



# **SQFI** Audit Report Edition 9

I. Company Information						
Company Name	Southeastern Seaproducts			Company #		7501
Address	1500 Maple Ave					
City	Melbourne	State	Florid	а	Zip Code	32935
Country	United States	Phone #	321-2	59-1914		
Primary Contact	Dana Brown	Email	dana@frozenliveshellfish.com		n	
Food Sector Categories	09 - Seafood Process	ing				
Modules Audited	Animal Product Manufacturing Module 2 GMP for Processing of Animal Products Module 9					
Certified Products	Fresh and frozen oyst	ters, clams, sca	lops, ar	nd mussels	3	

II. Certification Body					
Certifying Body	NSF Certification LLC		CB#		CB-1-NSF
Address	789 N. Dixboro Rd.				
City	Ann Arbor	State	MI	Zip Code	48105
Country	United States of America	Phone #	(734) 769	9-8010	
Accreditation Body	ANSI Accreditation Program	Accreditation Number	1181		

III. Audit Sche	dule		
Certification Type	Unannounced	Audit Level	HACCP-Based Food Safety
Start Date	11/Feb/2025 07:55:00 AM	End Date	13/Feb/2025 04:55:00 PM
Scope of Certification	Exclusions: Scope: Fresh and frozen oysters, clam		

IV. Audit Tear	n		
First Name	Last Name	Person #	Role
Blaine	Holmberg	123273	Lead Auditor

V. Audit Dura	tion		
Actual Start Date	11/Feb/2025 07:55:00 AM	Actual End Date	13/Feb/2025 04:55:00 PM
Hours Spent on Site	24	Hours Spent Writing Report	8





Hours of ICT	N/A	
Activites	IN/A	

VI. Certification	Decision		
First Name	Last Name	Person #	Role
Iqbal	Kamoonpuri	202914	Technical Reviewer
Certificate Decision Date	04/Mar/2025	Certificate Issue Date	04/MAR/2025
Audit Score	98	Audit Rating	Excellent
Certification #	C0791945-SQF2		
Re-certification Date	29/JAN/2026	Expiration Date	14/APR/2026
Surveillance Audit Due Date		Certification Decision	Certified





VII. Non-Conforming	
7	Evidence
Clause	9.1.5.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and
	proper seals to protect against entry of dust, vermin, and other pests.
Response	Minor
Evidence	There was a gap near the top of the receiving roll up door in the back of the facility.
Root Cause	The door sited during the audit had a hole at the top of the door due to wear and tear of using the door over time. The new door was scheduled to be installed on Monday (2/10/2025) but was not installed due to equipment failure that needed to be tended to right away. We currently only have two employees in our Maintenance department and they both were needed to take care of the equipment failure and couldn't install the roll-up bay door, as scheduled. The Vice President of our company had to schedule three Visa-Workers that work for Southeastern Seaproducts, Inc to install the roll-up bay door, which was completed on Saturday (2/15/2025).
Corrective Action	The damaged roll-up/bay door was uninstalled, and a new roll-up/bay door was installed. I updated the Weekly Equipment, Facilities, Glass and Brittle Plastics, Building Inspection Checklist to include the documenting of the conditions of the exit/bay doors. I also did a training on the updated Weekly Equipment, Facilities, Glass and Brittle Plastics, Building Inspection Checklist. Also, during the training, I informed the Trainee of the importance of making sure that all doors and vents must be good working order without holes/gaps for the importance of Food Safety and Pest Control.
Verification of Closeout	The door was repaired, audit revised, training conducted, and proof attached.
Completion Date	27/Feb/2025
Closeout Date	08/Mar/2025
	Evidence
Clause	9.6.5.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are approved for use and stored on-site; and iii. Supported by current Safety Data Sheets (SDS) made available to all staff.
Response	Minor
Evidence	There was an unlabeled mop bucket on a janitorial cart not in use, outside of the IQF room entrance. It had dirty liquid and a mop on the first 2 days of facility inspections and was empty on the 3rd day.





Root Cause	The mop bucket sited during the audit was not labeled due to the negligence of the Practitioner. The Practitioner conducts a weekly SQF Inspection Checklist that includes checking to make sure that all chemical bottles/containers are properly labeled. It didn't occur to the Practitioner that a mop bucket is technically a chemical container. The mop bucket that was sited during the audit with the dirty water wasn't dumped after the schedule cleaning due to the Janitorial Staff being needed on the production lines. The Janitorial Staff does empty and sanitize the mop bucket before each scheduled cleaning but was not documenting it prior to the audit. The emptying of the mop bucket wasn't documented prior to the audit due to thinking that it's common knowledge that mop buckets should be emptied and cleaned after each cleaning.
Corrective Action	The mop bucket was labeled, indicating the contents within the moping solution used. Also, the Bathroom Cleaning Record was updated to include a section to document the emptying and sanitizing of the mop bucket after each scheduled cleaning. A training was conducted on the topic of the updated Bathroom Cleaning Record and the importance of emptying and sanitizing the mop bucket after each use for Food Safety. A training was also conducted on the topic of Labeling Chemical Bottles/Containers.
Verification of Closeout	The cleaning record was revised, training conducted, and proof attached.
Completion Date	27/Feb/2025
Closeout Date	08/Mar/2025

Audit Statements	Audit Statements			
	Item	Evidence		
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas)	Kathryn Leedy: COO, Aaron Krager: Office Assistant, Dana Brown: SQF Practitioner, Blaine Holmberg: Auditor		
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details	Southeastern Seaproducts is located in Melbourne, Florida and has been in operation since 1992. The building itself was built around 1957 and located in a mixed, industrial/residential area. The site is housed in a 23,000 square foot building with approximately 35 employees. The site hours of operation are Monday through Friday 09:00 until 17:00 (occasional Sunday as needed). The site is a seafood processor of fresh and frozen oysters, clams, scallops, and mussels. It also performs steaming direct in bags of the clams and mussels. The product are sourced through certified dealers. The fresh products are packed in net for the molluscan shellfish (different clams, mussels) with 100 count based on size, which is around 1lb to 5 lbs. Oysters are packed in waxed boxes in 100 counts based on size, which is around 22-25lbs. Frozen products are packed in plastic trays and in waxed boxes depending on customer request by count. The site shackles mostly oysters		





		and when need clams. The shackled oyster is packed in a plastic box that goes in waxed box. The site performs steamed clams and mussels are packed in bags and in customer boxes or they own brand Salty Seas. The current audit was an announced SQF edition 9 Manufacturing audit for FSC 9 - Seafood Processing. The auditor entered the production area within 30 minutes of arriving at the facility for this unannounced audit.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas)	Kathryn Leedy: COO, Aaron Krager: Office Assistant, Dana Brown: SQF Practitioner, Blaine Holmberg: Auditor
Auditor Recommendation	Auditor Recommendation	Issue of Certification of Registration recommended once deficiencies rectified





Element	Description	Primary Response	Evidence
2.1.1.1	Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to: i. Supply safe food; ii. Establish and maintain a food safety culture within the site; iii. Establish and continually improve the site's food safety management system; and iv. Comply with customer and regulatory requirements to supply safe food. The policy statement shall be: v. Signed by the senior site manager and displayed in prominent positions; and vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel.	Compliant	
2.1.1.2	Senior site management shall lead and support a food safety culture within the site that ensures at a minimum: i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures; ii. Adequate resources are available to meet food safety objectives; iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained; iv. Staff are informed and held accountable for their food safety and regulatory responsibilities; v. Staff are positively encouraged and required to notify management about actual or potential food safety issues; and vi. Staff are empowered to act to resolve food safety issues within their scope of work.	Compliant	
2.1.1.3	The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify a backup for the absence of key personnel. Job descriptions for the key personnel shall be documented. Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.	Compliant	
2.1.1.4	Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF System; ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.	Compliant	
2.1.1.5	The primary and substitute SQF practitioner shall: i. Be employed by the site; ii. Hold a position of responsibility related to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to	Compliant	





	implement and maintain HACCP-based food safety plans; and v. Have an understanding of the SQF Food Safety Code: Animal Product Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.		
2.1.1.6	Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9, and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.	Compliant	
2.1.1.7	Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.	Compliant	
2.1.1.8	Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.	Compliant	

#### SS 2.1.1 Management Responsibility Summary

Policy Statement is available and includes the methods of meeting the requirements. Pre-requisite programs are in place and address elements. The company policy includes a commitment to establish and review food safety and quality objectives. It is signed by the CEO on 11/19/2024, and is effectively communicated to all staff in training and posted in the break room. The policy statement is posted in English and Spanish. The SQF Practitioner (DB), who has HACCP certificate from NC State from Spring 2021, and is a full time employee. The Backup practitioners include is the COO (KL), who has Seafood HACCP certificate from 6/20/2016. Food safety objectives have been established including: remain within acceptable limits for semi-annual testing for listerian and C-bot for frozen vacuum packed whole clams and frozen half shell oysters, and quarterly testing for vibrio for frozen whole oysters; maintain zero NCs from quarterly Department of Agriculture inspections; maintain zero food safety customer complaints; reduce number of NCs from previous SQF audit and achieve SQF certification. All objectives were met for 2024. There is an organizational chart in the SQF manual. It was observed to be up to date (dated 11/15/2023) and accurate to the current reporting structure of the company. The job descriptions are included to identify responsibility for food safety. The senior management supported the documented procedures, training, policy improvements and capital improvements to ensure the food safety practices were adopted and maintained. They support the continuous improvement through maintaining the facility and equipment. There were adequate resources observed during the audit. They have undergone multimillion dollar renovations over the past few years including new floors, walls, ceilings, coolers, equipment. A new multivac machine and room was installed in the past year. Blackout dates were submitted to the certification body at least 1 month before the audit window for this unannounced audit. The auditor entered th

2.1.2 Management Review Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence	
2.1.2.1	The SQF System shall be reviewed by senior site management at least annually and include: i. Changes to food safety management system documentation	Compliant		





	(policies, procedures, specifications, food safety plan); ii. Food safety culture performance; iii. Food safety objectives and performance measures; iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities; v. Hazard and risk management system; and vi. Follow-up action items from previous management reviews. Records of all management reviews and updates shall be maintained.		
2.1.2.2	The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented.	Compliant	

#### SS 2.1.2 Management Review Summary

Management Review procedures (2.1.4 reviewed 11/6/2024) documents management reviews. The entire SQF system is reviewed by upper management at least annually. The system was last reviewed by management with an SQF consultant on 11/4-6/2024 and Annual Senior Management Review on 1/2/2025. They also conduct management review meetings monthly, last on 1/28/2025. The SQF Practitioner is responsible for validating the food safety plan. If there are any changes to the food safety fundamentals or food safety plan, they are reviewed and validated by the management team including the SQF Practitioner.

