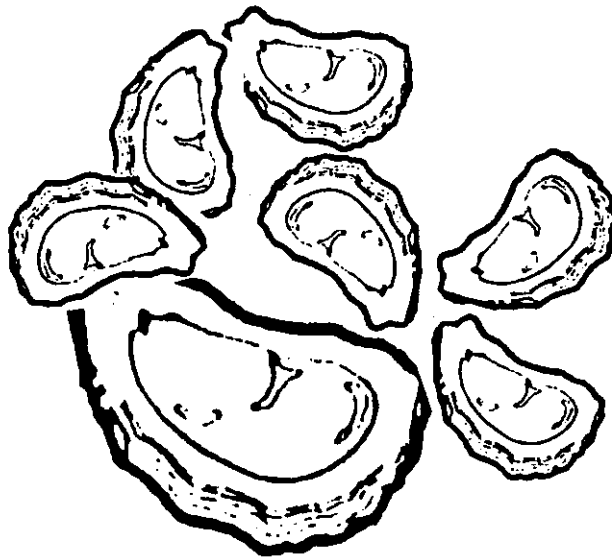


September 1995

TP - 79

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

MANUAL FOR OYSTER 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

**Sea Grant**
Florida



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Forward

This manual was prepared with 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 summarized 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 current format, this manual will be continually updated to incorporate 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

Acknowledgements

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 Sturmer)
- * National Fisheries Institute (V. President of Science and Technology, Roy Martin and Dir. of Food and Regulatory Affairs, Bob Collette)

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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 to 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 oysters and 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. Oyster and clam 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 oyster 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.

1. 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 most applicable to oyster culture or harvest from Apalachicola Bay, Florida. Conditions and hazard considerations may vary for different shellfish species and locations. Additional and similar considerations are outlined in the 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. 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 list some preventative measures.

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

The preventive measures, based on harvesting from approved waters, could simply refer to the most immediate regulatory authorities with jurisdiction for the approved 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 costumed 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.

SPECIAL NOTICE

Just prior to printing this document the ISSC Conference recommended the following harvest guidelines for molluscan shellfish. TQA programs should consider incorporation of similar guidelines.

ISSC Recommended Guidelines for Harvest (August 1995)

If a state has been confirmed as a source of product associated with two or more consumer illness do to pathogenic bacteria, *Vibrio vulnificus*, the state shall adopt the harvest time/temperature controls established in the following table. (This matrix is interim pending the results of the assessment outlined below)

| Action Level | Water Bottom Temperature* | Time to Refrigeration** |
|--------------|--|-----------------------------|
| Level 1 | November December January February March | Present manual requirements |
| Level 2 | 65 - 74 °F | 14 hours |
| Level 3 | 75 - 84 °F | 12 hours |
| Level 4 | > 84 °F | 6 hours |

* Water bottom temperature = average temperature of harvest waters (For more information, contact you local state regulatory office).

** Time to refrigeration = maximum time from product harvest until the product is placed in some form of refrigeration.

Table 1. Example: Typical Total Quality Assurance (TQA) development document based on oyster harvest in Apalachicola, Florida.

TQA Hazard Analysis Work Sheet
for Molluscan Shellfish Production (Apalachicola Bay, FL)

| 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 (Apalachicola Bay) have not been implicated in or suspected 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 sources) | Yes | Areas and method of harvest have not been implicated in 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 (safety) | No | Production governed by TQA with sanitation concerns and handling and storage conditions. | Production TQA |
| Parasites | No | No implicated or suspected occurrence 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 Oyster Production and Harvest

The undersigned oyster harvester and/or grower understands and will abide by the following TQA program guidelines for the production of Florida oysters (Crassostera virginica). (See special notice)

Product

- ◆ Oysters (Crassostera virginica) 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.
- ◆ Oyster size, bag limits and harvest seasons will be consistent with the Florida Marine Fisheries Commission, FL Administrative Code 46-27. Fill-in blank

Size: _____

Bag Limit: _____

Harvest Season: _____

Personnel

- ◆ All harvesters must have a 'Saltwater Products License'
Signee No. _____
- ◆ Harvesters working in Apalachicola Bay will have an "Apalachicola Bay Oyster Harvesting License".
If applicable, No. _____
- ◆ Harvesters can only sell oysters to dealers and/or processors with a Shellfish Processing Plant Certification License.
- ◆ Other requirements _____

