AUDIT REPORT

Distribution Center Food Safety and Quality Systems Audit

for:

Kool Pak, LLC: Clackamas, OR

Report Date
November 14, 2017

Audit by
Randy Minck

Merieux NutriSciences Certification LLC

Confidential

This audit report sets forth the findings of Merieux NutriSciences Certification LLC ("MNCertification") as of the date herein. MNCertification shall not assume any responsibility for the programs and/or facility being audited nor for events or actions occurring prior or subsequent to this audit. MNCertification does not endorse any of client's actions, and hereby expressly disclaims any liability related to the client carrying out MNCertification's recommendations, if any, contained in this report.

This report is furnished solely for the benefit of the above named client in connection with the auditing services indicated above and provided in accordance with "MNCertification Terms and Conditions for Services". This audit report may not be reproduced or published in full or in part, altered, amended, made available to or relied upon by any other person, firm or entity without the prior written consent of MNCertification.

The name of MNCertification or its affiliates or any of its employees may not be used in connection with any marketing or promotion or in any publication concerning or relating to the client or its products and services without the prior written consent of MNCertification.

The content of this audit report may not be copied, reproduced or otherwise redistributed other than for use by the client with appropriate reference to restrictions on reproduction and use. Except as expressly provided above, copying, displaying, downloading, distributing, modifying, reproducing, republishing or retransmitting any information, text or documents contained in this audit report or any portion thereof in any electronic medium or in hard copy, or creating any derivative work based on such documents, is prohibited without the express written consent of MNCertification. Nothing contained herein shall be construed as conferring by implication, estoppel or otherwise any license or right under any copyright of MNCertification, or any party affiliated with MNCertification.

Audit Summary

Company Name: **Parent Company:**	Kool Pak, LLC, Clackamas, OR: Kool Pak, Lake Oswego, OR	**Audit Date:** **Start/End Time (# hrs on records/plant observations):**	November 14, 2017: 8:00-2:30 (4/plant 2)
Center Address:	16221 SE 98th Ave. Clackamas, OR 97015	**Center phone & fax numbers, email:**	Phone: 503-978-2124 kroyce@kool-pak.com
Auditor:	Randy Minck randy.minck@mxns.com 216-346-7476	**Company Associate(s) accompanying auditor (Name & title):**	Katie Royce, Director of QA
		Audit Description:	Annual Announced

		Food Safety Modernization Act:	Registered
Audit Score:	96.5	**Rating:**	generally meets
Follow-up audit required:	No	**Reason for follow-up:**	NA

Audit Review

Company associate(s) with whom audit findings were reviewed:	Katie Royce, Director of QA

Auditor Signature: _____

Randy Minck 216-346-7476; randy.minck@mxns.com

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

Plant Description

The Kool Pak Clackamas, OR warehouse is a true cross-dock facility with 95% of product movement on LTL and within the facility less than 24 hours prior to outbound shipment.

The warehouse is about 40,000 sq. ft. with an additional 4,000 sq.ft. administrative space. There are dry, cooler and frozen storage rooms with 50-60 employees, including drivers, operating 2 shifts, 7 days/week. Fully packaged RTE food products are stored, no fresh proteins or shell eggs. Non-food products, such as light farm/landscaping equipment, are also stored in the dry storage location.

Most pick ups/deliveries are local on LTL with occasional nationwide shipments on contracted common carriers. The warehouse is located in a rural, light industrial areas and shares a common building with another distribution company, Three J's Inc., also audited by Merieux Nutrisciences.

Kool Pac operates several similar warehouse facilities along the west coast with a corporate office in Lake Oswego, OR.

Summary of Audit Findings

Company: Kool Pak, LLC: Clackamas, OR **Audit Date: November 14, 2017**

Major Non-conformances:

I. Product Protection

I.A.3 * Not all CCP identification is based upon a scientific hazard likely to occur, e.g. training. Potential allergen cross-contamination is not included in the analysis.

Note: The hazard analysis conducted identified 9 CCPs as folllows
(1) Point of Pickup
(2) In transit
(3) receiving
(4) storage
(5) 3PL or picking
(6) Loading/Shipping
(7) sanitation
(8) recall program
(9) employee training

I.A.4 * CCPs are not indicated on the flow charts where they occur. Not all CCPs have technical specific limits, e.g. training and sanitation.

I.A.5 * CCP #4 identification and monitoring procedures have not been defined.

Positive Comments

The facility was very well prepared for the audit. All documentation, policies and procedures were readily available and supplied immediately. The facility is well maintained, clean and suitable for the storage of frozen, refrigerated and dry food products.