2.1.3 Complaint I	2.1.3 Complaint Management Module 2 Animal Product Manufacturing			
Element	Description	Primary Response	Evidence	
2.1.3.1	The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.	Compliant		
2.1.3.2	Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.	Compliant		
2.1.3.3	Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.	Compliant		

### SS 2.1.3 Complaint Management Summary

The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities are documented in 2.1.5 revised on 11/6/2024. The SQF Practitioner handles customer complaints. The department manager to which the complaint is assigned performs an investigation and develops a corrective action. The facility's SQF Practitioners make the final decision on the resolution of the complaint. They have not received any customer complaints in the past year.

# 2.2.1 Food Safety Management System Module 2 Animal Product Manufacturing





Element	Description	Primary Response	Evidence
2.2.1.1	The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Animal Product Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The processes and products included in the scope of certification; iv. Food safety regulations that apply to the manufacturing site and the country(ies) of sale (if known); v. Raw material, ingredient, packaging, and finished product specifications; vi. Food safety procedures, prerequisite programs, food safety plans; vii. Process controls that impact product safety; and viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.	Compliant	
2.2.1.2	Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food. All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be documented.	Compliant	

## SS 2.2.1 Food Safety Management System Summary

A food safety and quality manual has been developed and is maintained in physical and electronic form in the share drive and maintained by the Director of Food Safety. The food safety and quality manual contains the scope of the certification, a list of products in the scope, the organizational chart and food safety and quality policies summary, programs and procedures that make up the site's SQF System. The food safety plan and site procedures and policies are reviewed during the monthly management review meeting last on 12/3/2024. The food safety and quality manual is made available to all relevant staff through the quality team.

2.2.2 Document C	2.2.2 Document Control Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence		
2.2.2.1	The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented. Current SQF System documents and amendments to documents shall be maintained.	Compliant			
	SS 2.2.2 Document Control Summary				





The facility's written Document Control Procedure (2.2.1 revised 11/6/2024) outlines the SQF practitioners are responsible for each department specific programs and policies. The programs are required to be assessed at least once per year. Documents are stored and controlled by the SQF practitioner. Company uses an electronic storage and document sharing program for accessibility.

2.2.3 Records Module 2 Animal Product Manufacturing			
Element	Description	Primary Response	Evidence
2.2.3.1	The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented.	Compliant	
2.2.3.2	All records shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed.	Compliant	
2.2.3.3	Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life, or established by the site if no shelf-life exists.	Compliant	

## SS 2.2.3 Records Summary

The facility's written Records Control Procedure outlines a Records Retention Schedule detailing the records will be maintained for a minimum of 2 years. Records are readily accessible, retrievable, securely stored electronically. Records were observed to be signed and dated by those completing the work.

2.3.1 Product Fo	2.3.1 Product Formulation and Realization Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence		
2.3.1.1	The methods and responsibility for designing and developing new product formulations and converting product concepts to commercial realization shall be documented and implemented.	Compliant			
2.3.1.2	New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by", "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where	Compliant			





	applicable, and storage and handling requirements.	
2.3.1.3	A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.	Compliant
2.3.1.4	Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.	Compliant
2.3.1.5	The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.	Compliant
2.3.1.6	Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.	Compliant

## SS 2.3.1 Product Formulation and Realization Summary

The policies defining the methods and responsibilities for commercialization of new products are called Product Formulation and Realization Policy dated 11/22/2021 which are implemented on site. Procedures conducted at the facility include checking formulations and processes with production trials and product testing as required by the customers. The food safety plan is validated and verified for each new product and process by review of the materials specifications, allergen status, letter of guaranties, CoAs and GFSI certifications, HACCP, LoG, etc. This review includes changes to distribution and ingredients. The site SQF Practitioner maintains records of all steps of the product development cycle including process development and facility trials. Shelf-life is being established and evaluated from the Florida Department of Agriculture. Based on communication with the SQF Practitioner and the COO, the site did not have any new product, ingredient, or process in the past year.

2.3.2 Specificat	2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services) Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence		
2.3.2.1	The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.	Compliant			
2.3.2.2	Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.	Compliant			
2.3.2.3	All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.	Compliant			
2.3.2.4	Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.	Compliant			





2.3.2.5	Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may be variable by season).	Compliant
2.3.2.6	Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.	Compliant
2.3.2.7	Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.	Compliant
2.3.2.8	Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements for all contract personnel.	Compliant
2.3.2.9	Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.	Compliant
2.3.2.10	Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current	Compliant

#### SS 2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services) Summary

Specifications for raw materials, packaging, ingredients, additives, chemicals and processing aids have been documented. Current registers were reviewed for raw materials, packaging materials and labels. Specifications for the clams, salt and bags were reviewed and found to be current. A policy defining the methods and responsibilities for developing and maintaining specifications has been documented and implemented in Methods and Responsibilities for Developing Specifications: dated 9/5/2016 and Supplier Approval Policy dated 11/14/2022. The fish and the packaging materials are verified to ensure product safety, regulatory requirements and fit for purpose requirements are met. These are done by means of receipt of Letters of Guarantee (LoG), Certificates of Compliance and Certificates of Analysis. Food contact packaging tin boxes and white tubs, have a certificate of conformance and LoG from the supplier, indicating that it does not present a risk of chemical migration to food products. Inventory and simple product identification labels are approved by the COO and the SQF Practitioner who are qualified to ensure they are accurate and meet regulatory requirements based on training and experience. During the audit were reviewed the specifications and labels for Frozen Half Shell Oysters and Vacuum Pack Cooked Frozen Clam products. The register of seafood and packaging materials is maintained in Approved Supplier List dated 1/31/2025, which was found to be current. Descriptions of services provided by all contract service providers having an impact on food safety are documented in Visitor and Contractor Health Screening with





GMPs dated 11/18/2022. A list of current contract service providers is maintained in Contract Service Providers dated 10/25/2023 and were found to include providers of services including waste removal, pest control, equipment maintenance and calibration. Contract arrangements for pest control and waste removal were reviewed during the audit and found to be satisfactory. All service contractors go through a GMP policy review before entering the site and are being asked if they understand the requirements or not by signing the form. Finished product specifications are current, documented and approved by the site and the site's customers. Specifications include labeling and packaging requirements. A current product specification document is maintained in Register of Finished Product dated 3/30/2023.

2.3.3 Contract Manufacturers Module 2 Animal Product Manufacturing			
Element	Description	Primary Response	Evidence
2.3.3.1	The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.	Compliant	
2.3.3.2	The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall ensure that: i. Products and processes of co-manufacturers that are considered high-risk have undergone an audit by the site or third-party agency to confirm compliance with the SQF Food Safety Code: Animal Product Manufacturing and regulatory and customer requirements; ii. Products and processes of co-manufacturers that are considered low risk meet the requirements of the SQF Food Safety Code: Animal Product Manufacturing, or other GFSI benchmarked certification programs, and regulatory and customer requirements; and iii. Changes to contractual agreements are approved by both parties and communicated to relevant personnel.	Compliant	
2.3.3.3	Contractual agreements with third-party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Animal Product Manufacturing. Contractual agreements shall be approved by both parties and communicated to relevant personnel. The site shall verify compliance with the SQF Code and ensure that customer and regulatory requirements are being met at all times.	Compliant	
2.3.3.4	Records of audits, contracts, and changes to contractual agreements and their approvals shall be maintained.	Compliant	

#### SS 2.3.3 Contract Manufacturers Summary

The procedures for ensuring agreements with third party warehouse are in place and implemented based on Supplier Approval Policy dated 11/14/2022. The site has in place a contract agreement with the third party storage warehouse C.L.L dated 2/20/2023 and the storage warehouse has GFSI certification, BRCGS certificate expires 4/15/2025.





Element	Description	Primary Response	Evidence
2.3.4.1	The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented. A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained. Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.	Compliant	
2.3.4.2	The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier; iii. A summary of the food safety controls implemented by the approved supplier; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of conformance, if required; and vii. Methods and frequency of reviewing approved supplier performance and status.	Compliant	
2.3.4.3	Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.	Compliant	
2.3.4.4	The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.	Compliant	N/A - The site does not receive seafood and packaging materials from non-approved suppliers.
2.3.4.5	Raw materials, ingredients, and packaging received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and receiving inspections as all other material providers.	Compliant	N/A - The site does is not have any other sites under t same corporate ownership.
2.3.4.6	Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.	Compliant	





The site has a written supplier approval policy Supplier Approval Policy dated 11/14/2022, which has been implemented and covers the procedures for approving suppliers of seafood and packaging materials and services. The policy includes a review of the specifications of products, the supplier's food safety controls, procedures for granting and monitoring approved suppliers, the level of risk of products to the site and details of requirements for Certificate of Conformance, Certificates of Analysis and testing. Approved supplier risk level and status is reviewed using form Packaging Supplier Questionnaire and Raw material Supplier Questionnaire. It was observed that the food defense plan contains methods to secure incoming products from sabotage, the food fraud vulnerability assessment identifies threats to incoming product substitution, mislabeling and dilution, and the food fraud mitigation plan demonstrates these threats are controlled. A register is maintained of all current approved suppliers of seafood, sister sites and packaging materials, which was reviewed during the audit and found to be acceptable in Approved Supplier List dated 10/25/2023. The clams, salt and bags found in the storage warehouse were verified to have come from approved suppliers audits are based on risk; GFSI audit certificates or HACCP LoG or CoC were on file for approved suppliers of the food contact packaging material bags (BRCGS certificate expires 5/13/2025), clams (questionnaire dated 4/23/2024 and COC dated 2/16/2024), oysters (SQF certificate expires 11/26/2025), salt (SQF cert expires 2/18/2026, COA dated 2/12/2024, and questionnaire dated 4/22/2024). 2.3.4.4 N/A - The site does not receive seafood and packaging materials from non-approved suppliers. 2.3.4.5 N/A - The site does is not have any other sites under the same corporate ownership.