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 oyster contamination.
Boats must have an elevated deck to keep the oysters 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 oyster beds.
- ◆ Sacks and other oyster 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 oysters will be harvested alive with no broken or cracked shells that could cause the shellstock to die.
- ◆ Harvested oysters will be delivered to the certified dealers before 6:00 PM on the same day of harvest. Harvested oysters 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 oysters in adequate refrigeration (45° F or 7.2° C) within 2 hours after receipt of the product.
- ◆ Live Oyster have a terminal sale date of 14 days from the date of harvest.
- ◆ During periods of warm weather and prolonged harvest, the oysters 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 oysters before landing (dockside). (see HACCP plan for sample)

- ◆ 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 the dealers tag can be used as the harvester's tag.

TQA Voluntary Commitment

By my signature _____, date _____. I (____ printed name ____)
indicate that I understand and will to the best of my ability abide by the listed voluntary TQA program as
compiled by the Florida oyster industry with reference to the pertinent State and Federal Regulations.

Growers Permit No. _____

Lease No. _____

Lease Location: _____

Apalachicola License No. (pending): _____

***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 HACCP PROGRAMS

The HACCP program will be an actual written plan to be filed at the processing plant. The program should focus 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 oyster and clam processing firms in Florida and Louisiana.

Assemble the HACCP Team

Depending on the size of the processing firm, the HACCP team can 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 Florida oyster HACCP program includes a rotating 'HACCP Coordinator' position to periodically share and better learn the HACCP responsibilities throughout the entire firm (p. 13, 14 of the HACCP Program for Oyster Processing).

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 types 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. 20). 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. The 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 _____ |

then 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. 21 - 25) 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. 26).

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. 26). Based on technical experience and/or preliminary trials, 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. 26).

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. 26). 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.26) 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. 26, 27). 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. 26, 32). 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 Oyster Processing

HACCP PROGRAM for Oyster Processing

HACCP Program - Safety Hazards

Name: Any Florida Oyster Co., Inc.
Plant address:
Phone No.:
FAX No.:

Company address:
Phone 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 sales 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. Monitors 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, arbitrates concerns and assures that 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.

Packing Room Supervisor -- Responsible for shucked product grading, cleansing, packing and shipping. Keeps HACCP records of production per batch number and packing room sanitation.

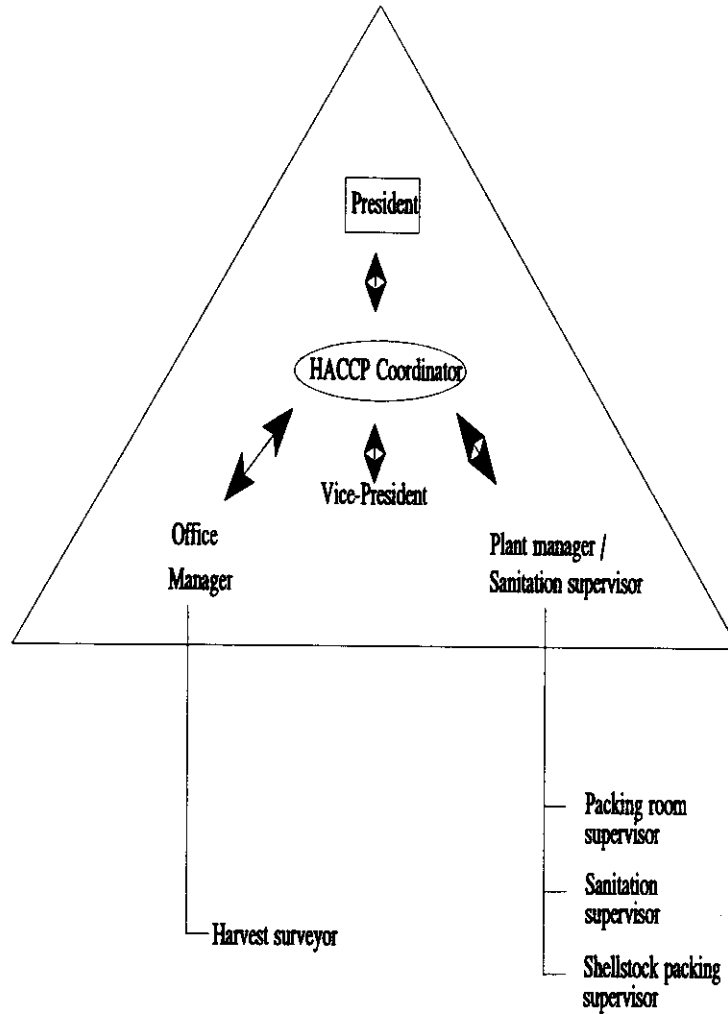
Harvest Surveyor -- Person in charge of supervising harvesters, making sure that all product is in compliance with the NSSP and state regulations (harvest from approved waters, legal size, product is not abused, etc.). The harvest surveyor will report to the Office Manager.