Distribution Center Food Safety and Quality Systems Audit Rating Analysis

Company: Kool Pak, LLC: Clackamas, OR **Audit Date: November 14, 2017**

Category	# Points Received	# Possible Points	Percentage (%)
I. Product Protection	139	150	92.7
II. Quality Systems	97	100	97
III. Equipment & Facility	77	80	96.3
IV. Pest Control	35	35	100
V. Sanitation	105	105	100
VI. Food Defense	15	15	100
Overall Score	***468***	***485***	***96.5***

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

I. Product Protection

A. HACCP or Hazard Based Risk Assessment

	Rating
1. A multi- disciplinary team is established and composed of personnel with knowledge of the facility processes. The team is led by a person who demonstrates knowledge and application of HACCP principles. The team meets on a routine basis and has documented descriptions and distribution method of all types of products stored and distributed. (2 Elements)	5
2. A flow chart must be prepared for each step in the warehouse and distribution process, including any intermediate steps, back hauls or returns activities. The flow charts are verified when initially established and after any revisions or changes. (3 Elements)	5
3. The written hazard analysis is risk based and identifies the significant food safety hazards associated with the steps in the process that are 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 assessment of allergen cross-contact. (2 Elements)	2
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. Control points identified to manage food safety or quality must have established limits based on scientific or historic data. (2 Elements)	2
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 Point understands the procedures. (2 Elements)	2
6. Employees who are responsible for HACCP related activities have been trained in the monitoring and or verification procedures required to maintain the safety of products. This training is documented as to date(s) given and is a part of the employee's records. The training should be conducted whenever changes to the program occur. (3 Elements)	3
7. Corrective action procedures have been identified for each CCP, and include all steps needed to identify, quantify and segregate affected product. Records of corrective actions taken are maintained and include product disposition. (2 Elements)	5
8. CORRECTIVE ACTION PROCEDURES ARE FOLLOWED WHEN CRITICAL LIMITS ARE NOT MET. (1 ELEMENT)	5
9. 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)	5
10. All records related to performing HACCP tasks and reviewing HACCP records are appropriately signed/initialed and dated. (1 Element)	5
11. At least annually or whenever there have been process, or products distributed or warehoused changes, the HACCP plan must be reassessed. The reassessment includes a review of 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)	5
12. HACCP or Hazard Based Risk Assessment Sectional Summary	N/A

I. Product Protection

B. FDA FSMA REQUIRED: Food Safety Plan

	Rating
1. A multi disciplinary Food Safety team lead by at least one person meeting the requirements as a PCQI has been established. The team meets on a routine basis and has documented the preliminary Food Safety plan developmental tasks of product description, intended use and consumer, and method of distribution. (2 Elements)	N/A
2. A flow chart must be prepared for each separate step in the warehouse and distribution process, including any intermediate steps, back hauls or returns activities. The charts must be revised when any changes are made to the process and verified and documented by the Food Safety Team. (3 Elements)	N/A
3. A written hazard analysis must be available and identify the significant food safety hazards known or reasonably foreseeable that are associated with the products and ingredients covered by the Food Safety plan. 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-contact and microbial cross-contamination). The Hazard Analysis has been completed for each step in the process, all inputs and outputs and considers all known or foreseeable hazards that include: biological, chemical (including radiological and allergens), and physical hazards (including the potential for economic adulteration). The hazard analysis must include an evaluation of the hazards identified in this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. (2 Elements)	N/A
4. Preventive measures including process, sanitation, and allergen preventive control points are identified on the process flow chart as well as in the documented Food Safety plan. Each process preventive control point must have scientifically validated parameters or values. (2 Elements)	N/A
5. Preventive Control Points are monitored according to written procedures at regularly scheduled intervals as written in the preventive control plan that ensure control of the process. Monitoring procedures are documented and monitoring records are maintained. (2 Elements)	N/A
6. Employees who are involved in the monitoring of preventive control points meet the criteria for qualified individuals and have been trained in the relevant aspects specific to their immediate work areas, to ensure compliance to the written plan. The qualified individual must demonstrate through education, training, and experience adequate knowledge to maintain safe food during manufacturing, processing, packing and holding of the food. The training should be conducted as needed. (2 Elements)	N/A
7. Corrective action procedures have been identified for each Process Preventive Control, 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)	N/A
8. When conditions and practices are identified that require corrections, the corrections are made in a timely manner. The corrections and corrective actions are document and verified by a preventive controls qualified individual. (3 Elements)	N/A
9. CORRECTIVE ACTION PROCEDURES ARE FOLLOWED WHEN PROCESS PREVENTIVE CONTROL PARAMETERS AND VALUES (CRITICAL LIMITS) ARE NOT MET. (1 ELEMENT)	N/A
10. VERIFICATION, ACCORDING TO THE FOOD SAFETY PLAN, HAS BEEN CONDUCTED BY OR UNDER THE SUPERVISION OF A PCQI. IF THE VERIFICATION IS CONDUCTED UNDER THE SUPERVISION OF A PCQI, THE INDIVIDUAL CONDUCTING THE VERIFICATION ACTIVITIES MUST BE TRAINED AND TRAINING RECORDS AVAILABLE VERIFICATION ACTIVITIES MUST INCLUDE A REVIEW TO ENSURE MONITORING IS OCCURRING AS SPECIFIED IN THE FOOD SAFETY PLAN, THAT APPROPRIATE CORRECTIVE DECISIONS ARE BEING MADE, AND A REANALYSIS OF THE FOOD SAFETY PLAN AT LEAST EVERY 3 YEARS. IF VERIFICATION ACTIVITIES ARE NOT CONDUCTED WITHIN 7 DAYS, DOCUMENTED JUSTIFICATION FROM THE PCQI MUST BE AVAILABLE. (5 ELEMENTS)	N/A