Element	islation Module 2 Animal Product Manufacturing  Description	Primary Response	Evidence
2.4.1.1	The site shall ensure that at the time of delivery to customers finished products comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.	Compliant	
2.4.1.2	The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.	Compliant	
2.4.1.3	SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.	Compliant	

#### SS 2.4.1 Food Legislation Summary

The SQF Practitioner is responsible for keeping informed of relevant changes to legislation through professional organizations, publications, regulatory email updates, continuing education, webinars. SQFI and the certification body will be notified in writing (email is preferred) within 24 hours of identification of a food safety event that requires public notification. This is specified in SQF 2.4.1. The site has quarterly regulatory visit from the Florida Department of Agricultural and Consumer Services-Division of Aquaculture, with the last visit on 10/29/2024 and no issues identified for all the inspections throughout the year.





2.4.2 Good Manufacturing Practices Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence	
2.4.2.1	The site shall ensure the applicable Good Manufacturing Practices described in module 9 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised.	Compliant		
2.4.2.2	The Good Manufacturing Practices applicable to the scope of certification outlining how food safety is controlled and assured shall be documented and implemented.	Compliant		

## SS 2.4.2 Good Manufacturing Practices Summary

All employees and visitors are required to follow GMPS. Employees are trained on GMPs upon initial hire and at least annually, records reviewed from 2024. Visitors are required to read and agree to GMPs before entering the facility and are escorted when in product areas. GMPs were observed to be followed during the audit.

2.4.3 Food Safe	Plan Module 2 Animal Product Manufacturing  Description	Primary Response	Evidence
2.4.3.1	A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.	Compliant	
2.4.3.2	The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging materials, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.	Compliant	
2.4.3.3	The scope of each food safety plan shall be developed and documented including the start and end points of the processes under consideration and all relevant inputs and outputs.	Compliant	





2.4.3.4	Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.	Compliant	
2.4.3.5	The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.	Compliant	
2.4.3.6	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging materials, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.	Compliant	
2.4.3.7	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.	Compliant	
2.4.3.8	The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.	Compliant	
2.4.3.9	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.	Compliant	
2.4.3.10	Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.	Compliant	
2.4.3.11	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard (s) and that all critical limits and control measures individually or in combination effectively provide the level of control required	Compliant	





	(refer to 2.5.2.1).		
2.4.3.12	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.	Compliant	
2.4.3.13	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.	Compliant	
2.4.3.14	The documented and approved food safety plan (s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.	Compliant	
2.4.3.15	Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).	Compliant	
2.4.3.16	Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.	Compliant	
2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.	Compliant	

#### SS 2.4.3 Food Safety Plan Summary

There are 10 food safety plans that have been developed, implemented and maintained by the site in hard copy in the HACCP Program folder by the SQF Practitioner. Also, it is kept on file electronically in the company share drive: (1) Shucked Oysters Traditional Harvest, (2) Frozen Whole or Half Shell Oysters, (3) Vacuum skin trays, (4) Vacuum skin Rockefeller, (5) Fresh Clams, (6) Wet Storage, (7) Fresh Oysters, (8) Stay Fresh Oysters, (9) Vacuum Clams, and (10) Whole Frozen Clams. The Food Safety Plans have been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines and the FDA Seafood HACCP. A multidisciplinary HACCP Team has been identified and trained, with documentation found in the HACCP certificates. The Plan includes a list of all products in the scope of the certification, a complete product description, intended product use (including vulnerable populations) and flow diagrams for each process including all input and output steps in the process. The process flow has been verified by the site per walk through. The food safety team has analyzed all hazards reasonably likely to occur including physical (foreign material), chemical (allergen, sulfites, radiological Aquaculture drugs) and microbiological (Pathogen contamination, C. bot, Parasites) hazards for each process step, ingredient and packaging. Control measures are in place to eliminate or reduce the food safety risk to acceptable levels. Critical Control Points have been identified for each plan: CCP#1-1 - Receiving temp less than < 50 F and from CCP#1-2 - Certified dealers and tagged; CCP#2 - Storage of Shell stock & Shucked Product in cooler < 45 F; CCP#3 - Storage of Shell stock & Finished Product in cooler < 45 F; CCP#4 - Shipping < 45 F; CCP#5 - Freezing of product at -150 F for 5-6 minutes; CCP#6 - Frozen storage of the product 0-10 F for minimum 29 days; CCP#7 - Wet Storage with Turbidity < 20 NTU, pH=7.0-8.4, flow rate of 60 gal/min, Dissolved





Oxygen >0.5 mg/ml, 60% maximum efficiency; CCP#8 - Cooking internal temperature of >158 | F for 2 minutes; CCP#9 - Storage of Shell stock & Finished Product in Freezer less than <20 | F; CCP#10 - Packing/Labeling making sure that Heating Instructions are present showing cooking of 145 | F and Allergen content. These are monitored and verified in the Food Safety Plan. Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plan is verified as part of the SQF System and reviewed annually or when changes occur, by the food safety team with the last review date on 5/31/2024 for all plans. National regulatory requirements for the site also require an FDA Seafood HACCP Plan which was observed to be implemented and the PC identified were labeling of the finished product, sanitation controls and environmental controls. The site has a letter from the Florida Department of Health and Human Services on 3/01/2012 for the approval of the process for the oyster freezing at -150F and kept frozen under 0 | F for 29 days that claims Vibrio free Oysters. The site has a letter from the Florida Dep of Ag and Consumer Services on 8/19/2022 for the approval of the Wet Storage System.

Element	Description	Primary Response	Evidence
2.4.4.1	The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in- progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements. Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.	Compliant	
2.4.4.2	Product analyses shall be conducted to nationally recognized methods, or company requirements or alternative methods that are validated as equivalent to the nationally recognized methods. Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses. External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).	Compliant	
2.4.4.3	On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. Signage shall be displayed identifying the laboratory area as a restricted area, accessible only by authorized personnel.	Not Applicable	There is no lab on site.
2.4.4.4	Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service food processing and handling areas.	Not Applicable	There is no lab on site.





2.4.4.5	Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelf life of the product.	Not Applicable	Retention samples are not kept.
2.4.4.6	Records of all inspections and analyses shall be maintained.	Compliant	

#### SS 2.4.4 Product Sampling, Inspection, and Analysis Summary

The site's procedures and criteria for sampling, inspecting and analyzing raw materials, work-in-progress and finished product have been documented and implemented in procedure Product Sampling and Inspection Policy dated 8/22/2024. CoC and LoG are required for all the seafood and packaging materials. Cooked Vacuum Pack clams are tested for L. mono and C. bot semi-annually (last on 9/13/2024 and 3/1/2024); Nitrogen frozen oysters are tested for Vibrio vulnificus and V. parahaemolyticus quarterly (last on 11/12/2024 and 8/2/2024); and Frozen raw RTE half shell oysters are tested for coliforms, S. aureaus, Salmonella, E.coli, and L. mono annually (last on 2/24/2024). There is no lab on site. All testing is performed only through 3rd party external laboratories which operate based on national recognized standards such as FDA BAM and AOAC. ISO 17025:2017 accreditations expire 1/31/2026 and 8/31/2026. SQF Practitioner and the COO conducts environmental swabbing for ATP and Listeria quarterly. The products are sampled by the Florida State DA quarterly and no issues have been identified. For the fresh oysters the site sends water samples weekly to the laboratory for total count and no issues have been identified. 2.4.4.3-4 N/A - There is no lab on site. 2.4.4.5 N/A - Retention samples are not kept.

2.4.5 Non-conforming Materials and Product Module 2 Animal Product Manufacturing			
Element	Description	Primary Response	Evidence
2.4.5.1	The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and ii. All relevant personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status.	Compliant	
2.4.5.2	Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.	Compliant	

#### SS 2.4.5 Non-conforming Materials and Product Summary

Non-conforming & Rework Control (2.4.6 reviewed 11/6/2024) outlines the methods and responsibilities for handling non-conforming products. Any facility management team member can place products on hold due to non-conformity issues. Non-conforming products are put on hold in the electronic inventory system, segregated and cannot be shipped. Documentation of non-conformances are stored electronically in the software. The Management team perform final release on all hold products. Auditor reviewed Hold log from 2024 and corrective actions for non-conforming product and equipment including: bad wheels on pallet jack on 3/19/2024 and were replaced and released on 3/20/2024; Lot# 2373 frozen oysters were put on hold on 12/27/2023 for observed poor quality and were inspected by the CEO and destroyed on 5/1/2024.





2.4.6 Product Rev	2.4.6 Product Rework Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence		
2.4.6.1	The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are overseen by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Reworked product is processed in accordance with the site's food safety plan; iv. Each batch of reworked product is inspected or analyzed as required before release; v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1; vi. Release of reworked product conforms to element 2.4.7; and vii. Reworked product does not affect the safety or integrity of the finished product. Records of all reworking operations shall be maintained.	Not Applicable	No rework is performed.		

## SS 2.4.6 Product Rework Summary

No rework is performed.

2.4.7 Product Release Module 2 Animal Product Manufacturing			
Element	Description	Primary Response	Evidence
2.4.7.1	The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained.	Compliant	
2.4.7.2	Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.	Compliant	
2.4.7.3	In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not	Compliant	





released until acceptable results have been received. In the event that off-site or contract warehouses are used, these requirements shall be effectively	
communicated and verified as being followed.	

## SS 2.4.7 Product Release Summary

All products are approved and released. All production checks are documented prior to product release. Finished Product Release Form must be completed and signed by QA for products to be approved to ship. The form includes: pre-op inspection, CCP checks, Packaging Log, Label Verification.

2.4.8 Environmental Monitoring Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence	
2.4.8.1	A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes. The responsibility and methods for the environmental monitoring program shall be documented and implemented.	Compliant		
2.4.8.2	An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.	Compliant		
2.4.8.3	Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.	Compliant		

## SS 2.4.8 Environmental Monitoring Summary

The site has implemented a risk-based environmental monitoring program documented in: Environmental Policy dated 11/17/2022; and Listeria Testing and Test Sites Environmental Monitoring dated 12/29/2020. At least 2 swabs are taken for Listeria quarterly in Zones 1-4. Auditor reviewed all results from the past year (3/28, 6/28, 10/2, and 12/30/2024), and all results have been negative. If any positives were found, corrective actions would be followed including investigations, recleaning and reswabbing. Products are kept on Hold until negative results are received.

2.5.1 Validation ar	nd Effectiveness Module 2 Animal Product Manufacturing		
Element	Description	Primary Response	Evidence
2.5.1.1	The methods, responsibility, and criteria for ensuring the effectiveness of all	Compliant	





	applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required results; ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and iii. Changes to the processes or procedures are assessed to ensure the controls are still effective. Records of all validation activities shall be maintained.		