Shucker -- Person responsible for shucking product, in a clean and sanitary manner, according to good GMPs (1993 NSSP manual Part II Section D17).

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 whereby the '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 that the staff is working in a HACCP mode.



| Position | Name | Date of Assignment |
|----------|------|--------------------|
|----------|------|--------------------|

| | | |
|-------------------------------|---------------------------------------|--|
| President | (to be filled by the processing firm) | |
| Vice-President | | |
| Office Manager/Communicator | | |
| HACCP Coordinator | | |
| Shellstock Packing Supervisor | | |
| Packing Room Supervisor | | |
| Harvest Surveyor | | |
| Shucker | | |

Oyster Products

The products prepared and sold by Any Florida Oyster Co., Inc. are named following the product definition specified in the U.S. FDA National Shellfish Sanitation Program (NSSP), "Interstate Certified Shellfish Shippers List" and 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.

Type

Molluscan Shellfish – Eastern Oysters (*Crassostera virginica*) harvested from approved and/or conditionally approved 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. Aquaculture sources would be provided in accordance with a Total Quality Assurance (TQA) program maintained by the supplier or producer (harvester or grower).

Forms

Shellstock -- Live shellfish (oysters) in their shell

Dry Storage - Product held in a refrigerated cooler set at a temperature no higher than the 45° F (7.2° C) limit, according to FL State Code 62R-7, FL DEP and NSSP 1993 manual.

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

Shucked Meats -- (hand shucked whole raw oyster meat)

