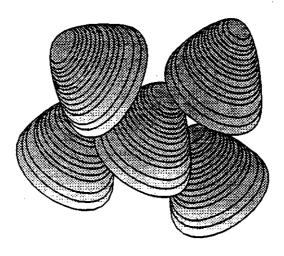
September 1995

TP - 80

Total Quality Assurance (TQA) and Hazard Analysis Critical Control Point (HACCP)

Manual for Clam Production and Processing



by

W. Steven Otwell and Victor M. Garrido

Florida Sea Grant -- University of Florida in Cooperation with US Department of Agriculture and Southern Regional Aquaculture Center



MANUAL FOR HARD CLAM PROCESSING

Total Quality Assurance (TQA) and **Hazard Analysis** and Critical Control Point (HACCP)

Authors

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September 1995

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Forward

This manual was prepared through support from the U. S. Department, of Agriculture's Extension Service. The project, "Implementation of TQA and HACCP Concepts for Processing Aquacultured Products" involved two parts. Plans for processing molluscan shellfish (oysters and hard clams) were conducted jointly through Cooperative Extension Services at the University of Florida and Louisiana State University, while plans for catfish processing were conducted jointly by Cooperative Extension Services at Mississippi State University and Virginia Polytechnical Institute and State University. The project has since been extended to include similar work for mussels by the University of California, Davis with the University of Alaska, rainbow trout by North Carolina State University with Virginia Polytechnical Institute and State University, and crawfish by Louisiana State University with the University of Florida.

This work precedes expected Federal mandates for HACCP programs for seafood and aquaculture products processing in the United States. The content and recommended approaches are-consistent with the basic HACCP concepts recently **summar**ized by the National Advisory Committee on Microbiological Criteria for Foods (1992) and proposed by the U.S. Food and Drug Administration (1994). Food safety is the featured concern.

This manual is intended to serve as a general or generic guideline for molluscan shellfish processors. In order to assure a currentformate, this manual is originally formatted for a three ring notebook anticipating future changes and additions to address FDA's final HACCP mandate. Since no two processing firms are identical in terms of initial resources, products and operations, it is impossible to provide one manual to satisfy the specific requirements of all firms. For further and future information on this topic contact the respective authors.

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Disclaimer

This manual is based on the expertise and experience of the respective authors mindful of basic TQA and HACCP concepts and pending regulatory programs. The recommendations and examples have been compiled in cooperation with industry participation and with certain pertinent State and Federal regulatory programs including the Interstate Shellfish Sanitation Conferences' Executive Office. The contents do not constitute any proposed position or approval by any State or Federal regulatory program, but they should be consistent with proposed and pending programs. Program additions and changes are probable, but should not significantly alter the basic concepts and intent of the manual

Acknowledgments

This manual was made possible through cooperative assistance from numerous individuals and programs providing background information, critiques and pilot-test participation. These participants formed an advisory team for project activity.

Industry

- * Leavins Seafood, Inc. (President and V. President, Grady and Alice Leavins, and processing staff)
- **★** Wilson's Seafresh Seafood (President, Donny Wilson)
- * Buddy Ward & Sons Seafood (President, Thomas Ward, Chairman of the Board, Buddy Ward)

Industry **Associations**

- * Apalachicola Oyster Dealers Association
- * Southeastern Fisheries Association (Executive Director, Robert P. Jones)
- * Pacific Coast Growers Association (Director, Tim Smith)
- * Florida Aquaculture Association (V. President, Leslie Stunner)
- * National Fisheries Institute (V. President of Science and Technology, Roy Martin and Dir. of Food and Regulatory Affairs, Bob Collette)

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- * Florida Department of Environmental Protection, Bureau of Marine Resources and Regulatory Development (Bur. Chief, David Hiel; Environmental Administrator, Mark Collins; Specialist, Nancy Horton; and numerous field specialists/inspectors)
- * Florida Department of Agriculture and Consumer Services (Food Laboratory Director, Betsy Woodward; Bur. Chief Food and Meat Inspection, John Fruin; and others)

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- **★** United States Food and Drug Administration's Office of Seafoods
- * National Seafood HACCP Alliance for Education and Training with **support from** the National Sea Grant College Program.

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* Harbor Branch Oceanographic Institute, Div. Of Applied Biology, Cedar Key Hard Clam Project, Aqueulture Division Director, David Vaughn

Why Develop a TQA and HACCP Program

Total quality assurance (TQA) and Hazard Analysis and Critical Control Point (HACCP) programs have been proven to enhance the quality and safety of food products. These programs should go hand-in-hand from production through processing. They basically serve as a reminder and record of commitments for producing safe, top quality foods. TQA and complementary HACCP programs have been developed for cultured catfish (Catfish Farmers of America, 1993), cultured trout (U.S. Trout Farmers Association, 1994), pork (National Pork Producers Council, 1991) and other foods. Similar programs are being developed for all types of food production and processing in the United States. The primary concern should always be food safety.

What is a TQA Program?

In terms of molluscan shellfish, TQA programs should address food production either during culture or harvest. Although the acronym includes 'quality', a TQA program for hard clams, as ready-to-eat foods, must feature product safety concerns. A more accurate acronym would be TSA (Total Safety Assurance). Numerous acronyms have been used to denote certain production programs (i.e. TQM-Total Quality Management, CQA-Catfish Quality Assurance, etc.), but for simplicity TQA is used in this manual.

The TQA program offers market and consumer confidence through reinforced and uniform industry practices. These programs are usually developed and enforced by industry trade associations to insure a positive image and market value for their products. Participating producers, be they harvesters or shellfish growers, can reference the TQA program to direct their practices. It is basically an education program developed through a commitment by industry. A producers participation usually involves a signature to designate their awareness and commitments. Most TQA's are not required by State or Federal regulations, but they can be essential components of a HACCP program.

What is a HACCP Program?

As proposed by FDA (1994) the anticipated mandatory HACCP program is for processing firms. The HACCP program is an actual documented plan of action which specifies various critical control points with monitoring and record keeping procedures to prevent food safety hazards. The HACCP program organizes and records the industry commitments to product safety through the processing procedures. Hard clams processing can involve shellfish handling, storage, preparing, shucking, freezing, changing into different market forms, manufacturing, preserving, heating, cooking, packing, labeling or holding.

As with the TQA program, the HACCP program is primarily an educational program with a referenced plan of action for industry practice. The recording requirements are a 'self-regulatory' feature proposed with government oversight by State and/or Federal authorities. The intent is to enhance and assure product safety in a cost-effective manner so as to protect public health and instill consumer confidence in consumption of molluscan shellfish.

HOW TO DEVELOP TQA PROGRAMS

Shellfish TQA Program Development

TQA programs are an industry responsibility. TQA programs are actual written plans for growers or harvesters. They can be programs best planned by local groups and trade associations. They must be developed mindful of potential food safety problems or hazards. They must comply with existing regulations pertinent to molluscan shellfish growing and harvesting. Industry representatives should combine their interest with regulatory authorities and technical expertise to develop a sound, recognized program. They should reference all existing regulations and include their own special considerations. The TQA plan should be more than just regulatory compliance. The industry reputation should be considered.