#### SS 2.5.1 Validation and Effectiveness Summary

The methods, responsibilities and criteria for ensuring the effectiveness of Good Manufacturing Practices, critical food safety limits and all other applicable elements of the SQF System have been documented and implemented based on policy Verification of Monitoring Records dated 5/1/2016 and were found to ensure that each has been implemented effectively. Critical food safety limits are re-validated at least annually by calibration of thermometers and monitoring of GMP practices. Records of all verifications of effectiveness and validations are maintained by the SQF Practitioner.

2.5.2 Verification	2.5.2 Verification Activities Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence		
2.5.2.1	The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.	Compliant			
2.5.2.2	A schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented. Records of verification of activities shall be maintained.	Compliant			

#### SS 2.5.2 Verification Activities Summary

The site has established a verification schedule outlining the verification steps, procedures and responsibilities for each verification activity. The schedule is maintained by the SQF Practitioner and found in Verification Schedule dated 8/27/2024. The procedures for verifying Good Manufacturing Practices, critical control points, other food safety controls and regulatory compliance include utilizing authorized personnel to verify all monitoring activities. Records of verification of monitoring activities including sanitation activities, trailer inspections, label verification, seafood temperature monitoring, coolers and freezer temperature monitoring, scales performance, weights, calms heat treatment, maintenance activities, knife and sharp tools control etc.

2.5.3 Corrective a	nd Preventative Action Module 2 Animal Product Manufacturing		
Element	Description	Primary Response	Evidence





2.5.3.1	The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented. Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.	Compliant	
2.5.3.2	Records of all investigation, root cause analysis, and resolution of non- conformities, their corrections, and the implementation of preventative actions shall be maintained.	Compliant	

## SS 2.5.3 Corrective and Preventative Action Summary

Corrective Action Procedure (2.5.5 reviewed 11/6/2024) details root cause analysis and resolution of non-conforming products and the responsibility is of the SQF Practitioner. The facility documents their corrective actions as part of the audits. The auditor reviewed a corrective actions (Corrective Action Response forms) from 2024 for previous SQF audit, internal audits, and non-conforming product.

2.5.4 Internal Audits and Inspections Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence	
2.5.4.1	The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code: Animal Product Manufacturing are audited per the SQF audit checklist or a similar tool; ii. Objective evidence is recorded to verify compliance and/or non-compliance; iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.	Compliant		
2.5.4.2	Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.	Compliant		
2.5.4.3	Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Animal Product Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii.	Compliant		





Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3.  Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).  Compliant		Maintain records of inspections and any corrective actions taken		
	2.5.4.4	actions taken as a result of internal audits shall be recorded as per 2.5.3.  Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF	Compliant	

## SS 2.5.4 Internal Audits and Inspections Summary

Internal Audits (2.5.7 reviewed 11/6/2024) addresses responsibility and methods of the internal audit process. SQF system is audited at least once each calendar year (last on 11/6/2024) and is the responsibility of the SQF Practitioner with the help of an SQF consultant. They also conduct weekly facility inspections, last on 2/10/2025. The internal audits are conducted effectively verify the SQF system and any findings are addressed with corrective actions. The SQF Practitioner and backup have received internal audit training and they conduct audits independent of their function.

2.6.1 Product Ide	2.6.1 Product Identification Module 2 Animal Product Manufacturing					
Element	Description	Primary Response	Evidence			
2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.	Compliant				
2.6.1.2	Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.	Compliant				

#### SS 2.6.1 Product Identification Summary

A policy defining how products are identified from receipt through production and shipping has been documented in Product Identification SOP dated 1/10/2018. The site's identification system ensures all raw materials, ingredients, packaging materials, work-in-progress, process inputs and finished goods are clearly identified at all stages of their process. Items are marked at receipt by the warehouse employee or Production Manager. Product identification records were reviewed during the audit for production activities and shipping activities July and August 2024 and February 2025. These records demonstrated the products were properly identified throughout the process. Product startup/changeover procedures during packing ensure that the correct product goes into the correct package with the correct label. The pre-operational inspection is performed by the Production Supervisors.





2.6.2 Product Tra	2.6.2 Product Trace Module 2 Animal Product Manufacturing					
Element	Description	Primary Response	Evidence			
2.6.2.1	The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier; ii. The receipt dates of raw materials, ingredients, food contact packaging, and materials and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products); iii. Traceability is maintained where product is reworked (refer to 2.4.6); and iv. The effectiveness of the product trace system is reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.2). Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.	Compliant				

## SS 2.6.2 Product Trace Summary

Product Identification-Trace-Withdrawal and Recall (SQF 2.6.2 reviewed 11/6/2024) outlines responsibilities and methods for recalls and withdrawals. Mock recalls and traceability exercises are conducted monthly. The traceability exercises are conducted one up and one back by the management team. The following trace exercises were reviewed during the audit: Trace exercise performed on 9/4/2024 traced an entire received truck load of clams from 7/19/2024, which were picked up from 3 clammers with 39,850 middleneck (MN) clams, 25,600 littleneck (LN), and 26,185 pastanecks (PN) (91,635 total clams). These went to the following: 17,000 MN packed for fresh orders, 2,700 LN for fresh orders, 22,850 MN cooked, 17,208 LN cooked, 14,304 PN cooked; and 17,573 scrapped as broken/dead sort outs (74% yield). All products were traced to shipping to multiple customers and none were remaining in inventory. They were able to trace all of the raw materials, packaging, and finished product in 1 hour and 32 minutes.

2.6.3 Product Withdrawal and Recall Module 2 Animal Product Manufacturing				
Element	Description	Primary Response	Evidence	
2.6.3.1	The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall; Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information; ii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate to the nature of the incident; and iii. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified	Compliant		





	in instances of a food safety incident of a public nature or product recall for any reason.		
2.6.3.2	The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.	Compliant	
2.6.3.3	Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.	Compliant	
2.6.3.4	SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.	Compliant	

## SS 2.6.3 Product Withdrawal and Recall Summary

Requirement to inform SQFI and the certification body was addressed in procedure 2.6.3. The plant manager is assigned as the Crisis manager who responsible for handling any product crisis. Product Identification-Trace-Withdrawal and Recall states investigation to determine root cause of a recall shall be undertaken and action documented. Recall system is tested at least annually as stated in 2.6.3 Mock Recall Requirement Protocol. Records of monthly mock recalls are on file and were reviewed from 9/4/2024.

2.6.4 Crisis Mana	gement Planning Module 2 Animal Product Manufacturing		
Element	Description	Primary Response	Evidence
2.6.4.1	A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum: i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure any responses do not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of	Compliant	





	legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.		
2.6.4.2	The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.	Compliant	

#### SS 2.6.4 Crisis Management Planning Summary

The Crisis Management Plan (reviewed 11/6/2024) is outlined for threats, methods and responsibility for coping with a crisis. All elements are included within the plan, which included training of a crisis management team; controls implemented to ensure a response to a crisis does not compromise product safety; measures to isolate and identify product affected by a response to a crisis; the preparation and maintenance of a current crisis alert contact list; the responsibility for internal communications and communicating with authorities, external organizations and media. Senior Management are responsible for overseeing the team. The crisis management plan is tested at least annually, last tested on 9/5/2024 for Hurricane Debby causing closures of clam harvest areas. They contacted additional clam suppliers and continued with oyster operations. There was no loss of power at this facility and no damage to product, and they were able to continue with operations.

Element	Description	Primary Response	Evidence
2.7.1.1	A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.	Compliant	
2.7.1.2	A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.	Compliant	





2.7.1.3	Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).	Compliant
2.7.1.4	The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.	Compliant

#### SS 2.7.1 Food Defense Plan Summary

The site has a Food Defense Policy dated 11/14/2022, in which the procedures, responsibilities and criteria for preventing deliberate food adulteration have been documented and implemented. A food defense protocol includes the name of the senior manager responsible for food defense, the President, methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials and hazardous chemicals and the control of access to contractors and visitors. Employees are trained at the time of hiring and also during annual refresh trainings. The USDA FSIS Food Security Self Assessment Checklist is conducted at least annually, last on 11/6/2024. Food Safety Culture - Food Defense meetings were reviewed from 6/25/2024 and 5/14/2024 including training and quizzes. The food defense plan is challenged at least annually, last on 11/6/2024.

2.7.2 Food Fraud	Module 2 Animal Product Manufacturing		
Element	Description	Primary Response	Evidence
2.7.2.1	The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.	Compliant	
2.7.2.2	A food fraud mitigation plan shall be developed and implemented, that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.	Compliant	
2.7.2.3	Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).	Compliant	
2.7.2.4	The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.	Compliant	

# SS 2.7.2 Food Fraud Summary

The Food Fraud Policy dated 12/4/2024 includes the site's susceptibility to fraudulent economic gain, including product substitution, mislabeling, counterfeiting and dilution that could impact food safety. The Food Fraud Vulnerability Assessment was last conducted on 7/11/2024. The site has developed a Food Fraud Mitigation Plan dated 11/22/2024, to address the control of the identified food fraud vulnerabilities. The company purchases clams and oysters from approved suppliers and all products are labeled with shellfish tags which include harvest location, date, and dealer. The only ingredients purchased are salt and butter.

## 2.8.1 Allergen Management Module 2 Animal Product Manufacturing





Element	Description	Primary Response	Evidence
2.8.1.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food-grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens.	Compliant	
2.8.1.2	Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.	Compliant	
2.8.1.3	Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.	Compliant	
2.8.1.4	Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.	Compliant	
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.	Compliant	
2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.	Compliant	
2.8.1.7	The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements, of those products produced on production lines and equipment on which foods containing allergens are manufactured.	Compliant	





2.8.1.8	The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen- containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.	Compliant	
2.8.1.9	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product changeover procedures.	Compliant	
2.8.1.10	Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.	Compliant	N/A - No rework is conducted.
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement, and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.	Compliant	

## SS 2.8.1 Allergen Management Summary

The Allergen Control Plan dated 11/14/2023, describes how to control allergens and prevent contamination of other products and is the responsibility the entire facility. The facility does not currently handle any of the Big 9 allergens and they only sell in the USA. They previously occassionally made Rockefeller Oysters which involved a butter and bread crumb addition to frozen oysters in a designated area. This product has not been run in over a year and they do not currently have the allergen ingredients in the facility. If they receive orders for this product in the future, the Allergen Control Procedures would be followed including segregated storage, designated production area and trained employees, and followed by validated cleaning procedures. A risk analysis was observed to be in place for allergens including raw materials, ingredients and processing aids such as food grade lubricants. Workplace allergens from locations such as lunchrooms, locker rooms and vending machines were found to be part of the allergen program and there was no restriction to allergens that are allowed to employees to bring inside the company. The operation was found to have a product identification system that includes clear identification and labeling of products to meet regulatory requirements when made on production lines used for allergenic products The product trace system ensures the complete trace of allergen ingredients including any rework containing allergens. The Allergen Control Plan includes procedures to control the accuracy of finished product labels, including labels of allergenic products. 2.8.1.10 N/A - No rework is conducted.