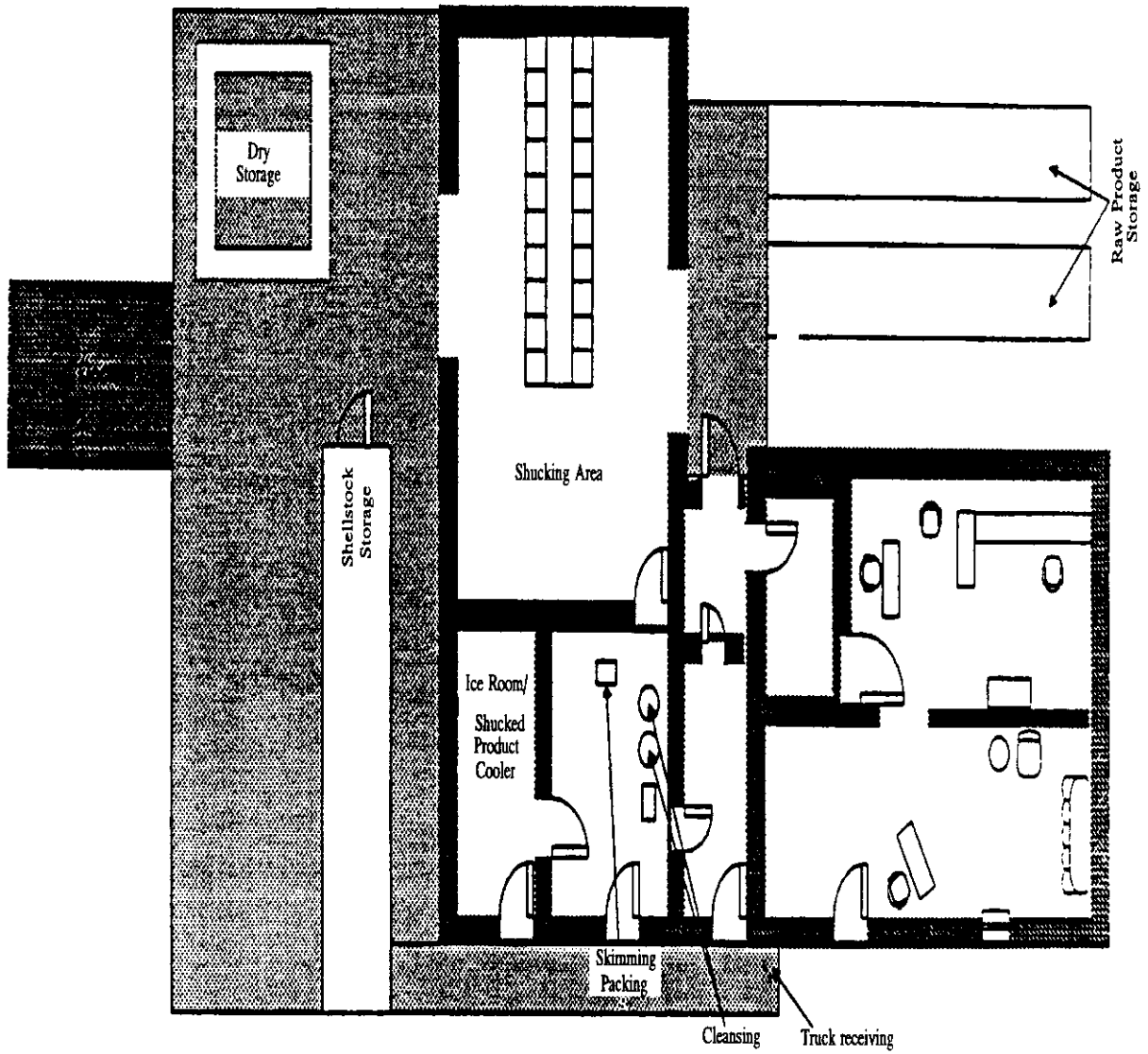
Fresh - Shucked oysters that have not received any significant thermal processing. Should be handled and stored at a temperature to attain an internal product temperature of 45° F (7.2° C) within two hours after delivering to the packing room according to FL State Code 62R-7 and NSSP 1993 manual. The FDA preferred prolonged storage temperatures for shucked meats below 40° F (4.4° C).

Fresh-Frozen - Fresh shucked oysters which have been frozen immediately after shucking, then kept at a temperature of less than 0° F (-17.8° C) (NSSP 1993, sec. D.22.b)

Repacked - Product is received as shucked meats in bulk containers and is packed into smaller containers for distribution or sale.

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

Plant Diagram



Processing Procedures

Shellstock (for packing and shucking)

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 oysters are purchased from local fishing vessels that harvest the shellstock by hand (tongs) from approved and/or conditionally approved coastal waters of Apalachicola Bay. Harvest can be subject to the surveillance of an assigned Harvest 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) comprehensive shellfish harvesting area survey, Apalachicola Bay, FL May 1990. 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, clusters, singles, 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 rules 46-27 & FL DEP Comprehensive Shellfish Control Code 62R-7). Likewise, live shellstock is received from distant locations beyond Apalachicola Bay in Florida and outside Florida.

Local Trucks - live oysters are delivered by truck to the processing plant, less than four 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 four 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.

All harvested product must be delivered before 6 pm on the day of harvest and placed in refrigeration within 2 hrs after receipt of product (62R-7)

2. Raw Product Storage

Dry Storage (45° F (7.2° 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 45° F (7.2° C). Temperature is monitored by a time-temperature chart recorder. (Note: This 45° F (7.2° C) limit is currently based on the FL Regulations 62R-7 and practice which accounts for product survival).

Wet Storage - (Optional) (See FL regulation 62R-7)

Depurated - (Optional) (See FL regulation 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 shucking.