This manual offers a recommended TQA program for the hard clam industry consideration. There are no standard methods for TQA development, but this manual recommends a simplified 7-step process that is consistent with the traditional HACCP development process.

I. Consider the possible food safety hazards that could occur during growing and harvesting.

A reasonable list of possible food safety hazards should include problems that are known and probable. This list does not need to include all possible hazards. For example, bacterial contamination is known and probable for most filter feeding shellfish. In contrast, it is possible that a drug residue could contaminate cultured shellfish, but it is not probable or reasonably relative to current commercial practice.

A reasonable listing of possible food safety hazards associated with molluscan shellfish is outlined in Table 1. This outline is only an illustrative example for educational purpose. Conditions and hazard considerations may vary for different shellfish species and locations. Additional and similar considerations are outlined in FDA's Fish and Fishery Products Hazards and Control Guide (1994). This federal guide was prepared to assist the seafood industry with recommendations for hazard controls (extracts in appendix). This guide is not a mandatory regulation, but references various FDA tolerances and action levels.

In most instances, the primary food safety hazards reasonably associated with molluscan shellfish harvest are natural toxins, microbial contamination and chemical contamination. These concerns are typically handled when product is cultured and harvested from 'approved' waters.

2. Identify the 'significant' food safety hazards or critical concerns.

Based on local and scientific knowledge, judge the significance and/or likelihood that the listed safety hazards could occur for the shellfish species and location of growth and harvest (see Judgement for Significance, Table 1).

3. Consider how to avoid or limit the significant food safety hazards.

Table 1 lists some preventative measures.

4. List the methods to confirm or monitor that the preventive measures are in place.

The preventive measures based on approved waters could simply refer to the most immediate regulatory authorities with jurisdiction for growing waters. This authority is usually a State-based program which maintains records and programs to substantiate the approved water status for molluscan shellfish commerce. Likewise, a TQA plan can reference the current system and examples for tagging, trip tickets, and other harvest records used to identify the source and time of product harvest.

All TQA programs should be linked with the current licensing programs for harvesters. The link can be through development of a pre-licensing requirement. These arrangements can strengthen the cooperation and understandings between producers and regulatory authorities.

The TQA program can also outline proper harvest and on-vessel handling procedures to assure product quality. These guidelines can be recommended by the industry and should at least comply with all existing regulations. The industry recommendations could be more comprehensive or specifically customized to a particular location or product. They can include harvest seasons, daily harvest time, handling procedures for temperature control and product protection, tagging requirements, and other specific procedures.

5. Consider corrective actions or alternative plans.

List what should be done if a preventive measure is not in place or is not considered. What should be done with questionable products?

6. Consider record keeping plans.

A record of the TQA program and program participants should be maintained, possibly as part of the HACCP programs by cooperating processors and/or as an addendum with the state regulatory licensing process.

7. Consider a verification plan.

Periodically, producers should review the utility and compliance with the TQA program. Verification could involve the annual licensing process linked with TQA participants, a third party (non-producer) reviewer of the program, and/or state reviews and reapproval of the growing waters. Similar considerations should emphasize the effectiveness of the program and industry participation.

Table 1. Example: Total Quality Assurance (TQA) development document based on the harvest of Florida's Hard Clams.

TQA Hazard Analysis Work Sheet for Molluscan Shellfish Production

Potential Hazard in Growing and Harvest Could the Potential Hazard be Significant		Judgement for Significance	Preventive Measure(s) during production and harvest	
Natural Toxins	Yes	Areas of harvest have not been implicated or suspect for any natural toxins, yet such contamination is possible	Approved waters, proper product identification (tags and trip tickets and licensed producers) and depend on State and Federal alerts and surveys. TQA program.	
Microbial Contamination	Yes	Known pathogens can accompany harvest	Approved waters, proper product identification (tags and trip tickets and licensed producer). TQA program.	
Chemical Contamination water or vessel surces)	Yes	Areas and method of harvest have not been implicated or suspected for any known chemical contaminants. Further assurance through approved waters and licensed producers.	Approved waters, proper product identification (tags and trip tickets and licensed producers). TQA program.	
Pesticides	Yes	Same as for Chemicals Contaminants	Same	
Drug Residues	No	Natural and cultured product is not exposed to antibiotics or other medicinals	Not Applicable	
Decomposition	Yes / No	Production governed by TQA with sanitation concerns and handling and storage conditions. Could be a quality or a safety issue.	Production TQA and sanitation program	
Parasites	No	No implicated or suspected occur- rence of health significance from area of harvest	Not Applicable	
Food and Color Additives	No	No additives used in production	Not Applicable	
Physical (e.g. metal, glass, wood)	No	Initial product, whole shellstock is not exposed to physical contamination	Not Applicable	
Others				

Total Quality Assurance (TQA) Program for Florida Hard Clam Production and Harvest

The undersigned clam harvester and/or grower understands and will abide by the following TQA program guidelines for the production of Florida hard clams (Mercenaria spp.). (See special notice).

Product

- Hard clams (<u>Mercenaria</u> spp.) will only be grown and harvested from approved or conditionally approved waters (when open for harvest) as approved according to the Florida Department of Environmental Protection's Comprehensive Shellfish Control Code, specified in Rule 62R-7.
- ◆ Clam size, bag limits and harvest seasons will be consistent with the Florida Marine Fisheries Commission, FL Administrative Code 46-17. Fill-in the blanks.

	Size:
	Bag Limit:
	Harvest Season:
Pei	rsonnel
•	All harvesters must have a 'Saltwater Products License' Signee No
•	Harvesters working in Brevard County will have an "Brevard County Hard Clam Harvesting License' If applicable, No
•	Harvesters can only sell hard clams to dealers and/or processors with a Shellfish Processing Plant Certification License.
•	Other requirements (i.e., aquaculture license pending)

Boat and Equipment

- Boats and all equipment used during harvest will be maintained in a clean manner to prevent product contamination from filth, chemicals and other contaminants.
- Harvest boats will be built and maintained to prevent hard clam contamination. Boats must have an
 elevated deck to keep the hard clams above any water or bilage.
 Other requirements ______
- Paint and other finishes used on boats will be non-toxic and in good condition.
- Decks and other internal parts of the boat will only be washed with approved or city water.
- Chemicals, fuel, and other hazardous materials required on the vessel will be securely stored in a separate space to prevent contamination of the shellstock or hard clam beds.
- Sacks and other hard clam containers will be clean and dry before use, and stored to prevent contamination from bilage, chemicals, or unapproved waters.
- Pets, including dogs and cats, will not be permitted on harvesting vessels at any time.
- Bilage water and human waste (feces, urine or vomit) will not be discharged from the boat or on the boat deck during harvest from approved waters. Proper sanitary facilities will be available.

