduled cleaning and pest activity inspection. • All materials are stored at an adequate height above the floor.	5
2.	Stock rotation practices are used and documented for all raw materials, in-process materials, and finished packaging. (1 Element) • Stock rotation practices are used for all finished products.	5
3.	All stored materials are clean, dry, intact, in good condition, and free from contamination. They are properly packaged or covered to prevent contamination of other products. They are stored under appropriate conditions. (3 Elements) • All materials and packaging are stored properly packaged or covered to prevent contamination of other products. • They are in good condition clean, dry, intact, and free from contamination. • They are stored under appropriate conditions.	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. Product on hold is clearly identified and held under appropriate conditions. (3 Elements) • Damaged cases are segregated and repacked or discarded • On hold materials are identified, segregated, and protected from contamination. • Product on hold is clearly identified and held under appropriate conditions.	5

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

5.	Storage or transfer containers for materials, which were removed from their originally labeled packages, must be clearly identified. Packaging containers manufactured by the facility should not be used to store or transfer materials. (2 Elements) • All containers are appropriately labeled to identify the contents. • Packaging materials manufactured by the facility must not be used to store or transfer items/materials.	5
6.	Inks, sealants, adhesives, and waxes are stored covered in areas having adequate ventilation. All containers must be properly labeled. (2 Elements) • All materials are stored in covered, labeled containers. • Adequate ventilation/exhaust is provided, as required.	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. (2 elements) • Material received for further processing/printing must be readily identifiable. • All materials are stored in covered, labeled containers.	5
8.	Dry storage areas are maintained in a clean and sanitary manner. All spills are immediately cleaned up; i.e., the floors and racks are not dirty and there is no evidence of spills, trash or other litter. (2 Elements) • Dry storage areas are maintained in a clean and sanitary manner. • Spills are cleaned up immediately.	5

Possible points	**60**
Actual points	**60**
Percentage	**100**

COMMENTS:

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

VII.Plant Sanitation

(Observation and review of records)

A.	Cleaning Equipment and Chemicals	Rating
1.	A written master cleaning/sanitation schedule lists all areas and equipment in the plant that require cleaning (including processing and non-processing areas and equipment) and provides the frequency of cleaning. Documentation by the person who completed the task and the verification that they were completed are available for review. (1 element) • A master cleaning/sanitation schedule of cleaning and sanitation duties exists. It lists all areas and all equipment to be cleaned and the frequency of cleaning. There are records available showing the tasks were completed and by whom, including verification that tasks were completed as planned.	5
2.	Written sanitation SOPs (SSOPs) are established and implemented for all cleaning tasks. They include all necessary and regulatory content, such as responsibility, task to be performed, chemicals and equipment to be used. The order of operations of the cleaning steps is established to prevent recontamination of already cleaned surfaces or overspray onto product contact areas of the equipment. Sanitation SOPs must address how equipment is to be cleaned after being out of service. (2 elements) • Sanitation SOPs for all tasks are written to prevent recontamination of cleaned surfaces. SOPs include all necessary tear down procedures, responsibility for the task to be performed and/or regulatory content and equipment needed to perform the cleaning and sanitizing. • Sanitation SOPs address how equipment is to be cleaned after being out of service.	5
3.	**THE FACILITY WATER IS FROM A POTABLE SOURCE. (1 element)** • **THE FACILITY WATER IS FROM A POTABLE SOURCE.**	**5**
4.	Water sourced from an on-site well, used as an ingredient or processing aid or for the cleaning and sanitation of direct product contact surfaces is tested annually for potability by a certified laboratory. The sample should be taken from different locations in the facility, each year. Records are maintained. (1 element) • The facility shall ensure that the potable water supply is verified at least annually. The testing of microbiological potability of the water supply must be done by an accredited laboratory.	5
5.	All chemicals used for cleaning, sanitizing, and processing must be approved for use in the production of food contact packaging materials and equipment and are properly labeled. They are used for their intended purposes and they are stored in secure, locked areas away from any processing or raw material, ingredient or packaging storage areas. 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. Facility maintains current MSDS and labels for all cleaners and sanitizers being used in an organized, accessible and easy-to-use system. (3 elements) • Evidence of regulatory approval for detergents, cleaner and sanitizers used on product contact surfaces must be retained on file at the site or be readily accessible. • Chemical storage cabinets, lockers, cages or rooms must be secure. • MSDS and specimen or sample labels or product technical data sheets must be retained on file at the site or be readily accessible.	5
6.	Containers, brushes and applicators used for cleaning and sanitizing are designed for use and color coded or labeled to properly identify them for their intended use. If a color-coding system is used, appropriate signage describing the system in languages appropriate for employees to understand is posted. Cleaning equipment is properly stored (when not in use) and is not stored in processing areas. (2 elements) • Equipment for cleaning and sanitizing are designed for use and are color coded/ labeled. • For color-coding systems, appropriate signage describing the system is posted.	5