2.9.1 Training Red	quirements Module 2 Animal Product Manufacturing		
Element	Description	Primary Response	Evidence
2.9.1.1	The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6)	Compliant	





Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.
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# SS 2.9.1 Training Requirements Summary

Policy 2.9 reviewed 11/6/2024, addresses requirements of employee training. Competencies and methods are detailed in the training documentation.

Element	Description	Primary Response	Evidence
2.9.2.1	A training program shall be documented and implemented that, at a minimum, outlines the necessary competencies for specific duties and the training methods to be applied to personnel carrying out tasks associated with: i. Implementing HACCP for staff involved in developing and maintaining food safety plans; ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs); iii. Personal hygiene for all staff involved in the handling of food products and food contact surfaces; iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment; v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products; vi. Environmental monitoring for relevant staff; vii. Allergen management, food defense, and food fraud for all relevant staff; and viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF Code. The training program shall include provisions for identifying and implementing the refresher training needs of the organization.	Compliant	
2.9.2.2	Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.	Compliant	
2.9.2.3	Training records shall be maintained and include: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Verification that the trainee is competent to complete the required tasks.	Compliant	





The site has implemented a training program, entitled Training Plan dated 1/2/2024, which covers the necessary competencies for plant personnel. This program requires training to ensure regulatory, food safety, food quality and all other requirements of the SQF System are met. Annual refresher training needs have been identified in the training program Training Schedule dated 1/2/2024. Different topics are covered monthly to cover all training annually; topics include: Food Safety Culture, Food Defense, Food Fraud, Crisis Management, HACCP CCPs, GMP & Personal Hygiene Policies, Allergen Management, Cleaning & Sanitation, Foreign Matter Control, Pallet & Box Inspections, Stock Rotation, Non-conforming product or Equipment, Scales and Cooker Calibration or Accuracy, Storage and Spill Clean Up, Document Control, Receiving Inspection, Loading Inspection, Chemical Training, Food Safety Quality Policy, ATP Swabbing & Listeria Swabbing, Condensate Condenser, etc. HACCP training for personnel involved in the development and maintaining the food safety plan is administered, last on 12/30/2024. Work instructions have been written explaining how tasks critical to maintaining food safety are performed. All employees were last trained on GMPs on 3/12/2024. Sanitation and Chemical Concentration training was last conducted by the Chemical Supplier on 1/25/2024 and they have provided training material on the website to provide in house training. The training languages and materials are in English and Spanish which are the languages used in the operation and understood by all plant personnel. Training records are maintained on Staff Training Records by the SQF Practitioner. During the review was found to have a listing of the trainee, trainer, the description of the training, the date of training and verification by supervision that the training was completed. The site verifies the effectiveness of training by monitoring the employees at performing. Plant employees interviewed on the production floor and warehouse were found to

Element	Description	Primary Response	Evidence
9.1.1.1	The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.	Compliant	
9.1.1.2	Pens, yards, and lairage shall be designed, located, constructed, and maintained to minimize stress, injury, or disease and have minimal impact on the surrounding area and natural resources. Fences, gates, and other surfaces in pens and yards shall be free from paints, dips, sanitizers, and other materials that are likely to cause contamination through ingestion, inhalation, or contact. They shall be designed so that liquid waste can drain away and be collected if required, and that aerial fecal contamination does not contaminate meat products.	Not Applicable	There is no animal housing.
9.1.1.3	Laneways, races, entrances, exits, and loading/unloading ramps shall be: i.  Designed to include consideration of the social behavior and movement of the species; ii. Designed and maintained to prevent potential injury points to the animals; iii. Free from sharp objects that may damage the animals; and iv. Free from chemicals other than those approved by the relevant authority for use on livestock	Not Applicable	There is no animal housing.





The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. Measures have been established to maintain a suitable external environment and the facility performs external inspections as part of their internal audit program. weekly. The site maintains the required approvals by relevant authorities for their ongoing operations including: FDA bioterrorism act registration #xxxxx1352 expires 12/31/2026; Florida Department of Agriculture and Consumer Services - Division of Aquaculture - Post Harvesting Processing Certification expires 6/30/2025; Florida Fish and Wildlife Conservation Commission - License to Wholesale Saltwater Products expires 6/30/2025; Florida DA for Shellfish Processing Certification expiring 6/30/2025; Florida DA for Aquaculture Certificate of Registration expires 6/30/2025; Florida DH Operating permit for Limited Use Water expiring 9/30/2025; Florida DA&CS - Division of Food Safety - Annual Food Permit expires 4/18/2025. 9.1.1.2/3 N/A - There is no animal housing.

Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.	Compliant	
Drains shall be constructed and leasted as they can be easily described as they		
Drains shall be constructed and located so they can be easily cleaned and not present a hazard.	Compliant	
Waste trap system shall be located away from any food handling areas or entrances to the premises.	Compliant	
Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 9.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.	Compliant	
Ducting, conduit, and pipes that convey ingredients, products, or services such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.	Compliant	
Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.	Compliant	
	present a hazard.  Waste trap system shall be located away from any food handling areas or entrances to the premises.  Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 9.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.  Ducting, conduit, and pipes that convey ingredients, products, or services such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.  Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and	Waste trap system shall be located away from any food handling areas or entrances to the premises.  Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 9.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.  Ducting, conduit, and pipes that convey ingredients, products, or services such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.  Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.  Compliant  Compliant  Compliant





	storage areas shall be of a material and construction that meet the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.		
9.1.2.8	Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.	Compliant	
9.1.2.9	Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 9.2.5).	Compliant	

## SS 9.1.2 Building Materials Summary

Surfaces are properly constructed. Product (stainless steel) and non-product contact surfaces are constructed of materials that do not pose a product safety risk. Floors are properly constructed and graded. The waste trap is located outside of the building on the opposite side from the employee entrance. Walls, ceilings, partitions and doors are properly constructed and maintained. Stairs and catwalks are properly designed and constructed with stainless steel and do not present risk to product contamination.

Element	Description	Primary Response	Evidence
9.1.3.1	Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.	Compliant	
9.1.3.2	Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.	Compliant	
9.1.3.3	Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.	Compliant	





The lights throughout the facility were shatter proof. The lighting was sufficient throughout.

Description	Primary	
	Response	Evidence
ction is required, a suitable area close to the processing line shall or the inspection of product (refer to 2.4.4). The inspection/quality hall be provided with facilities that are suitable for examination and type of product being handled/processed. The inspection area easy access to handwashing facilities; ii. Have appropriate waste removal; and iii. Be kept clean to prevent product contamination.	Compliant	
y)	be of product being handled/processed. The inspection area asy access to handwashing facilities; ii. Have appropriate waste	be of product being handled/processed. The inspection area asy access to handwashing facilities; ii. Have appropriate waste

SS 9.1.4 Inspection / Quality Control Area Summary

Inspection areas are provided and suitable with proper lighting.

Element	Description	Primary Response	Evidence
9.1.5.1	All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.	Minor	There was a gap near the top of the receiving roll up do in the back of the facility.
9.1.5.2	External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A pest-proof screen; iv. A pest-proof annex; and v. Adequate sealing around trucks in docking areas.	Compliant	
9.1.5.3	Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or	Compliant	





exposed.

SS 9.1.5 Dust, Insect, and Pest Proofing Summary

All doors and windows are adequately sealed to protect against dust and pest contamination. Rodent traps are located away from the processing areas and do not pose a risk to the products. Bait stations are located along the exterior perimeters only. Minor: There was a gap near the top of the receiving roll up door in the back of the facility.

Element	Description	Primary Response	Evidence
9.1.6.1	Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.	Compliant	
9.1.6.2	All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 9.2.5 to prevent unsanitary conditions.	Compliant	
9.1.6.3	Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).	Compliant	
9.1.6.4	Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and be kept clean.	Compliant	

### SS 9.1.6 Ventilation Summary

There was adequate ventilation throughout the facility during the audit. The steamers are properly vented to the outside and the exhaust vents are adequately sealed.

9.1.7 Equipment a	9.1.7 Equipment and Utensils Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence	
9.1.7.1	Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.	Compliant		
9.1.7.2	Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and so as not to pose a contamination threat to products.	Compliant		





9.1.7.3	Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.	Compliant	
9.1.7.4	Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.	Compliant	
9.1.7.5	Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.	Compliant	
9.1.7.6	Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned (refer to 9.2.5.1). Bins used for inedible material shall be clearly identified.	Compliant	
9.1.7.7	All equipment and utensils shall be cleaned after use (refer to 9.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.	Compliant	
9.1.7.8	Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.	Compliant	
9.1.7.9	Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.	Compliant	
SS 9.1.7 Equipment and Utensils Summary			

#### SS 9.1.7 Equipment and Utensils Summary

Food processing equipment, utensils and clothing are properly designed and maintained. All containers for food contact and trash cans are labeled. All cleaning utensils are color coded and labeled for dedicated areas including food contact, non food contact, floors and drains. Racks are located at the exit to production for storing smocks when employees go on break.

9.1.8 Grounds and Roadways Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.1.8.1	A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its	Compliant		





	surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.		
9.1.8.2	Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.	Compliant	
9.1.8.3	Paths from amenities leading to site entrances shall be effectively sealed.	Compliant	

# SS 9.1.8 Grounds and Roadways Summary

The grounds surrounding the plant are maintained and free from waste and accumulated debris. Surroundings are kept neat and tidy and do not present a hazard to sanitary operations.