Product Handling and Transport

- All hard clams will be harvested alive with no broken or cracked shells that could cause the clams to die.
- ◆ Harvested hard clams will be delivered to the certified dealers before 6:00 PM on the same day of harvest. Harvested hard clams will be directly delivered to a certified dealer as soon as possible without delays after landing (dockside) the catch.
- Certified dealers are expected to have the harvested hard clams in adequate refrigeration (below 50° F or 10° C) within 2 hours after harvesting the product (harvesting time as indicated in the harvester's tag).
- Live clams shellstock have a terminal sale date of 14 days from the date of harvest.
- ◆ At all times, hard clams will be protected with shading from elevated temperatures and direct sunlight. Harvest times will be reduced during warm weather.
- On-board, iced refrigeration will be provided for prolonged harvest trips during hot, seasonal weather.
- If necessary, landed shellstock will be delivered in clean trucks as soon as possible and proper refrigeration will be used during warm weather and prolonged trips.

Tagging

- ◆ All shellstock harvested from the same location will be clearly identified with an approved, durable, waterproof harvester's tag (2 5/8 x 5 1/4 inches) firmly attached to the container of hard clams before landing (dockside) (Attach approved example according to the Florida rule 62R-7)
- Certified dealers are expected to use similar tags before shipment of products and to complete trip tickets to record the harvest as required by the Florida Marine Fisheries Commission.
- If a harvester is also a certified dealer, then a combined tag may be used as the harvester's tag.

TQA Voluntary Commitment	
By my signature	
Growers Permit No.	_
Lease No.	_
Lease Location:	-
	•

* Special Notice *

This TQA plan is only a draft recommendation as a model for industry consideration as of June 1995. The recommended format is for industry consideration and does not denote industry or regulatory endorsement. The content is consistent with current Federal and Florida's molluscan shellfish regulations as adopted in Florida Rules 62R-7 through the FL Department of Environmental Protection's Comprehensive Shellfish Control Code. Additional consideration should rely on industry standards.

How to Develop a HACCP Program

The HACCP program will be an actual written plan to be filed at the processing plant. The program should be focused on food safety. Molluscan shellfish processors should develop their HACCP programs consistent with the traditional 7-step procedures:

- 1. Hazard Analysis
- 2. Critical Control Point Identification
- 3. Setting Critical Limits
- 4. Establishing Monitoring Procedures
- 5. Establishing Corrective Actions
- 6. Record keeping Requirements
- 7. Verification

Although this manual and others provide basic outlined HACCP models, a company's HACCP plan must be custom designed for the individual product types and processing operations. The HACCP program development should begin and continue as a "team effort." A successful HACCP program requires understanding and commitment through all levels of product handling and processing. In that HACCP is primarily a document of intuitive thinking, the plan development assures everyone on the team is thinking in the same manner.

Initially a 'HACCP Team' should be assembled to develop the plan. Prior training and technical assistance may be necessary, but the processing firm should not depend solely on outside help to develop the plan. HACCP plan development and continued adjustments are an essential part of the education process that assures an effective program. The following example (see Section - HACCP Plans) was developed in consultation with 'HACCP Teams' from individual hard clam processing firms in Florida and Louisiana, in accordance with the National Fisheries Institute HACCP workshop (1991).

Assemble the HACCP Team

Depending on the size of the processing firm, the HACCP Team could include 1 to 2 or over 20 to 30 individuals. Ideally the team would represent the various handling and processing procedures and upper management. A personnel organizational sheet and/or diagram is useful to recognize the staff and align responsibilities. The example in the Hard Clam HACCP program includes a rotating 'HACCP Coordinator' position to periodically share and better learn the HACCP responsibilities throughout the entire firm (p. 13-14).

STEP 1. Hazard Analysis (Food Safety)

The potential food safety hazards will depend on the shellfish species, product types and processing methods. The plan should declare the species (common and scientific names) and product type to be covered by the respective HACCP program. Additional shellfish species and product types handled by the same firm may require similar, yet distinct HACCP program development (p. 15).

A processing flow diagram from 'receiving' through 'shipping' the final processed products can be very helpful in identifying potential hazards and explaining the HACCP program (p.19). Detail in the flow diagram is optional, but more detail assures a more comprehensive hazard analysis.

Mindful of the species, products and processing scheme, the HACCP Team can begin to list possible (reasonable) food safety problems that could occur during processing. The team must use some discretion between 'possible' and 'reasonable' safety hazards. Although it may be possible for almost any type of food safety hazard, the team must use their experience and technical assistance to focus on the more probable and suspected safety problems. Future or unforeseen hazards can be addressed with HACCP plan modifications

as necessary. FDA's Fish and Fishery Products Hazards and Control Guide (1994) offers a listing of potential food safety problems for the various seafoods and aquacultured species and product types.

A useful approach is to list the common food safety hazards;

natural toxins	decomposition	
microbial contamination	parasites	
chemical contamination	food & color additives	
pesticides	physical contaminants	
drug residues	others	

Next, proceed through the flow diagram questioning the possible occurrence of these concerns at each processing level or procedure. The team should document their thought processes in a brief form or "hazard analysis worksheet" (see example,p.20-24) to serve as future reference. This approach encourages thorough plan considerations and serves to explain the final HACCP program. A positive (yes) food safety hazard must be addressed with preventative procedures. A negative (no) hazard documentation offers explanation for the team's decision.

STEP 2. Identifying the Critical Control Points (CCP's)

CCP's have been defined as any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. There must be a CCP for each positively (yes) identified food safety hazard. The CCP is usually a specific processing procedure or activity that can be monitored with record keeping to reflect trends and assure compliance with the HACCP program.

Identifying CCPs can be the most difficult part in developing the HACCP program The selection requires knowledge of the food safety hazards and processing requirements. It is common to identify excessive CCP's because the HACCP team has difficulty in distinguishing between product quality and safety concerns. In most molluscan shellfish processing there are at least two critical control points - product receiving and product refrigeration (storage and shipping) (p.25).

STEP 3. Setting Critical Limits (CL)

Each CCP must have a CL that can be monitored to assure prevention of the food safety hazard. The CL's must comply with any existing regulations, i.e., action levels, tolerances and specified temperature guidelines (p. 25). Based on technical experience and/or preliminary trials, a CL's can be established for CCP's which do not have any specified regulatory limits. The new FDA Hazard Guide (1994) offers some recommended CL's for shellfish.

STEP 4. Establish Monitoring Requirements

Monitoring involves observations or measurements to assure the CCP's is in control or does not exceed the CL's Monitoring can be continuous (i.e. temperature charts) or periodic (i.e. daily notices to assure approved waters). The monitoring methods and frequency should be adequate to reflect trends and any possible deviations at the CCP that could cause a food hazard (p 25).