I. Product Protection

B. FDA FSMA REQUIRED: Food Safety Plan

11. VALIDATION ACTIVITIES, PERFORMED OR OVERSEEN BY A PCQI, ARE REQUIRED FOR PROCESS PREVENTIVE CONTROLS. THEY MUST BE PERFORMED WITHIN 90 DAYS AFTER THE FIRST RECEIPT OF THE NEW PRODUCT (OR WITHIN A REASONABLE TIMEFRAME AS DOCUMENTED BY A PCQI). VALIDATION IS ALSO REQUIRED WHEN A SIGNIFICANT CHANGE THAT MAY AFFECT THE CONTROL OF HAZARDS OCCURS, OR WHEN REANALYSIS OF THE FOOD SAFETY PLAN INDICATES THAT NEED FOR ADDITIONAL VALIDATION. (2 ELEMENTS)	N/A
12. Food Safety Plan Sectional Summary	N/A

I. Product Protection

C. Product Protection & Food Safety Practices

	Rating
1. Written procedures must be in place defining the practices to be used for physical segregation of fresh proteins (fresh poultry, fresh meat of any kind, fresh fish and seafood and shell eggs) in storage. Written procedures must be in place defining the practices to be used for physical segregation of fresh proteins during transportation and delivery. (2 Elements)	N/A
2. NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED. (1 ELEMENT)	5
3. No condition or practice exists that may potentially contaminate product or could lead to product contamination. (1 Element)	5
4. Written guidelines are established and practiced to ensure product is held in the proper location within the center, and handling, and storage, conditions meet general label or customer standards. (2 Elements)	5
5. Written guidelines are established and practiced to assure and maintain product integrity during storage. There is no product re-labeling or other activity that could compromise tracking product codes/lot numbers. (3 Elements)	5
6. Written guidelines are developed and practiced for palletizing and loading to protect product integrity during distribution. Products are loaded into appropriate areas of transport vehicles to ensure proper temperatures can be maintained. (2 Elements)	5
7. A manual or computerized system is in place to assure products are from approved suppliers. Receivers verify inbound products are from the approved supplier list. (2 Elements)	5
8. Written procedures exist to assess each product's condition at receipt. Defined criteria are utilized to assure product condition, and recording of code dates and taking of product temperatures. (2 Elements)	5
9. Inbound product assessments are documented, signed, and verified. At a minimum, records include quantity, load conditions, code dates and product temperature. Records are available for review. (3 Elements)	5
10. A receiving pallet tag is place on the lowest unit of a pallet of product at receipt or a verifiable method is established to ensure proper product rotation using first expired/first out (FEFO) product rotation. Oldest code date product is distributed first. (2 Elements)	5
11. Facility builds pallets for distribution with all raw protein items (shell eggs, fresh meat and poultry) and chemicals stored on the bottom or separate pallets. Auditor verifies that no foodstuffs or RTE products are stored below fresh protein products or chemicals on a pallet picked for distribution. (1 Element)	N/A
12. Procedures for maintaining center's temperature controls are established with upper and lower settings and operating limits. The procedures define frequency and responsibility for checking temperatures daily, (including non-operational hours, off, shifts, weekends and holidays) or via continuous recording devices, and thermometers / recording devices are verified as accurate weekly or per manufacturer's directions. Documentation of temperatures and calibrations must be maintained and available. Recommended controls are refrigerated < 40F, freezer < 0F and cool dock 45F. (4 Elements) Cooler: _____ Freezer: _____ Cool dock: ____	5
13. CORRECTIVE ACTIONS MUST BE TAKEN FOR DEVIATIONS IN THE CENTER'S TEMPERATURE CONTROLS. (1 ELEMENT)	5
14. Procedures for maintaining proper product temperatures are established. Required controls are in place to ensure refrigerated products are at </=40F and frozen at </=0F. Any customer requirements for frozen and refrigerated products must be available for review and documented to show compliance. (3 Elements)	5