Element	Description	Primary Response	Evidence
9.2.1.1	The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.	Compliant	
9.2.1.2	Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.	Compliant	
9.2.1.3	Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.	Compliant	
9.2.1.4	Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas.	Compliant	
9.2.1.5	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times.	Compliant	





9.2.1.6	Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.	Compliant	
9.2.1.7	Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.	Compliant	
9.2.1.8	Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.	Compliant	

#### SS 9.2.1 Repairs and Maintenance Summary

Maintenance Policy and Procedure is dated 11/20/2024. Maintenance schedule is maintained on paper with maintenance schedules and forms. Maintenance staff and contractors follow company GMP policies. Preventative maintenance schedules and work orders are prepared to cover equipment, the buildings and facility grounds. The maintenance schedule is posted by the maintenance shop in the production area. The work orders have checks for the removal of tools and parts and cleaning of the area after maintenance work is complete. Temporary repairs are not allowed. Food grade lubricant is used on all food processing equipment. PMs and WOs were reviewed during the audit including: annual PM of the entire facility including all equipment, building, grounds on 12/5/2024; weekly PMs from September and December 2024 and January 2025; and WOs for reset dock plate on 5/13/2024, replaced steamer cart wheel on 8/21/2024, changed bad defrost timers on blast freezer on 9/24/2024, and repaired broken light on forklift on 12/27/2024.

9.2.2 Maintenance Staff and Contractors Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence
9.2.2.1	Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 9.3).	Compliant	
9.2.2.2	All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.	Compliant	
9.2.2.3	Maintenance staff and contractors shall remove all tools and debris from any maintenance activity, once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to restarting site operations.	Compliant	

#### SS 9.2.2 Maintenance Staff and Contractors Summary

Maintenance staff and contractors follow company GMP policies. The maintenance records in include checks for removal of tools and debris and cleaning of the area when maintenance activity is complete.





Element	Description	Primary Response	Evidence
9.2.3.1	The methods and responsibility for calibration and re-calibration of measuring, test, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans, and other process controls, or to demonstrate compliance with customer specifications, shall be documented and implemented. Software used for such activities shall be validated as appropriate.	Compliant	
9.2.3.2	Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.	Compliant	
9.2.3.3	Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.	Compliant	
9.2.3.4	Procedures shall be documented and implemented to address the resolution of potentially affected products, when measuring, test, or inspection equipment is found to be out of calibration.	Compliant	
9.2.3.5	Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.	Compliant	
9.2.3.6	A directory of measuring, test, and inspection equipment that requires calibration and records of the calibration tests shall be maintained.	Compliant	

### SS 9.2.3 Calibration Summary

The methods and responsibility for the Calibration Procedures (dated 1/27/2025) are defined. The methods and responsibility for addressing disposition of potentially affected product is detailed and Hold procedure is followed. All equipment is calibrated against reference standards as stated in 9.2.3. Auditor observed calibration records: scales (weekly with certified weights, annually by 3rd party, last on 1/17/2025), steamer cooker (temperature sensor calibrated by 3rd party annually, last on 1/15/2025), all thermometers and coolers are verified with NIST certified thermometer in an ice bath and/or boiling water monthly, NIST certified thermometer (certificate dated 7/15/2024).

9.2.4 Pest Prevention Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.2.4.1	A documented pest prevention program shall be effectively implemented. It shall: i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods	Compliant		





	and the appropriate documentation for each inspection; v. Outline the frequency with which pest status is to be checked; vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map; vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available; viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.		
9.2.4.2	Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and vii. Provide a written report of their findings and the inspections and treatments applied.	Compliant	
9.2.4.3	Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to food products, raw materials, or packaging. Records of all pest control inspections and applications shall be maintained.	Compliant	
9.2.4.4	Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.	Compliant	
9.2.4.5	Pesticides shall be clearly labeled and stored (refer to 9.6.5) if kept on-site	Not Applicable	Pesticides re not stored onsite.
9.2.4.6	No animals shall be permitted on-site in food handling and storage areas.	Compliant	

# SS 9.2.4 Pest Prevention Summary

The Integrated Pest Management (9.2.4 reviewed 11/6/2024) details the methods and responsibility for integrated pest management within the facility. Pest inspections are performed by the 3rd party PCO monthly and all records are kept in binders in SQF Practitioner's office. Pest control management plan is maintained and includes a labeled site map (dated 1/29/2024), approved chemical labels and SDS, inspection reports, trending, and proper licensing. Inspections are conducted by technicians licensed by Florida Department of Agriculture and





Consumer Services - Bureau of Licensing and Enforcement licenses expire 10/31/2025. Inspection reports are left with the site by the technician after each inspection. Pesticides were not stored on site and are only applied by the licensed technicians of the Pest Control Operator. Auditor observed pest findings and trending logs from 2024 and 2025. There have been no significant trends or infestations in the past year. No animals are permitted on-site in food handling and storage areas. 9.2.4.5 - Pesticides re not stored onsite - N/A.

9.2.5 Cleaning a	9.2.5 Cleaning and Sanitation Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.2.5.1	The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Validation of the cleaning procedures for food contact surfaces (including CIP); vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.	Compliant			
9.2.5.2	Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements and purchased in accordance with applicable legislation. The organization shall ensure that detergents and sanitizers are stored as outlined in element 9.6.5 and are handled only by trained staff.	Compliant			
9.2.5.3	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.	Compliant			
9.2.5.4	Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.	Compliant			
9.2.5.5	Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.	Compliant			
9.2.5.6	Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these	Compliant			





	cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.	
9.2.5.7	Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production. Pre-operational inspections shall be conducted by qualified personnel.	Compliant
9.2.5.8	Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.	Compliant
9.2.5.9	The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.	Compliant

#### SS 9.2.5 Cleaning and Sanitation Summary

The site has a cleaning and sanitation program documented in multiple SSOPs including: Frozen Half Shell or Whole Oyster SOPs dated 9/25/2014; Frozen Half Shell Clams SOP dated 9/25/2014; Frozen Vacuum pack Standard dated 12/11/2024; and Fresh Department Clam SOP dated 9/25/2014. These SSOPS describe the methods and responsibilities for cleaning of processing equipment, the environment, storage areas, bathrooms and break rooms. Sanitation Standard Operating Procedures are written and include what is cleaned, chemical usage (concentrations), cleaning methods and who is responsible. A master sanitation plan includes all areas of the facility with frequencies and responsibilities for deep cleaning. Cleaning records were reviewed from September 2024 and January 2025 for each area including: IQF Daily Cleaning, Fresh Daily Cleaning, Cooking Daily Cleaning, and Sanitation Monitoring Log. There is a suitable area, Sanitation Room, for cleaning containers, knives and other utensits that does not cause a food product contamination. The racks used by the site to store clean tools and containers are in good working conditions and clean. Sanitation tasks and pre-operational inspections by qualified personnel are documented. A verification schedule includes the methods, frequencies and responsibilities for verifying the effectiveness of cleaning methods. Pre-operational inspections for production activities on 09/13/2023 and weeks of 10/28/2024 and 12/7/2024 were reviewed and had proper corrective actions documented as required. Cleaning materials are stored securely and properly labeled with SDS information available to all employees. Chemicals including Madison 75, Multipurpose Disinfectant Cleaner, Bleach and Spectrum Yellow HD were observed to be included on a list of approved chemicals, labeled consistent with regulations and had SDS on hand. Dispensed cleaning chemicals were properly stored and identified. Cleaning chemicals mixed on-site have concentration checks conducted by the SQF Practitioner and recorded in Sani

9.3.1 Personnel Welfare Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.3.1.1	Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packaging or storage processes shall not engage in the processing or packaging of food or enter storage areas where	Compliant		





	food is exposed.		
9.3.1.2	The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned and that all materials and products have been quarantined and/or disposed of.	Compliant	
9.3.1.3	Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.	Compliant	

#### SS 9.3.1 Personnel Welfare Summary

Employees are trained on infectious disease concerns in their GMP refresher training and during their new hire training. Medical screening procedure are in place for all employees, visitors and contractors. Anyone showing signs of infectious diseases are not allowed to handle exposed product or food contact surfaces. During the audit, there were no employees observed in production areas who showed signs of infectious diseases. Employees are trained on exposed cuts and lesions in their GMP refresher training and during their new hire training. During the audit, there were no employees observed in the production areas who showed signs of having open wounds or lesions. Blue, metal detectable bandages are available to cover minor cuts and abrasions.

9.3.2 Handwashir	9.3.2 Handwashing Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.3.2.1	All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.	Compliant			
9.3.2.2	Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.	Compliant			
9.3.2.3	Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.	Compliant			





9.3.2.4	The following additional facilities shall be provided in high-risk areas: i. Hands-free operated taps; and ii. Hand sanitizers.	Compliant
9.3.2.5	Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.	Compliant
9.3.2.6	When gloves are used, personnel shall maintain the handwashing practices outlined above.	Compliant

## SS 9.3.2 Handwashing Summary

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the employee entrances, in the bath rooms and break rooms. All hand wash basins are constructed of stainless steel or non-corrodible materials. Hand wash basins are supplied with water, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English and Spanish. Gloves are used over clean hands.

Element	Description	Primary Response	Evidence
9.3.3.1	The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination.	Compliant	
9.3.3.2	Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products.	Compliant	
9.3.3.3	Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.	Compliant	
9.3.3.4	Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.	Compliant	
9.3.3.5	Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and, when not in use, stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.	Compliant	
9.3.3.6	Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen	Compliant	





	contamination.	
9.3.3.7	Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities	Compliant
9.3.3.8	Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.	Compliant

## SS 9.3.3 Clothing and Personal Effects Summary

Clothing worn by staff is properly maintained, clean and did not pose a risk to the product. Disposable gloves are used over clean hands. The facility does not allow the use of jewelry except medic alert jewelry and plain wedding bands. There was no observation of employees wearing jewelry.

9.3.4 Visitors Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence
9.3.4.1	All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas.	Compliant	
9.3.4.2	All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 9.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.	Compliant	
9.3.4.3	Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed.	Compliant	
9.3.4.4	Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.	Compliant	

### SS 9.3.4 Visitors Summary

Visitors are required to sign-in at the visitor's entrance. Visitors are also required to read and sign the GMP requirements prior to entering the facility. Appropriate clothing and footwear are covered in the requirements. All visitors are required to follow the employee GMP and clothing requirements.





Element	Description	Primary Response	Evidence
9.3.5.1	Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.	Compliant	
9.3.5.2	Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.	Compliant	
9.3.5.3	High-risk change areas shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.	Compliant	
9.3.5.4	Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas.	Compliant	
9.3.5.5	Where required, a sufficient number of showers shall be provided for use by staff.	Compliant	
9.3.5.6	Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.	Compliant	
9.3.5.7	Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.	Compliant	
9.3.5.8	Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 9.3.2.3.	Compliant	
9.3.5.9	Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.	Compliant	





9.3.5.10	Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests, to the site.	Compliant	
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## SS 9.3.5 Staff Amenities (change rooms, toilets, break rooms) Summary

Staff amenities have sufficient lighting and ventilation to accommodate the maximum number of plant personnel. Change rooms are provided, smocks are worn over personal clothing. Lockers are provided for storing personal items. Showers are not required. There are no high risk areas, all products are raw. Smocks are used in the production area and cleaned by a 3rd party. Toilets are adequate in number for the maximum number of staff. Toilets are constructed so that they can be easily maintained and are tidy and clean. They are located in the offices separate from the processing areas. Hand wash sinks are provided inside each rest room. The hand washing sinks are designed and constructed as per section 9.3.2.3. The lunch room is located in a separate building by the employee entrance, separated from the processing areas. It is equipped with refrigerators, microwaves and sink. It was observed to be well lit, maintained and clean. The outside eating area is also well maintained and covered. Hand wash signs are posted in English and Spanish.