STEP 5. Pre - Establish Corrective Actions

Plan of actions or procedures should be predetermined in case monitoring indicates a CL is exceeded or a CCP fails. Actions can involve holding or isolation of product to determine possible safety problems

(p.25). The results may indicate the product is safe for continued processing and commerce, or that the product must be treated, reprocessed, rejected or destroyed. Regardless of the results, a record of the corrective action (i. e. CAR= Corrective Action Record, p.25) must be recorded as part of the HACCP program. These records stand as evidence for the firm's commitments to the HACCP program. A HACCP program without any recorded CAR's is ideal, but not probable.

STEP 6. Records

Based on the selected monitoring procedures each HACCP program will have specified records to be maintained for company and regulatory review(p. 25-29). These records stand as a continuous 'view' of the firms practices and commitments to food safety. The records can include:

- 1. HACCP plan and original development documents which specify the records to be maintained.
- 2. Monitoring records
- 3. Corrective actions
- 4. Employee training programs and TQA's

STEP 7. Verification

Verification procedures are basically a specified audit system to assure the current HACCP program and practices are in compliance with the HACCP plan and food safety expectations. Verification procedures should be specified in the HACCP plan (p. 25, 31). The procedures can involve basic plan reviews, equipment calibrations (i.e. thermometer accuracy), and product sampling and testing. The reviews help validate that the HACCP plan has identified the CCP's, CL's and proper monitoring procedures. Calibration checks assure monitoring procedures are accurate. Sampling and product testing reflects on the consequence of the HACCP plan. The frequency of verification will vary per product type and production schedules. Scheduling should be mindful of licensing requirements, process modifications and other factors that could influence the product, processing scheme or HACCP procedures.

HACCP PROGRAM for HARD CLAM PROCESSING

HACCP PROGRAM for Hard Clam Processing

HACCP Program- Safety Hazards

Name: Any Florida Hard Clam Co., Inc.

Plant address:

Phone No.:

Phone No.: FAX No.:

FAX No.:

Personnel Organization and HACCP Responsibilities

President - Owner, treasurer and primary person responsible for all plant activity, products, personnel and business liaison. Primary authority for design and operation of the HACCP inspection program. In charge of the budget and operational expenses. Member of the HACCP team.

Vice President -- Co-owner and secretary. Oversees and assists the office manager with the HACCP program.

Office **Manager/Communications** – Oversees plant sale records and company cash flow. Reviews, accepts and signs HACCP records. Responsible for public relations of the company and serves as an initial spokes person in case of a product concern.

Plant Manager/Sanitation supervisor - Person responsible for the day to day operation of the plant. In charge of the production and general plant supervision. Monitor routine plant inspection, cleaning, sanitation and HACCP record keeping. Responsible for receiving and shipping product. In charge of personnel training.

HACCP Coordinator - Aligns all responsibilities, arbitrate concerns and assure the staff is working in a HACCP mode. This position will rotate amongst upper management.

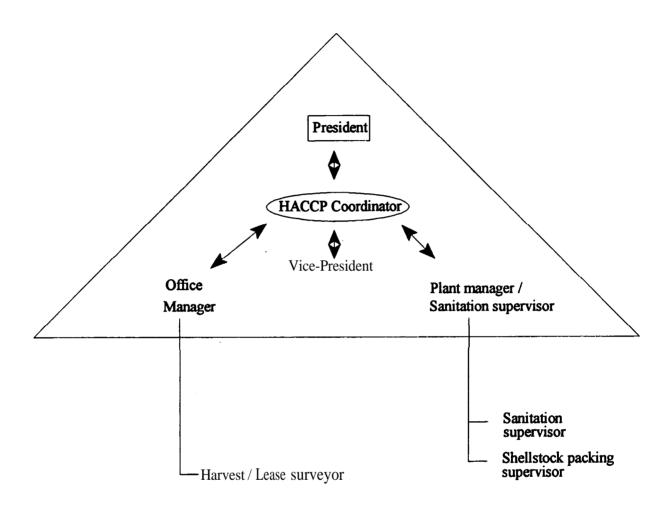
Shellstock Packing Supervisor - Responsible for shellstock grading, packing, shipping and receiving. Keeps HACCP records of production per batch number and sanitation in the shellstock packing area.

Harvest/Lease Surveyor - Person in charge of supervising harvesters, making sure that all products are in compliance with the NSSP and State regulations (harvest or cultivated from approved waters, legal size, product is not abused, etc.). The Harvest/Lease surveyor will report to the Office Manager.

Additional Staff - All oriented and trained in accordance with the HACCP program. Includes packers, Loaders, Drivers, etc.

HACCP ORGANIZATIONAL DIAGRAM

This organization reflects a team approach where bythe 'HACCP Coordinator position rotates amongst upper management (president, office manager and plant manager). The rotation (monthly, semi-annual or seasonal) will be determined by the president. The HACCP Coordinator position simply serves to align all responsibilities, arbitrate concerns and assure the staff is working in a HACCP mode.



1 OSITION Part of Assignment	Position	Name	Date of Assignment
------------------------------	----------	------	--------------------

President

(to be filled by the processing firm)

Vice-President

Office Manager/Communicator

HACCP Coordinator

Shellstock Packing Supervisor

Harvest / Lease Surveyor

Hard Clam Products

The products prepared and sold by Any Hard Clam Co., Inc. are named following the product definition specified in the U.S. FDA National Shellfish Sanitation Program, "Interstate Certified Shellfish Shippers List", the Florida State Code (62R-7) specified by the Florida Department of Environmental Protection, Bureau of Marine Resources, Division of Marine Resources, Regulation and Development and the Florida Marine Fisheries Commission Rule 46-17.

Type

Molluscan Shellfish – Hard clams or quahogs (<u>Mercenaria</u> species) harvested from approved and/or conditionally approved waters; public and leased beds cultured in coastal waters from Texas through west Florida.

Source

The original source can be from natural harvest or cultured harvest. Aquacultured sources would be provided in accordance with a Total Quality Assurance (TQA) program maintained by the supplier or producer (harvester or grower).

Forms

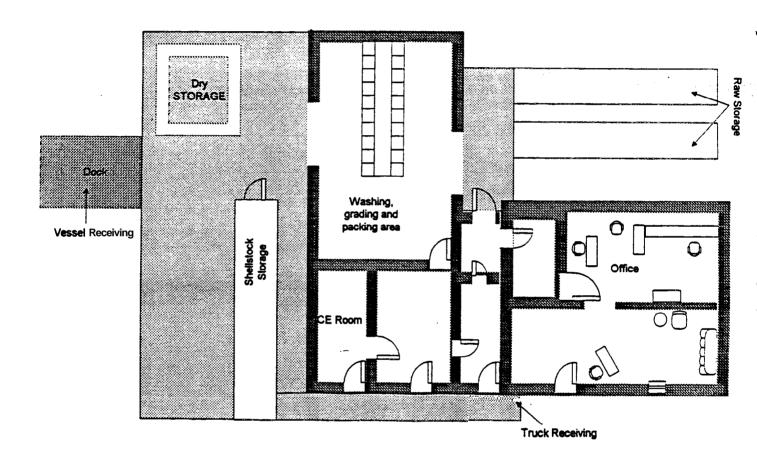
<u>Shellstock</u> - Live shellfish (hard clams) in their shell

Dry Storage - Product held in a refrigerated cooler set at a temperature no higher than the 50° F (10° C) limit, according to NSSP manual 1993.