I. Product Protection

C. Product Protection & Food Safety Practices

15. PRODUCT TEMPERATURE CHECKS ARE TO BE WITHIN REQUIRED TEMPERATURE RANGES. AUDITOR TO MEASURE TEMPERATURE OF MINIMUM OF 1 PRODUCT PER STORAGE UNIT. (1 ELEMENT) **COOLER:** **PRODUCT: _____ TEMP:_____** **FREEZER:** **PRODUCT: _____ TEMP:_____**	5
16. CORRECTIVE ACTIONS MUST BE TAKEN FOR DEVIATIONS IN MAINTAINING PROPER TEMPERATURES. (1 ELEMENT)	5
17. Product stored on cool dock must be maintained at customer-required temperatures. Product is to be stored at least 10 feet from but not above dock doors and not between the dock doors. Product is allowed to be staged on the cold dock; however, the product must not be staged for more than 1 hour. (4 Elements)	N/A
18. FROZEN AND REFRIGERATED PRODUCT STAGED IN THE COOL DOCK DURING LOADING AND RECEIVING PROCESSES MUST MEET CUSTOMER OR FACILITY (IF CUSTOMER HAS NO ESTABLISHED SPECIFICATIONS) TEMPERATURE SPECIFICATIONS. ANY CUSTOMER/FACILITY REQUIREMENTS FOR FROZEN AND REFRIGERATED PRODUCTS MUST BE AVAILABLE FOR REVIEW AND DOCUMENTED TO SHOW COMPLIANCE. (1 ELEMENT) **COOL DOCK:** **PRODUCT:____ TEMP:_____**	5
19. Transport equipment temperature settings and pre-cooling practices are established and practiced prior to loading. Pre-cool records are maintained. Reefers on refrigerated delivery vehicles will be turned off during loading if the dock is warmer than the trailer temperature. (4 Elements) Auditor to record temperature settings. Reefer setting prior to loading: Freezer: _____ Cooler: _____	5
20. Procedures are in place to ensure the food safety and quality status of product in the event of a reefer failure during delivery prior to release to the customer. (2 Elements)	5
21. Employees are complying with GDPs. No eating, drinking and use of tobacco are observed in distribution center. Personal items are stored away from center internal areas. (3 Elements)	5
22. EMPLOYEE PERSONAL HYGIENE PRACTICES ARE SANITARY. EMPLOYEE MEDICAL PROBLEMS ARE NOT A SOURCE OF CONTAMINATION. NO CROSS CONTAMINATION OR CROSS CONTACT PRACTICES ARE OBSERVED. (3 ELEMENTS)	5
23. Chemicals (for sale) are stored segregated. (1 Element)	N/A
24. Product Protection & Food Safety Practices Sectional Summary	N/A

I. Product Protection

D. FDA FSMA REQUIRED: Sanitary Transportation

	Rating
1. Are foods not completely enclosed by a container including an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag protected against contamination or allergen cross-contact? (2 Elements)	N/A
2. If third party carriers are used for product transport, written agreements or specifications are available specifying the responsibilities, necessary training, sanitation and temperature requirements for maintaining food safety during transport. A process for verification of the controls has been implemented and records are maintained. (3 Elements)	N/A
3. If product is shipped on company owned/controlled vehicles/trailers, temperature controls are maintained and documented during transport. Drivers are trained in regards to handling possible food safety problems that can occur during transport. Records for the training and transportation temperatures during transport are maintained. (3 Elements)	N/A
4. Sanitary Transportation Sectional Summary	N/A

Possible Points	**150**
Actual Points	**139**
Percentage	**92.7**

I. Product Protection

Comments

I.A.1 Note: Multi-functional HACCP team established with annual review notes and documented changes listed/dated.

I.A.2 Note: Flow charts are current, dated and list all operational steps performed at the facility.

I.A.3 Not all CCP identification is based upon a scientific hazard likely to occur, e.g. training. Potential allergen cross-contamination is not included in the analysis.

Note: The hazard analysis conducted identified 9 CCPs as folllows
(1) Point of Pickup
(2) In transit
(3) receiving
(4) storage
(5) 3PL or picking
(6) Loading/Shipping
(7) sanitation
(8) recall program
(9) employee training

I.A.4 CCPs are not indicated on the flow charts where they occur. Not all CCPs have technical specific limits, e.g. training and sanitation.

I.A.5 CCP #4 identification and monitoring procedures have not been defined.

I.A.6 HACCP training is provided initially at date of hire, but only thereafter if an exception occurs and is documented in KIK program.

I.A.8 Note: KIK (Keep It Kool), CA program is used to document any CAs required by the program. Several examples were reviewed and well maintained.

I.A.11 Note: Annual reviews are conducted and documented and good records maintained.

I.A.12 NA

I.B.1 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.2 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.3 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.4 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.5 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.6 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.7 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.8 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.9 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.10 N/A- 4/28/2018 is the facility FSMA compliance date.

I.B.11 N/A- 4/28/2018 is the facility FSMA compliance date.

I.C.1 N/A- No storage of any fresh proteins at this facility.

I. Product Protection

I.C.2 Note: No exposed containers or open boxes observed.

I.C.5 Note: Products are probe- temped during transport. No relabeling activities occur.

I.C.7 Approved supplier (customer) system is in effect and controlled by the corporate office. approval number identification supplied to the warehouse.

I.C.9 Note: Inbound product and trailer assessments were reviewed and acceptable.

I.C.10 Note: Traditional pallet tags are not used due to the cross-dock nature of the operation. Product identification tags are applied showing the delivery customer.

I.C.11 N/A- No raw proteins pr chemicals are distributed.

I.C.12 Note: PMC (Portland Mechanical Contractors) is responsible for any adjustments to the system to maintain defined temperatures (dock 34-45 deg. F., cooler 33- 38 deg. F and freezer -5 to +5 deg. F. Monitoring records were reviewed and well maintained.

I.C.14 Note: customer specific requirements are defined on the B/L and maintained.

I.C.15 Note: Frozen Nan was at 5.4 deg. F and cooler Coffee with dairy product was at 33.5 deg. F.

I.C.17 N/A- No product storage on the cool dock.

I.C.18 Note: Cool dock maintained at 35 deg. F with all staged product resident less than 1 hr.

I.C.19 Note: Pre-cool standards are defined as 5 deg. F. and 34 deg. F. in the warehouse operations manual.

I.C.21 Note: Good employee GDPs/GMPs were observed during the facility audit.

I.C.23 N/A- No chemicals are stored or distributed.

I.D.1 N/A- 4/28/2018 is the facility FSMA compliance date.