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

B. Cleaning, Sanitation and Housekeeping Practices (Observation)

1.	Cleanliness is maintained in all non-processing areas. (1 element) • Cleanliness is maintained in all non-processing areas.	5
2.	Excess moisture and pooling water is removed from equipment and the processing environment. Cleanliness is maintained on all product contact surfaces. Significant accumulations of product build-up are not observed during production. (2 Elements) • Excess moisture and pools of water are removed from equipment and the processing environment. • Cleanliness is maintained on all food contact surfaces. No accumulation of gross product build-up is observed during production.	3
3.	Proper cleaning and sanitizing procedures are followed and are accessible to employees needing them. Equipment is disassembled as necessary to ensure thorough cleaning. Results are being documented to verify cleaning and sanitation was completed per procedure. (3 Elements) • 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.	5
	Possible points	**45**
	Actual points	**43**
	Percentage	**95.6**

COMMENTS:
VII.A4- Comment: The city water was tested on April 20, 2017 by Liaocheng CDC, with the report number of 2017W00027, and all the test results were satisfied.
VII.B2: A long dust line was hanging on the forming equipment. Lots of dusts were noted on the belt axle of sanitizing machine. Some water was found on the operational table surface located at automatic forming machines.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

VIII. Manufacturing

(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) • Roll stock can be stored in directly contact with the floor, only if edges are trimmed and several turns of the material are discarded prior to use. • Staged packaging materials are stored so as not to pose a risk to the finished product.	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) • Recycling (regrinding or shredding) or baling of packaging materials is done separate from the manufacturing processes. • Recycling or baling areas are maintained so as not to pose a risk to the manufacture of the packaging materials.	5
3.	Single service containers must not be reused. They must be discarded when empty. (2 Elements) • Single use material containers must not be reused. • Single use containers must be discarded in compliance with any regulatory requirements.	5
4.	Rolls, dies, and support equipment must be stored at an adequate height above the floor to prevent contamination. (1 Element) • Processing equipment must not be store in direct contact with the floor.	5
5.	Temperature sensitive operations are monitored to ensure proper temperature controls are maintained. (1 Element) • Temperature sensitive operations such as heating or cooling are appropriately monitored with suitable instruments.	5
6.	Food packaging materials must not be manufactured on equipment used for non-food applications, unless the equipment has been adequately purged and cleaned of the non-food materials. Documentation of the cleaning must be maintained. (2 Elements) • Cleaning procedures for non dedicated food grade equipment are established. • Change over cleaning for non dedicated food grade equipment is documented.	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) • Process controls points and limits are observed being monitored, and the results are being recorded per the procedures. • Employees questioned understood their monitoring points.	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) • Corrective actions are being taken as required and documented.	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) • Packaging manufacturing systems are adequately protected to minimize the risk of foreign materials contamination.	5

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

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 that could be introduced into the product. (1 Element) • No equipment or processing operation used has the potential to contribute to the contamination / adulteration of product with physical, chemical or microbial contaminants.	1
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 or ingredients. (2 Elements) • Raw material packaging that is glass or brittle plastic is controlled in the manufacturing areas. • Controls are in place when glass or brittle plastic containers are used for the storage of raw materials.	3
12.	When magnets, screens, sieves, etc. are used in the manufacturing lines, they must be inspected on a scheduled basis to ensure proper performance. Inspection records must be documented and maintained. (2 Elements) • Magnets, screens and sieves are inspected on a scheduled basis. • Inspection records are documented and maintained.	5
13.	Any compressed air or other gases (e.g., carbon dioxide, nitrogen) 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) • Any compressed air or other gases used in processing, packaging or cleaning are treated in such a way to prevent contamination. • Filters are inspected and maintained on a pre-determined schedule. • Filtration systems are not directly located over exposed product or product conveying systems.	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) • Maintenance tools and other miscellaneous materials are not found on or near processing equipment. • Tools used for equipment adjustment must be clean and in good repair.	5
	Possible points	**70**
	Actual points	**64**
	Percentage	**91.4**