Repacked/Transhipped - Shellstock is received from out-of-state, washed, properly tagged, boxed and shipped to restaurants.

Secondary Products – (option reserved for future commerce, i.e., strips, fritters, stuffing, spiced, etc)

Plant Diagram



Processing Procedures

Shellstock (for packing)

1. Receiving

Shellfish product will be received into the plant only if it satisfies all requirements specified in the NSSP manual part II 1993 revision Section B-2, Items a through d.

Direct Vessel- live hard clams are purchased from local fishing vessels that harvest the shellstock by hand from approved and/or conditionally approved coastal waters. Harvest can be subject to the surveillance of an assigned Harvest/Lease Surveyor. Harvesting should be according to an existing TQA (Total Quality Assurance) Program. Shellfish harvesting water classification is defined by the FL Department of Environmental Protection (DEP, formally DNR) in the current comprehensive Shellfish Harvesting Area Survey. The live shellstock is off-loaded at the plant's dock or at the satellite landing locations, where the product is inspected for survival, legal size, and general condition (mud and appearance), then monitored for legal harvester's tags. At receiving, all products are assigned a dealer's lot number for traceability purposes. (FL Marine Fisheries Commission rule 46-17 and FL DEP rule 62R-7) Likewise, live shellstock is received from distant locations in Florida and outside Florida.

Local Trucks - live hard clams are delivered by truck to the processing plant, less than two hours from the landing site. Product is off-loaded and inspected for temperature and general condition. All product is monitored for legal harvester's tags, then is re-tagged and a dealer's lot number is assigned.

Distant Trucks - live product transported for greater than two hours must be delivered to the processing plant, by refrigerated trucks. Refrigeration is monitored by a time-temperature device. Temperature of the product, tag and product condition are also checked. Product is then tagged and a lot number is assigned.

2. Raw Product Storage

Dry Storage (50° F (10° C) or less)

Shellstock – Within 2 hours after receipt of product, post-harvest live shellfish are placed into walk-in coolers, set for an operating temperature low enough to achieved a product internal temperature no higher than 50° F (10°)C). Temperature is monitored by a time-temperature chart recorder. (Note: This 50° F (10° C) limit is currently based on the FL DEP Regulations and practice which accounts for product survival).

Wet Storage- (Optional) (See FL regulation62R-7)

Depurated - (Optional) (See FLregulation 62R-7)

3. Processing

Washing- Shellfish are rinsed with high pressure water hose to remove dirt from surface. Dirt could result in bacterial contamination of edible portion at time of consumption.

Shellstock - Shellfish are washed, graded and culled to select only product that meets the requirements defined by Any Hard Clam Co. for commerce. Product is re-tagged, bagged and sent to final storage. All product which does not meet the required standards is rejected.

Bagging – Properly tagged shellfish destined for shellstock consumption are placed into mesh bags for distribution.

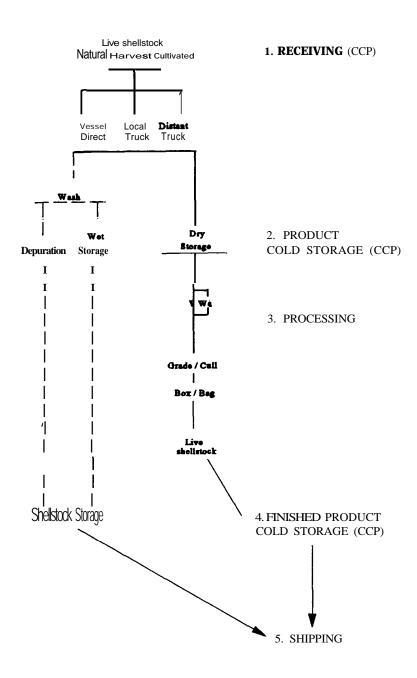
4. Finished Product Cold Storage

Fresh products - All live shellstock is placed inside separate refrigerators set at a temperature of 50° F (10° C) or lower. Temperature is monitored with a time-temperature recorder.

5. Shippinq

Product is placed into refrigerated trucks for distribution to warehouse or retail outlets. Invoices will list the appropriate lot numbers for all shellstock included in the shipment.

HACCP FLOW DIAGRAM



Critical Control Point (CCP) - Processing step or procedure at which, if controlled, potential food safety hazards could be eliminated, reduced or prevented.

____ = future or optional procedures

____ = current operational procedures

Hazard Analysis Worksheets

The following worksheet reflect the assessment for probable hazards through each processing step as depicted in the processing flow diagram. The identified critical control points are summarized in the 'Basic HACCP Plan for Product Safety (p. 25).

Processing Step	Potential Hazard	Could the Potential Hazard be Signifi- cant	Judgement for Significance	Preventive Measure(s)	Critical Control Point
RECEIVING	Natural Toxins	Yes	Areas of harvest have not been implicated or suspect for any natural toxins, yet contamination is possible	Approved waters, proper product identification (tags and trip tickets and dealer's certification) and depend on state and federal alerts and closures	Yes
	Microbial Contamination	Yes	Known pathogens can accompany harvest	Approved waters, proper product identification (tags and trip tickets and dealer's certification) and TQA.	Yes
	Chemical Contamination (water or vessel sources)	Yes	Areas and method of harvest have not been implicated or suspected for any known chemical contaminants. Further assurance through approved waters and certified dealers	Approved waters, proper product identification (tags and trip tickets and dealer's certification) and TQA plan for production	Yes
	Pesticides	Yes	Same as for Chemicals Contaminants	Same	Yes
	Drug Residues	No	Natural and cultured product is not exposed to antibiotics or other medicinals	Not Applicable	No
	Decomposition	No	Production governed by TQA plan and sanitation program monitors handling and storage conditions	Production TQA, time-temperature storage records, sanitation records	No
	Parasites	No	No implicated or suspected occurrence of health significance from area of harvest	Not Applicable	No