I.D.2 N/A- 4/28/2018 is the facility FSMA compliance date.

I.D.3 N/A- 4/28/2018 is the facility FSMA compliance date.

II. Quality Systems

A. Quality Systems

	Rating
1. A DOCUMENTED GDP PROGRAM HAS BEEN ESTABLISHED. IT COMPLIES WITH ALL APPLICABLE REGULATIONS. (1 ELEMENT)	5
2. The facility has documented and implemented a document control and record management program. (4 Elements)	5
3. A written procedure is established for significant changes in distribution practices due to natural disasters or emergency. A current dated phone list for internal and external support contacts must be included with the procedures and must be updated annually. (2 Elements)	5
4. A documented, product recovery program that can trace the distribution of specific production lots has been established and is maintained. The program must comply with US FDA/USDA or equivalent guidelines for conducting a product recovery. The program must define procedures for contacting customers. Contact lists for responsible employees, customers and vendors are current. Responsibility for managing the recovery program is assigned. Facility has an inventory management system in place to manage the rotation and shelf life of received goods. (3 Elements)	5
5. NO EXPIRED PRODUCT IS FOUND "READY FOR DISTRIBUTION" IN A PICK SLOT OR ON A PALLET READY TO BE DELIVERED. (1 ELEMENT)	5
6. Audits of the inventory management system test the tracking system's stock rotation and cycle counts accuracy. Those inventory items that are not shelf life sensitive have a defined method of rotation. Corrective actions are in place to ensure expired product or close to end of shelf life product is properly dispositioned and employees are made aware of results of the audit. (1 Element)	5
7. Center has established procedures for the identification, segregation and disposition of non-conforming/recoup items. (3 Elements)	5
8. Records defining reason for hold and disposition actions taken are maintained. Records must include product code dates, quantities, and disposition. (2 Elements)	5
9. Procedures are developed for the calibration of measuring equipment, all facility thermometers and trailer refrigeration units. The procedures include a weekly calibration for handheld thermometers or follow manufacturer's recommendations. Records of the calibrations are maintained. (2 Elements)	5
10. There is a planned system for continuing preventative and corrective maintenance of key equipment including but not limited to material handling equipment (MHE), transport equipment and refrigeration units in the facility. (3 Elements)	5
11. Customer complaints are categorized and maintained with corrective actions. The complaints are analyzed by category on an established frequency to identify improvement opportunities. (2 Elements)	5
12. An ongoing written training program has been established for all center employees and drivers on GDPs, Distribution Work Place Safety, Food Safety, and Food Defense. Additional specific driver training must be included for drivers and helpers (if helpers are used). Training records are maintained including the following: date, topics covered, who conducted the training, who attended the training. (3 Elements)	5
13. An ongoing written training program has been established for receivers and loaders including contract receivers used to unload trailers. Training records are maintained. (2 Elements)	5
14. DC personnel must conduct monthly self-inspections of the entire facility and grounds using these or similar written criteria. Documentation of self-inspections must be on file and available for review by auditor. Corrective actions from the audits must be identified and addressed to include what is to be done, completion date, and by whom. Inspections have cross functional participation, and not conducted by the same individual every month. (3 Elements)	4
15. Written procedures have been established to ensure product protection for customer pick-ups at the center (will calls) and will include guidelines for pulling, staging, and transport of products. Temperature sensitive product temperatures must be recorded at the time of customer pick up. Will call records are maintained. (3 Elements)	5

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

II. Quality Systems

A. Quality Systems

16. Written procedures have been established on how to handle product returns for both safety and security reasons. Guidelines must define what if anything can be returned, integrity parameters, delivery options and disposition of returned product. Product return records must be documented including the lot and or code dates of any products being disposed of. (2 Elements)	5
17. Quality Systems Sectional Summary	N/A

B. Facility Management

	Rating
1. Management Review: At least annually, the management team must meet to review audit results, complaints, corrective actions, and overall assessment of the health of the food safety management system. This could include items such as trend analyses, continuous improvement projects, and capital expenditures that are planned and ongoing. The management review meeting must be documented and include specific outcomes and action items, as necessary. (1 Element)	5
2. Change Management: The organization has a documented change management program that identifies the processes and responsibilities for managing changes to programs, equipment, facility, etc. The program must include a review and validation of major changes that are made. (2 Elements)	3
3. Facility has completed the required registration for the Food Safety Modernization Act. The auditor must verify that the facility has gone through the registration process. (1 Element) http://www.fda.gov/food/complianceenforcement/rfr/default.htm (Not required if facility is exclusively under USDA FSIS inspection)	5
4. If FDA regulated and located in the USA, the facility is aware of the 2009 FDA regulation establishing a Reportable Food Registry (RFR) and its accountability as a food or feed manufacturer to report when there is reasonable probability that an article of food will cause serious adverse health consequences. (1 Element)	5
5. Facility Management Sectional Summary	N/A

Possible Points	**100**
Actual Points	**97**
Percentage	**97**

II. Quality Systems

Comments

II.A.1 Note: Warehouse SOP defines the GMP/GDP program and is acceptable.

II.A.2 Note: Corporate SOP defined document control and acceptable.