9.4.1 Staff Engaged in Food Handling and Processing Operations Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.4.1.1	All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.	Compliant		
9.4.1.2	Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 9.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be	Compliant		





	stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.		
9.4.1.3	The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.	Compliant	
9.4.1.4	In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment.	Not Applicable	Sensory evaluations are not conducted in processing areas.

## SS 9.4.1 Staff Engaged in Food Handling and Processing Operations Summary

Plant personnel were observed only entering or exiting the facility through the designated employee entrances. Employees have been instructed to keep exterior doors closed when not in use. During the audit, all exterior doors in the production areas were observed to be maintained closed by plant personnel. There were no employees observed wearing false fingernails or fingernail polish in the processing areas of the facility. Trash containers were observed to be properly identified and emptied at a regular frequency. Wash down hoses are properly stored on racks. 9.4.1.4 N/A - Sensory evaluations are not conducted in processing areas.

9.4.2 Animal Hu	9.4.2 Animal Husbandry Module 9 GMP for Processing of Animal Products					
Element	Description	Primary Response	Evidence			
9.4.2.1	Ante-mortem inspections by a qualified person shall be carried out to ensure animals are free from disease and fit for human consumption.	Not Applicable	There is no animal husbandry.			
9.4.2.2	Animals that are subject to the control of prohibited substances such as veterinary medicine, heavy metals, or pesticides shall be identified and procedures implemented for their segregation and processing.	Not Applicable	There is no animal husbandry.			
9.4.2.3	Animals for slaughter shall have clean water at all times, and clean feed, if held in lairage for extended periods. e flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.	Not Applicable	There is no animal husbandry.			
9.4.2.4	Employees responsible for the care and management of animals ante-mortem shall be trained and competent in animal handling and welfare. They shall be able to recognize the early signs of distress and disease and ensure pain and stress to animals is minimized.	Not Applicable	There is no animal husbandry.			





9.4.2.5	Animals deemed to be diseased or otherwise unfit for human consumption must be segregated from healthy animals and condemned or otherwise excluded from processing.	Not Applicable	There is no animal husbandry.
9.4.2.6	The site shall implement measures to prevent cross-contamination of animals for slaughter from agricultural or cleaning chemicals, waste materials, or other materials that could contaminate the animals.	Not Applicable	There is no animal husbandry.
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SS 9.4.2 Animal Husbandry Summary

There is no animal husbandry.

Element	ing and Butchering Module 9 GMP for Processing of Animal Prod  Description	Primary Response	Evidence
9.4.3.1	Only slaughtering methods that are humane and approved for use for a given species by national or international regulations shall be used.	Not Applicable	Slaughtering is not conducted.
9.4.3.2	Where a two-stage process is used, the time interval between stunning and killing shall not exceed regulatory requirements. The use of direct air injection is not permitted.	Not Applicable	Slaughtering is not conducted.
9.4.3.3	The site shall have a pathogen control program that addresses known biological hazards and demonstrates compliance to regulations and customer standards.	Not Applicable	Slaughtering is not conducted.
9.4.3.4	Knives and tools used for skinning shall be cleaned and sterilized between each carcass. Knives and tools that become contaminated shall be cleaned and sterilized prior to use on edible tissue.	Not Applicable	Slaughtering is not conducted.
9.4.3.5	Procedures shall be documented and implemented to maintain the hygienic condition of the carcass and avoid contamination. Fecal matter shall be removed at the slaughter floor and the carcass shall be inspected by an authorized person postmortem for signs of disease or contamination. Where applicable, procedures shall be in place for the grading of carcasses.	Not Applicable	Slaughtering is not conducted.
9.4.3.6	Cooling processes shall have defined time and temperature requirements and be regularly monitored and recorded.	Not Applicable	Slaughtering is not conducted.
9.4.3.7	Procedures shall be in place for the safe and hygienic evisceration and primal cutting of the carcass and the identification of edible and non-edible parts. Edible parts of the carcass shall be processed and stored using clean, sanitized tools	Not Applicable	Slaughtering is not conducted.





9.4.3.8 inspection p	parts of the carcass shall be identified through the post-mortem		
slaughter.	n process and traceable back to the animal and date and time of .	Not Applicable	Slaughtering is not conducted.
	r and butchering hygiene shall be regularly monitored for, at minimum, nogens. Risk-based species-specific microbiological analysis may also se.	Not Applicable	Slaughtering is not conducted.

# SS 9.4.3 Slaughtering and Butchering Summary

Slaughtering is not conducted.

Element	Description	Primary Response	Evidence
9.5.1.1	Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.	Compliant	
9.5.1.2	Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.	Compliant	
9.5.1.3	Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.	Compliant	
9.5.1.4	The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.	Compliant	
9.5.1.5	The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage.	Not Applicable	There is no non-potable water.
9.5.1.6	Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination.	Compliant	





#### SS 9.5.1 Water Supply Summary

Potable water is sourced for use in the facility for processing and cleaning the premises and equipment. Potable water is supplied from the city (2024 City of Melbourne Annual Drinking Water Quality Report was reviewed on file), and from 3 onsite wells. It was determined that there was adequate hot and cold water for cleaning and processing. In case of contaminated water or the ice, the site will start treating the water as described in the Water Supply Procedure. Water is stored on site in the concrete basins outside the building which were protected with screened enclosures. Water in the wet storage system (for clams) is tested weekly by an FDA lab. The well water and city water are also tested quarterly by a 3rd party accredited lab, last on 12/10/2024. Back flow devices are installed on water lines. Back flow devices are checked as part of the PM program and tested by the state annually, last on 8/14/2024. 9.5.1.5 N/A - There is no non-potable water. There is no non-potable water.

9.5.2 Water Tre	9.5.2 Water Treatment Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.5.2.1	Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable.	Compliant			
9.5.2.2	Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 9.5.2.1).	Compliant			
9.5.2.3	Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.	Compliant			

#### SS 9.5.2 Water Treatment Summary

Well water used in the process of Wet Storage for the clams is UV treated. The UV light hours are recorded monthly and the bulb is changed every 9000 hours (annually). The system is flushed, cleaned, and sanitized weekly after use with 200 ppm sanitizer. The verification checks are conducted by the Production Supervisor at the time of the process startup and recorded in Wet Storage Sanitation Record. Water samples from the Wet Storage process are sent to an FDA lab weekly and tested for total count and no issues have been identified.

9.5.3 Water Quality Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.5.3.1	Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and	Compliant		





	equipment; vi. The manufacture of ice; or vii. The manufacture of steam, which will come into contact with food or be used to heat water that will come into contact with food.		
9.5.3.2	Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.	Compliant	
9.5.3.3	Water and ice shall be analyzed using reference standards and methods.	Compliant	

## SS 9.5.3 Water Quality Summary

Potable water is supplied from the city (2024 City of Melbourne Annual Drinking Water Quality Report was reviewed on file), and from 3 onsite wells. Water in the wet storage system (for clams) is tested weekly by an FDA lab. The well water and city water are also tested quarterly by a 3rd party accredited lab, last on 12/10/2024.

1.5.4 Ice Supply Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.5.4.1	Ice provided for use during processing operations, as a processing aid or an ingredient, shall comply with 9.5.3.1.	Not Applicable	Ice is not used.	
9.5.4.2	Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and tested as appropriate.	Not Applicable	Ice is not used.	
9.5.4.3	Ice rooms and receptacles shall be constructed of materials as outlined in element 9.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.	Not Applicable	Ice is not used.	

### SS 9.5.4 Ice Supply Summary

Ice is not used.

9.5.5 Air and Othe	er Gasses Module 9 GMP for Processing of Animal Products		
Element	Description	Primary Response	Evidence





9.5.5.1	Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety.	Compliant	
9.5.5.2	Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.	Compliant	

## SS 9.5.5 Air and Other Gasses Summary

The site uses Nitrogen for the freezing process and comes in contact with the food. Each load of Nitrogen comes with a COA from the supplier. Last load received on 2/12/2025 Lot# LIN0431005B assay 99.9999% nitrogen. The nitrogen system is maintained by the maintenance team. No other gases or compressed air contact product or product surfaces.

9.6.1 Animal Tran	9.6.1 Animal Transport Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.6.1.1	Vehicles used for transport of animals for slaughter shall be fit for purpose and clean before use. Vehicles shall be inspected and a record kept of the inspection.	Not Applicable	No animal transport is conducted.		
9.6.1.2	Transport times for animals for slaughter shall be kept to a minimum and times recorded.	Not Applicable	No animal transport is conducted.		
9.6.1.3	Where animals are held for extended periods in pens and yards, adequate supplies of water and fodder shall be provided.	Not Applicable	No animal transport is conducted.		

## SS 9.6.1 Animal Transport Summary

No animal transport is conducted.

9.6.2 Receipt, Storage, and Handling of Goods Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence
9.6.2.1	The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals.	Compliant	
9.6.2.2	Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-	Compliant	





	contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.		
9.6.2.3	The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.	Compliant	
9.6.2.4	Procedures shall be in place to ensure that all ingredients, materials, work-in- progress, rework, and finished product are utilized within their designated shelf- life.	Compliant	
9.6.2.5	Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination, or adverse effect on food safety.	Not Applicable	No temporary or alternate storage is used.
9.6.2.6	Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products.	Not Applicable	No temporary or alternate storage is used.
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### SS 9.6.2 Receipt, Storage, and Handling of Goods Summary

All packaging and dry ingredients are properly stored on racks in the warehouse, away from wet areas. Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used. No temporary or alternate storage is used. 9.6.2.5/6 N/A - No temporary or alternate storage is used.