Processing Step	Potential Hazard	Could the Potential Hazard be Signifi- cant	Judgement for Significance	Preventive Measure(s)	Critical Control Point
	Food and Color Additives	No	No additives used in processing	Not Applicable	No
Receiving Cont.	Physical (e.g. metal, glass, wood)	No	initial product whole shell- stock	Not Applicable	No
	Others				
PRODUCT COLD STORAGE	Natural Toxins	No	Not introduced or enhanced during storage	Not Applicable	No
	Microbial Contamination	Yes	Thermal abuse could increase bacteria during improper storage	Time-temperature charts (records) and Sanitation Program (SOP)	Yes
	Chemical Contamination	No	Not introduced or enhanced during storage	Sanitation Program (segregated storage of in-plant chemi- cals)	No
	Pesticides	No	Not introduced or enhanced during storage	Sanitation Program	No
	Drug Residues	No	Not introduced or enhanced during storage	Not Applicable	No
	Decomposition	Yes	Thermal abuse could increase decomposition during improper storage. Product quality concern	Sanitation Program and time-tempera- ture charts	No
	Parasites	No	Not introduced or enhanced during storage	Not Applicable	No
	Food and Color Additives	No	Not introduced or enhanced during storage	Not Applicable	No
	Physical	No	Not introduced or enhanced during storage	Not Applicable	No
	Other: Cross- Contamination	Yes	Improperly stored product	Sanitation Program and product segregation	No

Processing Step	Potential Hazard	Could the Potential Hazard be Significant	Judgement for Significance	Preventive Measure(s)	Critical Control Point
PROCESS- ING	Natural Toxins	No	Not introduced or enhance in processing	Not Applicable	No
(sorting, bagging, handling, etc)	Microbial Contamination	Yes	Possible cross-contamination, thermal abuse or exposure	Sanitation Program and processing schedule	No
	Chemical Contamination	No	Not introduced or enhanced in processing	Sanitation Program (segregated storage of in-plant chemi- cals)	No
·	Pesticides	No	Not introduced or enhanced in processing	Sanitation Program	No
	Drug Residues	No	Not introduced or enhanced in processing	Not Applicable	No
·	Decomposition	No	Not introduced or enhanced in processing	Processing can provide additional screening for decomposition	No
	Parasites	No	Not introduced or enhanced in processing	Not Applicable	No
	Food and Color Additives	No	Not introduced or enhanced in processing	Not Applicable	No
·	Physical	No	Not introduced or enhanced in processing. Product handle as whole shellstock	Not Applicable	No
	Others:				
FINISHED PRODUCT COLD STORAGE	Natural Toxins	No	Not introduced or enhanced during storage	Not Applicable	No
	Microbial Contamination	Yes	Thermal abuse could increase bacteria during improper storage	Sanitation Program with time-temperature charts	Yes
	Chemical Contamination	No	Not introduced or enhanced during storage	Sanitation Program	No
	Pesticides	No	Not introduced or enhanced during storage	Sanitation Program (segregated storage of in-plart chemi- cals)	No

Processing Step	Potential Hazard	Could the Potential Hazard be Signifi- cant	Judgement fo Significance	Preventive Measure(s)	Critical Control Point
Finished Product Cold Storage - Cont.	Drug Residues	No	Not introduced or enhanced during storage	Not Applicable	No
-	Decomposition	Yes	Thermal abuse could increase decomposition during improper storage. Product quality problem	Sanitation Program and time-tempera- ture charts	No
-	Parasites	No	Not introduced or enhanced during storage	Not Applicable	No
	Food and Color Additives	No	Not introduced or enhanced during storage	Not Applicable	No
	Physical	No	Not introduced or enhanced during storage	Not Applicable	No
	Other Cross- Contamination	Yes	Improperly stored product	Sanitation Program (product segrega- tion)	No
SHIPPING	Natural Toxins	No	Not introduced or enhanced during shipping	Assure proper ID and certification records	No
	Microbial Con- tamination	Yes	Cross-contamination and/or if product is thermally abused	Sanitation Plan for shipping conditions and temperature	Yes
	Chemical Contamination	No	Not introduced or enhanced during shipping	Sanitation Program with time-temperature charts	No
	Pesticides	No	Not introduced or enhanced during shipping	Sanitation Progran	No
	Drug Residues	No	Not introduced or enhanced during shipping	Not Applicable	No
	Decomposition	Yes	Thermal abuse during shipment could enhance or initiate decomposition that reduces product quality	Sanitation Program for shipping and temperature controls	No
	Parasites	No	Not introduced or enhanced during shipping	Not Applicable	No

Processing Step	Potential Hazard	Could the Potential Hazard be Signifi- cant	Judgement for Significance	Preventive Measure(s)	Critical Control Point
Shipping Cont.	Food and Color Additives	No	Not introduced or enhanced during shipping	Not Applicable	No
	Physical	No	Not introduced or enhanced during shipping	Not Applicable	No
	Other: Labeling	No	Product is properly identified as received	Lot Number	No

BASIC HACCP PLAN for PRODUCT SAFETY

Based on the hazard analysis worksheets, the following critical control points have been designated with the appropriate critical limits and records for monitoring.

SAFETY HAZARDS	CRITICAL CONTROL POINTS	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	RECORDS
Natural Toxins Chemical Contamination Microbial Contamination	Receiving	Source from approved waters Proper tag or labels Certified dealer	DEP (formerly DNR) water classification report Interstate Certified Shellfish Shippers List DEP and NSSP tag and label requirements	Do not accept any product that does not comply with critical limits	Form No.1 Shellfish Harvest/Purchase Records, Harvest/Lease Surveyor report/CAR Form No.2 Harvester's Tag/Trip Tickets Form No.3 Dealer's Tag Production Record
Potential Growth of Bacterial Pathogens	Refrigeration Prod. Storage Shipping	50° F (10° C) for Shellstock	Continuous Time-Temperature chart recorder for refrig. units. Temperature indicators with shipments	-Inspect product that has been submitted to temperature abuse -Discard dead shellfish and/or decomposed product	Form No.4 Time - Temp Charts

CAR = Corrective Action Records

Note: Daily verification of the records is conducted by the HACCP Coordinator, as well as a semi-annual calibration of temperature recorders and the annual evaluation of the company's HACCP plan. Plan verification is based on annual company review aligned with licensing and periodic DEP inspections.

HACCP RECORDS

These forms will serve as records for the HACCP plan and will be kept for a period of one year on refrigerated products and for three years for frozen products. All records will be filled out as frequently as indicated in the company's HACCP document.

Receiving (source)

Form 1. HACCP Shellstock Harvest and Purchase Records

Harvest / Lease Surveyor Reports (CAR)

Form 2. Harvester's Tags and Trip Ticket

Form 3. Dealer's Tag*

Refrigeration (storage and shipping)

Form 4. Refrigeration / Cooling Time-Temperature Chart (continuous record) All coolers used

during the processing of the shellfish are monitored by continuous time - temperature

chart recorders updated weekly.

shipping. Time-Temperature records for transported product.

^{*} Tag containing the information required by the FL Dept. of Environmental Protection and NSSP is generated and attached to every bag of shellfish received into the processing plant.