II.A.3 Note: Internal reefer equipment failure SOP in effect. Terminal managers, warehouse and VP Ops phone numbers are listed.

II.A.5 Note: No expired inventory was observed.

II.A.6 Note: Due to the cross-dock nature of the facility, inventory accuracy is specific to customer requirements, e.g. one account reviewed requires their case count to be audited weekly.

II.A.8 Note: Current OSD report reviewed and indicates product retained, reason, codes date, etc.

II.A.9 Note: Thermometer calibration using the ice bath method was reviewed with associated records and well maintained.

II.A.11 Note: Customer complaints are rare as no product is picked. Most complaints are due to drivers and road issues.

II.A.12 Note: Specific driver training program developed and reviewed with pertinent information defined.

II.A.14 Quarterly audits are conducted instead of monthly.

Note: The internal audit template in use is extensive and covers significantly more topics than the facility and grounds.

II.A.15 Note: Will-Call SOP reviewed and acceptable.

II.A.16 Note: Product returns are handled as OSD even though not picked at the warehouse.

II.B.1 Note: Strategic retreat meetings are corporate responsibility with the action plan distributed to the warehouse. Current plan reviewed and acceptable.

II.B.2 Elements of a change control program exist, but a procedure has not been established.

II.B.3 Note: Facility is registered through 12/2018.

III. Equipment & Facility

A. Facility Exterior

	Rating
1. Roads, yards, grounds, and parking lots are maintained in neat and good condition, and free of trash and litter. Weeds and ground cover are controlled within 20 feet of the building to prevent harborage areas. Ornamental landscaping must not provide potential harborage next to the building. (3 Elements)	5
2. The exterior surroundings, including neighboring land, facilities, buildings, etc, should be assessed for potential contamination risks and controls should be implemented based upon risks. Distribution Center grounds have adequate drainage to prevent pooling of water, which can serve as 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. The parking areas adjacent to the building should be maintained in a manner to minimize dust. (3 Elements)	5
3. Equipment stored on Distribution Center grounds is at least 20 feet away from the buildings. Equipment stored within 20 feet must be at least 6 inches above the ground, and in an organized manner to prevent breeding areas and harborage from pests. Any pipes within 20 feet of the building must have closed ends. Drains protruding from outer building walls must be screened and vents must be equipped with proper louvers that close when fans are off. (3 Elements)	5
4. All bumpers, levelers and shelters are in good repair and dock pits are clean. (3 Elements)	5
5. 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 (Roof drains are exempt). (3 Elements)	5
6. Facility Exterior Sectional Summary	N/A

III. Equipment & Facility

B. Facility Interior

	Rating
1. Interior floors, walls, and ceilings are constructed of materials that can be adequately cleaned and maintained in good repair. (3 Elements)	4
2. Dock doors are immediately closed upon a trailer's leaving the dock. Door levelers are adjusted when dock doors are closed to prevent gaps. (2 Elements)	3
3. Lights and other breakable materials such as brittle plastic are shielded and protected from breakage over any product in shipping and receiving and in storage areas to prevent potential contamination. (1 Element)	5
4. 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 items being sold and clean-up procedures for breakage. (3 Elements)	5
5. There is adequate lighting in all areas of the facility, including storage, receiving, shipping, locker rooms, restrooms and break rooms. (1 Element)	5
6. Only approved food-grade lubricants are used on food handling equipment, and they are appropriately stored and labeled. Food grade lubricant must be used when product comes into direct contact with equipment. (2 Elements)	N/A
7. All items are on racks or pallets. No items are stored on the floor of distribution center (Slip sheet storage is acceptable, if the customer's program allows it or the center has written customer approval.). Products are allowed to be stored in trailers without pallets. (1 Element)	5
8. Pallets are in good repair and are not broken when used in the facility. Pallets are clean and do not contain aged debris. All slats of pallets are intact. Empty pallets stored on the interior of the facility are stacked in straight stacks and well organized. (2 Elements)	5
9. Break areas, locker rooms, and restrooms are maintained in a clean, sanitary condition. Drains function properly and are free of standing water. Break areas are separated from the food storage areas and are free of center garments, etc. Ladies' restrooms must have covered trash receptacles. Hand washing signage is posted in all of these areas either as pictures or in languages appropriate for workers to understand. (4 Elements)	5
10. Forklifts / floor scrubbers / vacuums are well maintained, cleaned and properly stored. Idle equipment and spare parts are properly cleaned and stored. (2 Elements)	5
11. Battery storage areas are cleaned, maintained and separate from food storage areas. (2 Elements)	5
12. Doors with curtains or automatic doors are evident at all refrigeration/freezer door storage areas. They are in good repair; seals are maintained. Mold and frost removal practices are acceptable. (3 Elements)	5
13. Facility Interior Sectional Summary	N/A

Possible Points	**80**
Actual Points	**77**
Percentage	**96.3**

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

III. Equipment & Facility

Comments

III.A.1 Note: The facility grounds are in very good condition.

III.A.3 Note: No equipment is stored on the grounds.

III.A.5 Note: External dock overhang is screened for bird protection.

III.B.1 Loose ceiling insulation bats noted in several areas.

III.B.2 Dock door #8 has an open gap at the bottom seal.

III.B.3 Note: Damaged, not-working plastic wall mounted clock removed from service and discarded (5' from floor).