9.6.3 Cold Storage	9.6.3 Cold Storage, Freezing, and Chilling of Foods Module 9 GMP for Processing of Animal Products		
Element	Description	Primary Response	Evidence
9.6.3.1	The site shall provide confirmation of the effective operational performance of freezing, chilling, and cold storage facilities. Chillers, blast freezers, and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and be easily accessible for inspection and cleaning.	Compliant	
9.6.3.2	Sufficient refrigeration capacity shall be available to chill, freeze, store chilled, or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.	Compliant	
9.6.3.3	The site shall have a written procedure for monitoring temperatures, including the frequency of checks and corrective actions if the temperature is out of specification. Freezing, chilling, and cold storage rooms shall be fitted with temperature-monitoring equipment that is located to monitor the warmest part of the room and be fitted with a temperature-measurement device that is easily	Compliant	





	readable and accessible. Records shall be kept of frozen, cold, and chilled storage room temperatures.		
9.6.3.4	Discharge from defrost and condensate lines shall be controlled and discharged into the drainage system.	Compliant	
SS 9.6.3 Cold Storage, Freezing, and Chilling of Foods Summary			

Freezers are designed and constructed to allow for hygienic and efficient refrigeration. There appeared to be sufficient capacity for the facilities requirements and sufficient space for periodic cleaning. The condensate lines were connected directly to the plant drainage system. Temperature monitoring devices are located at the warmest part of the refrigerators/freezers, and temperatures are continuously monitored digitally on phones and will alarm if any temperatures are exceeded. Temperatures are also manually recorded by production supervisors at least twice daily. Refrigeration equipment is maintained on the PM schedule, and last by the 3rd party contractor on 12/30/2024.

9.6.4 Storage of	9.6.4 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence	
9.6.4.1	Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin.	Compliant		
9.6.4.2	Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.	Compliant		

## SS 9.6.4 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods Summary

All packaging and dry ingredients are properly stored on racks in the warehouse separate from the wet areas. Equipment storage area allows access for cleaning. Storage areas are properly designed and constructed for hygienic storage. Proper stock rotation (FIFO) is used and expiration dates are checked on raw materials before use.

9.6.5 Storage of Hazardous Chemicals and Toxic Substances Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence
9.6.5.1	Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are approved for use and stored on-site; and iii. Supported by current Safety Data Sheets (SDS) made available to all staff.	Minor	There was an unlabeled mop bucket on a janitorial cart not in use, outside of the IQF room entrance. It had dirty liquid and a mop on the first 2 days of facility inspections and was empty on the 3rd day.
9.6.5.2	Storage of hazardous chemicals and toxic substances shall be: i. Located in an	Compliant	





	area with appropriate signage indicating that area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.		
9.6.5.3	Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-inprogress, finished product, or product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation.	Compliant	
9.6.5.4	Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.	Compliant	
9.6.5.5	Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided with first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.	Compliant	
9.6.5.6	The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor	Compliant	
9.6.5.7	In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment	Compliant	

## SS 9.6.5 Storage of Hazardous Chemicals and Toxic Substances Summary

Any hazardous chemicals were observed to be properly stored and labeled and did not appear to present a hazard to personnel or food products. No processing utensils or packaging were stored next to chemicals. Chemical storage areas were observed to have instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. Daily supplies of chemicals were properly stored in production room. Maintenance chemicals were observed to be stored safety. All stored chemicals have current SDS information on file electronically and a SDS register. All cleaning chemical containers are triple rinsed and then disposed in the garbage cans. Paints and other maintenance chemicals are disposed directly in garbage cans without any further actions. Minor NC - There was an unlabeled mop bucket on a janitorial cart not in use, outside of the IQF room entrance. It had





dirty liquid and a mop on the first 2 days of facility inspections and was empty on the 3rd day.

Element	Description	Primary Response	Evidence
9.6.6.1	The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination.	Compliant	
9.6.6.2	Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may negatively impact the product.	Compliant	
9.6.6.3	Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.	Compliant	
9.6.6.4	Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport.	Compliant	
9.6.6.5	Refrigerated units shall maintain the product at the required temperature. The unit's temperature settings shall be set, checked, and recorded before loading and the product temperature shall be recorded at regular intervals during loading, as applicable.	Compliant	
9.6.6.6	The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals, and the storage temperature at regular intervals during transit.	Compliant	
9.6.6.7	On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.	Compliant	
9.6.6.8	Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.	Compliant	





The methods and responsibilities are outlined in: Frozen Half Shell or Whole Oster SOPs dated 9/25/2014; Frozen Half Shell Clams SOPs dated 9/25/2014; Frozen Vacuum pack Standard dated 9/25/2014; and Fresh Department Clam SOPs dated 9/25/2014 define the practices for loading, unloading and storage of food products has been documented and implemented. It was observed during the audit tours that food is unloaded, stored and loaded under conditions that prevent cross contamination. The sites policies requires that all trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading and that vehicles be secured from tampering by use of seal or other agreed method. Refrigerated trailer temperatures are monitored and documented before unloading of product, operation below 10 F for frozen products and below 50 F for fresh shellfish. This was observed to be recorded in form Sack Verification Incoming. It is the responsibility of the delivery team members (truck drivers) to maintain the required temperatures during transport to the final destination and monitor the delivery truck for required temperature level of less than 45 F. It was observed during the audit tours that loading and unloading practices do not expose products to detrimental conditions. Trailers and vehicles used for transport were observed to be properly secured from tampering by padlocks or seals.

9.7.1 High-Risk Processes Module 9 GMP for Processing of Animal Products			
Element	Description	Primary Response	Evidence
9.7.1.1	The processing of high-risk food shall be conducted under controlled conditions such that sensitive areas, in which the high-risk food has undergone a "kill" step, a "food safety intervention" or is subject to post-process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials, to ensure cross-contamination is minimized.	Compliant	
9.7.1.2	Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.	Compliant	
9.7.1.3	Areas in which high-risk processes are conducted shall only be serviced by staff dedicated to that function.	Compliant	
9.7.1.4	Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.	Compliant	
9.7.1.5	Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.	Compliant	

## SS 9.7.1 High-Risk Processes Summary

Oysters may be consumed raw by the consumer. This facility only cleans and freezes the oysters. The only cooking process involves cleaning clams and sealing in bags. The clams are steamed in the bags and are frozen and shipped, and the cooked clams remain sealed in the bags. The process of manufacturing high risk foods takes place under controlled conditions in a protected/segregated. Employees working in the high-risk areas (RTE area) were observed to follow high standards of personal hygiene with minimal risk to the controlled environment and product. Based on the Ambient Air Testing Procedure dated 10/29/2024, the environmental air is monitored at least annually for inside the processing rooms for APC, Yeast and Mold last on 11/1/2024 in each RTE area (Vac Pack #1, Vac Pack #2, and IQF rooms).





9.7.2 Thawing of F	9.7.2 Thawing of Food Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.7.2.1	Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose. Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor or shall be appropriately plumbed.	Not Applicable	No thawing is conducted.		
9.7.2.2	Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.	Not Applicable	No thawing is conducted.		
9.7.2.3	Provision shall be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.	Not Applicable	No thawing is conducted.		

## SS 9.7.2 Thawing of Food Summary

No thawing is conducted.

Element	Description	Primary Response	Evidence
9.7.3.1	The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.	Compliant	
9.7.3.2	Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.	Compliant	





	2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.	
9.7.3.4	Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.	Compliant
9.7.3.5	In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.	Compliant
9.7.3.6	Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.	Compliant
9.7.3.7	Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.	Compliant
9.7.3.8	Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.	Compliant
9.7.3.9	Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).	Compliant

## SS 9.7.3 Control of Foreign Matter Contamination Summary

Policy Control of Foreign Matter dated 1/8/2021 define the methods and responsibilities to prevent foreign material contamination. The policy's implementation was demonstrated by preoperational inspections and regularly scheduled maintenance inspections, that are conducted and documented for the condition of equipment and any potential contaminants. A glass register has been documented with glass, brittle plastic and ceramic sources included in all areas of the plant. The Glass and Brittle Plastic Register documented, and Equipment, Facilities, Glass and Brittle Plastic, Building Inspection Checklist is completed weekly. Wood pallets were clean and in good condition, and the facility has a policy prohibiting and/or controlling wooden utensils in processing/food handling areas. The site has documented a knife policy, and knives are controlled, cleaned and required to be in good condition. Periodic maintenance inspections include looking for loose objects and potential contaminants from overheads. The site's policy requires that any product affected by foreign material contamination be isolated, inspected, reworked or disposed of. The glass policy requires that a thorough cleanup and inspection (including of cleaning equipment and footwear) occur if a glass breakage were to occur. A responsible person, from the management team, is required to inspect the affected area before the restarting of production. Gaskets are being inspected by the operators during the pre-op activities and recorded in different pre-operational forms for different areas.

9.7.4 Detection of Foreign Objects Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence	
9.7.4.1	The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or	Not	No foreign material detection devices are used.	





	detect foreign matter shall be documented and implemented.	Applicable		
9.7.4.2	Where detection and/or removal systems are used, the site shall establish limits for detection based on a risk assessment of the product and its packaging and identify the location(s) of the detector(s) in the process.	Not Applicable	No foreign material detection devices are used.	
9.7.4.3	Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.	Not Applicable	No foreign material detection devices are used.	
9.7.4.4	Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.	Not Applicable	No foreign material detection devices are used.	
9.7.4.5	In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.	Not Applicable	No foreign material detection devices are used.	

# SS 9.7.4 Detection of Foreign Objects Summary

No foreign material detection devices are used.

9.8.1 Waste Disp	9.8.1 Waste Disposal Module 9 GMP for Processing of Animal Products				
Element	Description	Primary Response	Evidence		
9.8.1.1	The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented.	Compliant			
9.8.1.2	Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.	Compliant			
9.8.1.3	Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.	Compliant			
9.8.1.4	Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.	Compliant			





9.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging.	Compliant	
9.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials or waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.	Not Applicable	There is no requirement for controlled disposal of trademarked material.
9.8.1.7	Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health.	Not Applicable	There is no inedible waste designated for animal feed.
9.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.	Compliant	
9.8.1.9	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.	Compliant	
9.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports.	Compliant	

## SS 9.8.1 Waste Disposal Summary

The responsibility and methods are outlined in the Waste Management procedure (9.8.1 reviewed 11/6/2024). Waste is removed daily from the warehouse. No areas observed with waste accumulation. Containers for waste are properly maintained and vehicles and equipment used for waste are properly cleaned. Product waste is adequately contained, held in a separate area, and disposed daily. Daily monitoring of the control of waste materials is performed. 9.8.1.6 N/A - There is no requirement for controlled disposal of trademarked material. 9.8.1.7 N/A - There is no inedible waste designated for animal feed.