Comments:
VIII.A.10: The plastic bag inside the basket for containing finished product after inspection or after metal detecting was damaged with part missing.
VIII.A11: One lamp was not covered in raw material warehouse, which was far from raw material storing area.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

IX. Facility and Product Defense

(Review of written program)

A. Program

1.	The facility must have a documented product defense plan that designates a multidisciplinary team. The team must initially assess all facility operations to determine potential deliberate contamination risks and appropriate strategies to reduce these identified risks. The team must reassess the risks and strategies on at least an annual basis. (4 elements) Guidance: • A team is identified and has assessed the risk of deliberate contamination of products during production storage, receiving and shipping. • The facility defense plan is documented. • The defense plan or other pre requisite programs include procedures to ensure security of the facility and the products produced, stored, received or shipped from the facility. • The team conducts a reassessment of the risks and mitigation strategies on an annual basis.	Fully Meets
All scoring in this question is based on food defense risk and thorough risk assessment. The number of requirements missed and the severity of the finding may justify a rating lower that indicated in scoring guidance. Fully Meets = 10 pts, Generally Meets = 8 pts, Partially Meets = 6 pts, Minimally Meets Rating = 0 pts, N/A		

B. Facility and Product Defense Practices(Observation and Review of Records)

1.	The facility product defense protocol is implemented and effective. (14 elements) Guidance: • The following practices have been put in place to ensure security of the facility and the products during manufacturing, storage, receiving or shipping. • Visitors and or non employees are supervised for compliance to required visitor policies. • Access points to the facility are secured and employees are identified. • Facility follows their procedures for the screening prior to hiring and can include reference checks and basic felony background checks for all supervisors and above. • Facility employees understand how to report suspicious activity and who to report it to. • Restricted or critical areas within the facility are identified and secured. • There is restricted access to documents and software associated with ingredients or finished products. • Finished product has tamper evident packaging. • Inbound raw material deliveries are verified as secure, i.e. sealed or locked, receiving documents are verified and there is an evaluation of product integrity. • Outbound trailers are secured with seals or locks with records indicating compliance. • A system is in place and utilized for identifying delivery drivers (inbound or outbound). • Less than full load shipments are inspected according to policy that documents the100% inspection of inbound less than full load unsecured deliveries. • Stored, loaded trailers ready for shipment must be secured while on premises. • Bulk receiving ports for food products or chemicals must be secured. • On site water handling facilities or wells are secured.	Fully Meets
All scoring in this question is based on Food Defense risk and severity of finding. Lower number of requirements missed that result in a serious risk to food safety or show poor implementation of the program may justify a rating lower than indicated in scoring guidance. Fully Meets = 10 pts, Generally Meets = 8 pts, Partially Meets = 6 pts, Minimally Meets Rating = 0 pts, N/A		

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

Possible points	**20**
Actual points	**20**
Percentage	**100.0**

Comments:
IX.A.1 Comment: The food defense plan was established.
IX.B1. Comment: The facility defense protocol was implemented well and records were available.

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.

A

Food and Non-Food Packaging Materials 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.***

Questions are scored per the matrix, with 5 being the highest rating possible and 1 being the lowest. If isolated issues for any element are found, an additional one point deduction will be applied to the question's rating *OR* if numerous issues for any element are found, an additional two point deduction will be applied to the question's rating.

Number of elements in question	>3 elements missed	3 elements missed	2 elements missed	1 element missed	All elements fulfilled	
>3	**1**	**1**	**3**	**4**	**5**	**Rating given To question**
3	N/A	**1**	**2**	**4**	**5**	
2	N/A	N/A	**1**	**3**	**5**	
1	N/A	N/A	N/A	**1**	**5**	

Definitions:

- Single issue - One observation, occurrence or instance of a specific/same issue or element
- Isolated issues - Two observations, occurrences or instances of a specific/same issue or element.
- Numerous issues – Three or more observations, occurrences or instances of a specific/same issue or element.

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.

Numerical Score	Further Guidance
98% or higher	**Meets audit expectations**
91 – 97.9 %	**Generally meets audit expectations**
85 – 90.9 %	**Partially meets audit expectations**
< 85%	**Minimally meets audit expectations**

Items in CAPS and bold will result in a critical non conformance if a "1 or a minimally meets" is scored by auditor.