Shellstock - Shellfish are washed, graded and culled to select only products that meet the requirements of clustering or size as defined by Any Oyster Co. for half shell commerce (clustering refers to more than one oyster adjoined vs. single or 'cup' oysters). Product is re-tagged, bagged or boxed and sent to final storage. All product which does not meet the required standards for shellstock consumption is taken to the shucking room with proper lot identification.

Boxing - Properly tagged shellfish destined for shellstock consumption are placed into water-proof carton boxes for distribution.

Hand Shucking - Live shellstock are taken into the shucking room and distributed between the workers by a conveyor belt or bulk delivery. Oysters are shucked into a stainless steel container (1-2 gallons) with ice-water., in compliance with FL rule 62R-7 and 1993 NSSP manual vol II section D17. When the container is filled, it is taken to the packing room for further processing.

Cleansing (Blowing) shucked meats - Shucked meats are inspected and placed into a stainless steel vat with ice-water. Filtered air is blown through the ice water and oyster mixture in accordance with 21 CFR 161.130 appendix B 1993 NSSP manual part II. Cleaned product is unloaded to the skimming table to be graded and packed. The skimming table is built to specifications per section D NSSP Manual Part II, 1993 revision.

Skimming, Grading & Packing - At the skimming table product is rinsed, drained, visually graded for size and packed into the final containers in accordance with FL DEP Code 62R-7 and section D20 and appendix B 1993 NSSP manual part II. All packed containers are marked with the appropriate lot number for the corresponding batch of oysters.

4. Finished Product Cold Storage

Fresh products - All live shellstock is placed inside separate refrigerators set at a temperature of 45° F (7.2° C) or lower, meanwhile the shucked product is kept at a maximum temperature of 40° F (4.4° C) (FDA's Fish and Fishery Products Hazards and Controls Guide. Feb., 1994 Draft. Page 107). Temperature is monitored with a time-temperature recorder.

Frozen Product - In the case of any over production, product is packed in 4 lbs pillow bags or suitable containers, frozen as rapidly as possible and kept frozen (0° F = -17.8° C) until needed. Product should be frozen solid within 12 hrs of starting the freezing process.

5. Shipping

Product is placed into refrigerated trucks for distribution to warehouse or retail outlets. Invoices will list the appropriate lot numbers for all shellstock and/or shucked product.

Previously Shucked Meats (for re-packing)

1. Receiving (See FL regulation 62R-7)

Local Trucks - Shucked meats are delivered to the processing plant by refrigerated trucks and/or properly iced in non-refrigerated trucks. Product is off-loaded at the processing plant, less than 4 hours from the original shucking plant, and inspected for lot number, internal temperature and general condition. Only product from approved shucking house will be purchased.

Distant Trucks - Same procedure as for local trucks for deliveries greater than 4 hours. Refrigeration on the truck is monitored by a time-temperature device, which could be a continuous chart or periodic recordings by the driver. Temperature of the product, certification number of the original shucker and product conditions are also checked and recorded.

2. Storage

Shucked Meats - Shucked product is placed in refrigerators after inspecting and receiving to prevent the internal temperature from getting higher than 40° F (4.4° C).

3. Processing (Re-packing)

Cleansing (shucked meats) - Shucked meats are removed from storage, inspected and placed into a stainless steel vat with ice-water, where filtered air is blown through in accordance with 21 CFR 161.130 (appendix B, 1993 NSSP manual part II). Product is unloaded to the skimming table to be graded.

Skimming & Grading & Packing - At the skimming table product is rinsed, drained, graded and packed into the final container (FL DEP Code 62R-7 and section D20 1993 NSSP manual part II). Final packed container are marked with the appropriate lot number.