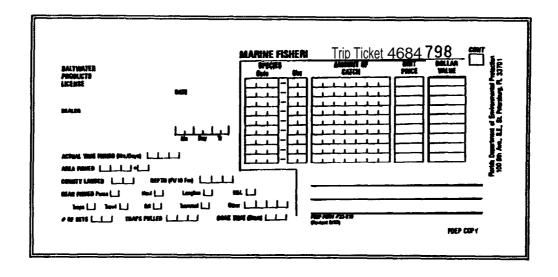
Purchase Date	Lot Number	Cert. Number	Invoice Number	Quantity	Harvest Area	Harvest Date	Incoming Product Temperature

Process Supv:	Date:
HACCP Record Mang:	Date:

Form No.2 - Harvester's Tag (To Be Determined) and Trip Ticket

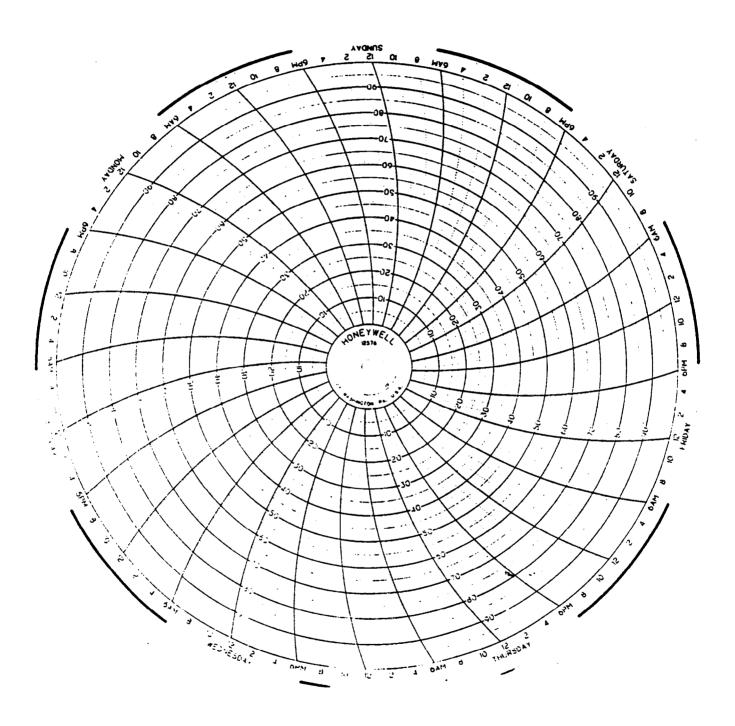
Harvester's Tag (To Be Determine)

Trip Ticket



Form No.4 - Continuous Time-Temperature Chart

Corrective actions and special notes will be written directly on time-temperature log sheets.



HACCP VERIFICATION PLAN

- 1. Daily and weekly review of all required records for critical control points and related sanitation program records.
- 2. Weekly calibration checks for temperature recorders.
- 3. Seasonal microbial checks for incoming and finished product consistent with State regulatory checks.

SANITATION PROGRAM FOR CLAM PROCESSING PLANT

Standard Sanitary Operating Procedures

Sanitation programs are an essential part of an effective HACCP program. They should be a specified, written part of the HACCP program. The plan could specify record keeping procedures.

This plan outlines the standard sanitary operating procedures (SOP) in accordance with FDA's proposed HACCP regulation, the National Shellfish and Sanitation Program (NSSP) standardized shellfish inspection form, and the NSSP Manuals of Operations parts I and II as adopted by the FL Department of Environmental Protection's rules 62R-7. The SOP includes daily, monthly and annual procedures, plus Corrective Actions Records (CAR).

(key: 'cont' = continuous monitoring; and 'per' = periodic monitoring)

General Plant Design

Daily Activities.

- (cont) Plant will not be subject to flooding during normal tide changes.
- (cont) Processing and sanitation water will be obtained from a safe and sanitary source.
- (cont) There will be no cross-connection between potable water supply and waste water;
- (cont) Adequate sewage system will be maintained.
- (cont) No pets should be allowed in any of the food processing plant.
- (cont) All equipment and food contact surfaces are designed and constructed of non-toxic, impervious materials capable of withstanding the environment for its intended use, cleaning and sanitizing agents, and is easy to clean.
- (cont) All surfaces are made of impervious materials, ease to clean and sanitize and free of cracks.
- (cont) Floors should be designed and constructed with adequate drainage.
- (per) All waste should be removed promptly removed from the plant.
- (per) Restroom should be kept clean and in good repair.
- (per) All toxic materials must be held, used and stored in a manner that protects against contamination of food product

Weekly Activities.

- (Per) Insects and rodents should be kept excluded and controlled.
- (per) All storage facilities, including supplies, employee storage, chemicals, etc., should be maintained clean and free from rodents and insects.

Personnel

Daily Activities.

- (cont) No worker with any illness, open or infected wound will be allowed to come in contact with product that may result in contaminated product.
- (cont) No worker will be allowed into the processing area without any previous training on sanitation and food handling practice and the HACCP program.

Operations - Receiving

Daily Activities.

- (cont) Control personnel and equipment (carts, pallets, shovels, etc.) traffic to avoid transporting mud, and possible contaminants to packing areas.
- (per) Dry clean area, wash and sanitize [cleaner and sanitizer]].
- (per) Clean all equipment used during unloading and receiving product.

Weekly Activities.

- (per) Inspect area surrounding receiving dock to remove debris, waste and grass, weeds and **other** items that may attract pest.
- (per) Inspect areas for presence of any insects and rodents and take measures to prevent occurrence. (i.e., spraying, application of proper insecticides, possible use of traps, etc.)

Operations - Raw product cooler

Daily Activities.

- (cont) Inspect for proper product segregation and product inventory rotation.
- (per) Dry clean the area to remove any debris or waste from floor.

Week/v Activities.

- (per) Clean all floors and walls with a general purpose cleaner followed by a rinse and sanitation [cleaner and sanitizer: ()].
- (per), Inspect condition of all surfaces (walls, floor and ceiling).

Monthly Activities.

(per) Clean drip pan from refrigeration unit with sanitizer [sanitizer: ()].

Annual Activities.

(per) Clean refrigeration coils with a brush using a general purpose cleaner. Sanitize with non-corrosive agent. [sanitizer: ()].

Operations - Processing

Dailv Activities.

(per) Wash and sanitize all areas and equipment at the beginning of the day (before operations), and at the end of the day after shutdown [sanitizer: ()].

Operations - Washing, Culling and Bagging area Daily Activities. Rinse area and equipment. (per) Clean with a general purpose cleaner using a low pressure spray followed by rinse and (per) sanitizer [cleaner: (_____)]. Weekly Activities. (per) Dry clean storage room (packing material and containers). **Operations - Finished Product Cooler** Daily Activity. (cont) Control personnel, product and equipment traffic to avoid cross contamination. Dry clean area. (per) Week/v Activity. (per) Clean [cleaner: 0], followed by rinse and sanitation [sanitizer: Month/v Activity. (per) Clean drip pan of refrigeration unit with noncorrosive sanitizer [sanitizer: ()]. Annual Activity. Clean refrigeration coils with a brush using a general purpose cleaner and sanitizer [sanitizer: (per) ____)]. **Operations - Shipping area** Daily Activity.