III.B.5 Note: Supplemental skylighting is utilized.

III.B.6 No food grade lubricants are required.

III.B.10 Note: Floor scrubbing is a contracted service.

III.B.13 NA

IV. Pest Control

A. Pest Control

	Rating
1. A WRITTEN PEST CONTROL PROGRAM, BASED UPON RISK, HAS BEEN ESTABLISHED. IT MUST INCLUDE A DESIGNATED PEST CONTROL OPERATOR (INTERNAL OR AN OUTSIDE SERVICE), SCHEDULED FREQUENCY OF SERVICE, 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 training/certification for all PCOs in accordance with state requirements. The files also include a current list of approved pesticides to be used in the facility. SDS 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)	5
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 location treated, targeted pests, signs of activity and applicable follow-up actions. Trends in activity must be assessed by the PCO or plant to identify areas of improvement in the pest control program. (2 Elements)	5
4. The plant has an adequate number of interior pest control devices are checked at least twice monthly. The spacing is at consistent intervals (typically 20-40ft., but based upon risk) around the interior perimeter of the building area and around interior perimeter of any walled in dry food storage, packaging or cooler areas. Inside of any exterior wall and cooler walls. Mechanical stations should be 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. All devices must be located so that they do not contaminate product, packaging or equipment. The PCO must initial and date, or sign, scan the barcode or use the punch cards on all devices. These labels should be on the inside of the devices. (4 Elements)	5
5. The plant has an adequate number of tamper-resistant exterior pest control stations, that are checked at least monthly, spaced at appropriate intervals (usually 25-50 ft., but based upon risk) 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. The PCO must initial and date, or sign, scan the barcode or use the punch cards on all devices. These labels should be on the inside of the devices. (4 Elements)	5
6. 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. (2 Elements)	5
7. 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. The site is controlling all internal and external pest activity, based on the pest control reports and observations during the audit. (3 ELEMENTS)	5
8. Insect light traps (ILTs) (both low and high voltage) and flying insect traps may be used. Placement must be according to manufacturer instructions and comply with applicable regulations. If instructions are not available, ILTs must be between 2 and 5 feet off the ground. High voltage ILTs should be at least 10 ft. from covered/protected products or packaging and at least 30 ft. from exposed product, packaging, or equipment. Low voltage ILTs must not be above covered/protected or exposed product, packaging or equipment. Low voltage ILTs must also include sticky boards. 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)	N/A
9. 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. Avicides are prohibited from being used inside of the facility and if used on the exterior, must be used according to the program and label requirements. (2 elements)	N/A
10. Pest Control Sectional Summary	N/A

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

IV. Pest Control

Possible Points	**35**
Actual Points	**35**
Percentage	**100**

Comments

IV.A.1 Note: Sprague is the PCO selected for use. All documentation has been converted over to the on-line system.

IV.A.3 Note: Rodents are well controlled at this facility. Trend reports indicate a single internal catch in the past 12+ months.

IV.A.8 N/A- Not used.

IV.A.9 N/A- No chemical storage on site or use of avicides.

V. Sanitation

A. Sanitation Program

	Rating
1. A written master sanitation program has been established and is being used for all daily, monthly, and other scheduled sanitation activities. The program covers all areas and equipment of the facility and grounds, including the buildings, grounds, offices, and all trailers. (2 Elements)	5
2. Cleaning and sanitation tasks and responsibilities are assigned and noted on the schedule. Verification of satisfactory completion of these tasks is recorded. (2 Elements)	5
3. Written sanitation standard operating procedures (SSOPs) are developed for sanitation tasks within the facility, including trailers, that require chemicals or water. (2 Elements)	5
4. Written cleaning and sanitation standard operating procedures (SSOPs) are developed specifically for refrigerated raw product storage areas. There are procedures for the cleaning and sanitizing to be done when spills of raw products occur. Dedicated sanitation equipment is available for refrigerated raw product areas, and it is identified appropriately by labeling or color-coding. (3 Elements)	N/A
5. A program for conducting ongoing training for cleaning and sanitation procedures and safe handling of chemicals has been established. The training is for employees completing sanitation tasks. Training documentation includes the date(s) given, topics covered, name of trainer, and is part of the employee's records. The training must be conducted annually. (3 Elements)	5
6. Cleaning chemicals and sanitizers used in the facility are approved by the appropriate regulatory agency or have a letter of guarantee from the supplier stating the specific chemical or sanitizer can be used in a food facility. SDS and sample labels are available for all chemicals used in the center. (3 Elements)	5
7. Cleaning chemicals and sanitizers must be appropriately labeled if they are not in their original container. (1 Element)	5
8. Cleaning tools and chemicals used in the center are stored in designated, clean and organized areas when not in use. The chemical storage area is labeled, segregated from food items and secured. (3 Elements)	5
9. Sanitation Program Sectional Summary	N/A