- (cont) Control personnel traffic frequenting this area.
- (per) Dry clean area.
- (per) Clean [cleaner: ()] and sanitize area and utensils.

Month/v Activity.

- (per) Inspect and clean areas surrounding shipping area for waste, grass, weeds or any other items that could attract pest.
- (per) Inspect areas for presence of any insects and rodents and take measures to prevent occurrence. (i.e., spraying, application of proper insecticides, possible use of traps, etc.)

Operations - Ice Room

As needed*.

Remove	residual	ice,	clean	with	general	purpose	cleaner	[cleaner:	()],	hand	scrub	and
sanitizer	[sanitize	er: (`	1.									

(*) **As** often as necessary to prevent any contamination or bacterial transfer.

Dry clean = physically remove debris without the use of water.

SANITATION PROGRAM RECORDS

Sanitation Program Records can be used to monitoring continuous and periodic Standard Sanitary Operating Procedures. The following forms are recommended for such activities. Similar approaches should be considered to assure more effective sanitation.

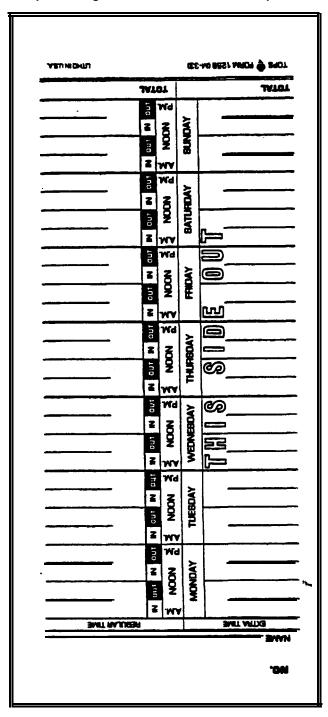
Form A-1 - Time / Procedure card log for continuous activities.

Form A-2 - Time / Procedure check log for continuous activities.

Form B - Sanitary Operating Procedures (SOP's) for periodic activities.

Form A-I -Time/Procedure card log for continuous activities.

Time/procedure cards used to record an individual "continuous" sanitation activity. This record indicates the responsible person was on duty and provided CAR's (Corrective Action Record) when necessary. Signatures of the individual performing the tasks and the record supervisors check validate the card.



Form A-2 - Time / Procedure check log for continuous activities.

Time/procedure cards are used to record an individual "continuous" sanitation activity. This record indicates the responsible person was on duty and provided CAR's (corrective action record) when necessary. Signatures of the individual performing the tasks and the record supervisor need to validate the card.

Plant Manager - Daily Sanitation Record

Continuous Items (From pre-operation review thru end of work day)	CAR
General housekeeping to avoid clutter that hampers plant operations and sanitation.	
Plant layout and general condition helps prevent product contamination and assures sanitation.	
No condensation on pipes, ceilings or other surfaces that could result in product contamination.	
Equipment, facilities and processing utensils in good operating condition and able to sanitized.	
All wet and dry waste materials segregated and removed from the plant into proper disposal.	
Brushes, trash cans and clothes used to clean and sanitize are color coded to distinguish.	
Clean and sanitize all utensils after each use during the workday; gloves, aprons, etc.	
All product containers stored in clean, dry area free of personnel and product traffic, and protected from pests.	
All chemicals for equipment use, pest management, cleaning and sanitizing must be stored segregated and separate from the processing area.	
Convenient hand wash facilities, clean and property equipped.	
Water supply approved.	
Ice supply clean and protected from contaminants due to floor traffic or equipment contact.	
No worker with illness, open or infected wound will be allowed to come in contact with product or plant operations.	
No worker will be allowed into the processing area without previous training for food handling and sanitation.	
No personnel will be allowed in the processing area without clean garments and hair covering.	
Control all personnel traffic. Only authorized personnel in processing plant operation area.	

Process Supervisor - Daily Sanitation Record

"Continuous Items"	CAR	
Control all personnel traffic. Only authorplant operation area.	rized personnel in processing	
OTHER:		
Area Supervisor:	Date:	
HACCP Record Manager:	Date:	

Form B - Sanitary Operating Procedures (SOP's) for periodic activities

Records will be kept by the assigned individual(s) to indicate that this person supervised or performed the listed periodic activities. Positive records will be indicated by the time the task was performed (daily, weekly or annually). If any activity other than those listed was performed aCAR (corrective action records) form will be attached;

Plant Manager - Periodic SOP's

& Day)	Time & CAR
dition and sanitation,	D=
oroduct; tables, drains, laily and/or before each	D= D=
e. Daily for dry dean and	D=
	₩ =
	D=
areas and completely	D=
	W=
nat may attract pests; , etc.	W=
dent and implement	W=
or possible product	W=
ocessing area and po ssi -	D=
•	
Date:	_
Date:	_
	product; tables, drains, laily and/or before each e. Daily for dry dean and areas and completely that may attract pests; etc. Ident and implement or possible product Occessing area and possi-

Processing Supervisor - Periodic SOP's

'Periodic Items'' (D = Daily Time; W = Weekly Time& Day)	Time & CAR
Clean and sanitize working area and surfaces that contact product; tables, drains, floor, walls, utensils and equipment; At least once	D=
daily and/or before each break and at the end of operations.	D=
Clean and sanitize packing supplies room. Dry clean daily and clean	D=
and sanitize weekly.	W=
Inspect packing supplies room for presence of insect and / or rodent and implement rodent control program.	W=
Clean and sanitize all utensils used during the workday; knifes, gloves, aprons, etc.	D=
	

EMPLOYEE HACCP TRAINING PROGRAM

The HACCP Coordinator will explain and provide a copy of all HACCP related concerns to employees per their respective positions. This activity will be recorded per these forms. Likewise, daily, weekly and annual activities of the HACCP Coordinator will support a continuing HACCP education program for all employees. Sanitation procedures will be posted per area to facilitate the employees training.

All employees will receive a copy of the Any Florida Hard Clam Company, **Inc.'s** Seafood Hard Clam Quality Assurance Program. This program is consistent with and will be supported by annual training with the assistance of the FL DEP and University of Florida's Cooperative Extension Service (Sea Grant).

The HACCP Coordinator is someone in upper management that has completed a HACCP training program provided through a recognized professional organization.

References

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- National Fisheries Institute **(NFI)** 1991. Seafood Industry HACCP Workshop and Model Tests: **Molluscan** Shellfish (Oysters, Clams and Mussels). NFI Education and Research Foundation, Arlington, VA, 121 pages and Appendix.
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- U. S. Food & Drug Administration (FDA). 1994. Fish and Fishery Products Hazards and Control Guide, FDA Office of Seafoods, Washington, DC, 228 pages.