V. Sanitation

B. Facility

	Rating
1. Trailer washing areas attached to the facility are well maintained, have operating drains or water capturing systems, and are clean with no evidence of debris or residue build-up. (3 Elements)	5
2. Inbound and outbound trailers are clean, sanitary, and show no signs of infestation, and no debris. Trailers are in sound condition and capable of maintaining proper product temperatures and preventing any product contamination. Door seals are in good repair and light cannot be seen around doorframes. (2 Elements)	5
3. Sanitation inspections of inbound and outbound trailers must be documented. The inspections should include evaluation of sanitation, off odors, and pest activity. (2 Elements)	5
4. Dumpster/compactor area is clean with no debris/residue build up evident. All exterior trash receptacles are covered to prevent the attraction of pests. A bait station must be within 20 feet of the dumpster/compactor if the dumpster/compactor is within 20 feet of the building. (3 Elements)	5
5. Dry storage racking including footings is clean with no signs of dust buildup or debris in the footings. Pipes, overhead structures, electrical boxes, conduit and fans are free from dust. (2 Elements)	5
6. Dry storage areas are organized, clean, sanitary and well-maintained. All spills are immediately cleaned up. The floors, walls and ceilings are not dirty, and there is no evidence of spills, trash or other litter. (3 Elements)	5
7. In all storage areas, wall and floor areas behind racking are clean, clear of stored items and easily accessible for inspection and cleaning. (1 Element)	5
8. Floors, walls and ceilings of coolers, freezers and cool docks are in good repair and maintained in a clean and sanitary condition. There is no evidence of spills trash or clutter. Floors are kept dry. (3 Elements)	5
9. Racking in the coolers, freezers, and on the cool docks is clean and free from heavy dust. Racks and pallets of product are not dirty or damaged. No trash, spills, or other litter is on the racking. (2 Elements)	5
10. Coolers show no sign of condensation. Freezers have no ice on floors, walls, or ceilings. (2 Elements)	5
11. Products stored in freezers and coolers should be free from condensation and ice or snow. (1 Element)	5
12. All product hold areas, return areas and recoup areas are clean with no aged product spills, residue, or leaking product. (2 Elements)	5
13. Dock levelers and wells are clean with no wood pieces, product or packaging present upon inspection. Brushes or gaskets are in place. (2 Elements)	5
14. The loading dock areas are clear of debris and spilled products. Equipment or items stored on the docks should be clean and organized. (2 Elements)	5
15. Small wares storage areas are clean. Racks are free from heavy dust. All items are properly stored. (2 Elements)	N/A
16. Facility Sectional Summary	N/A

Possible Points	**105**
Actual Points	**105**
Percentage	**100**

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

V. Sanitation

Comments

V.A.1 Note: The master sanitation program is divided into daily, weekly and monthly tasks.

V.A.2 Note: The schedule is well maintained with initialed dates of tasks checked off as completed.

V.A.3 Note: SSOPs have been developed that are adequate for the facility.

V.A.4 N/A- No raw storage refrigerated rooms are maintained.

V.A.6 Note: Minimal chemicals are used (Simple Green) and floor-scrubber services are contracted out.

V.A.9 NA

V.B.1 Note: Trailer washing services are contracted.

V.B.15 N/A- No small wares are inventoried.

VI. Food Defense

A. Food Defense Program & Practices

	Rating
1. The facility must have a documented food defense plan that designates a multidisciplinary team, which meets at least annually to assess all facility operations to determine potential deliberate contamination risks and appropriate strategies to reduce these identified risks. The facility is in compliance with their documented program. (4 Elements)	5
2. The plan documents how access is controlled into the facility and within the different areas of the facility. There must be a system for screening, training and easy identification of personnel within the facility. The plan must identify how any areas deemed critical based upon the risk assessment are secured. (3 Elements)	5
3. The facility complies with their program on restricting access to the plant. The facility has systems in place to alert personnel about restricted areas. All access points are secured or monitored. (4 Elements)	5
4. Food Defense Program & Practices Sectional Summary	N/A

Possible Points	**15**
Actual Points	**15**
Percentage	**100**

Comments

VI.A.1 Note: The Warehouse Security program was reviewed and acceptable. Annual reviews are conducted by the Food Defense Team, reviewed and acceptable.

VI.A.3 Note: All employees are assigned photo ID cards. Pre-screen hiring SOP in effect.

VII. Fresh Produce Repack & Trimmed Repack

A. Repack

	Rating
1. Procedures are required for Distribution Centers that repack or trim fresh produce. The procedures must identify the location of the work station, the necessary tools & equipment, sanitation requirements and product traceability method. (4 Elements) Note: This question is N/A if no repacking of raw produce is occurring at the DC.	N/A
2. Repack Sectional Summary	N/A

Possible Points	**0**
Actual Points	**0**
Percentage	

Comments

VII.A.1 N/A- No repack procedures are conducted.

Distribution Center Food Safety and Quality Systems Audit Assessment Rating System

This rating system describes a food facility's level of compliance with recognized food safety and Good Manufacturing Practices or good distribution practices. The point system and definitions are objective guidelines for evaluating the facility'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.

Auditors may use their discretion regarding ratings considering the severity of food safety issues and numbers of observations of issue noted. The comment for non-conformity must be detailed to explain the 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	Score given to question
3	NA	1	2	4	5	
2	NA	NA	1	3	5	
1	NA	NA	NA	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 or a specific/same issue or element.

Each facility 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	Overall Audit Rating
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

If a critical non conformance is identified by the auditor, the overall rating will result in a "minimally meets audit expectations."

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