4. Finished Product Cold Storage

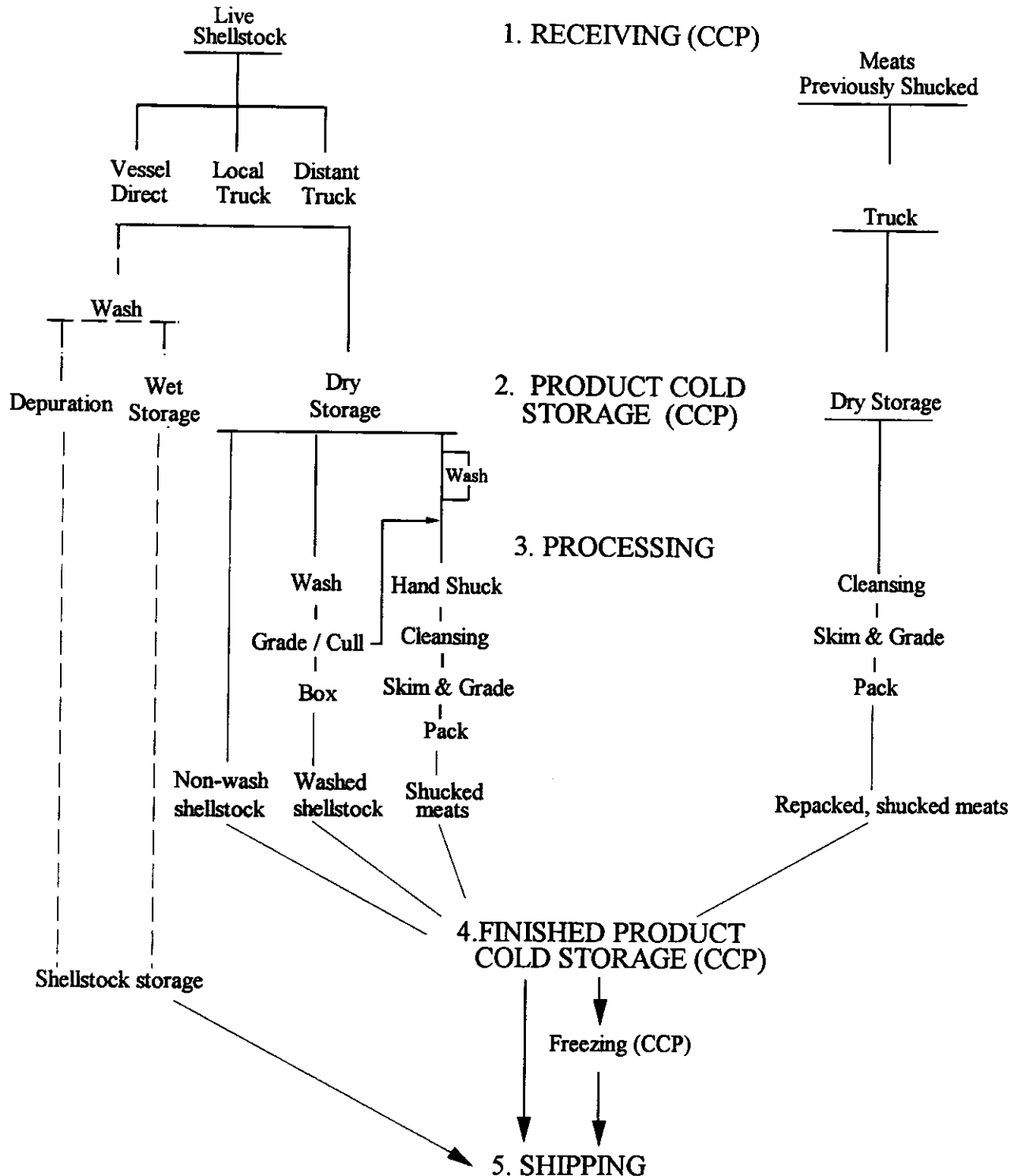
Fresh products - All shucked product is placed inside separate refrigerators set at a temperature low enough to maintain internal product temperature no higher than 40 ° F (4.4° C). Refrigerator ambient temperature is monitored with a time-temperature recorder.

Frozen Product - In the case of any over production, product is packed in 4 lbs pillow bags and frozen (0° F = -17.8° C) until needed or to be sold as frozen product.

5. Shipping

Product is placed into refrigerated trucks for distribution to warehouses or retail outlets.

HACCP FLOW DIAGRAM



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

----- = future or optional procedure.

———— = current (1995) procedures.

Hazard Analysis Worksheets

The following worksheets reflects 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. 26).

| Processing Step | Potential Hazard | Could the Potential Hazard be Significant | Judgement for Significance | Preventive Measure(s) | Critical Control Point |
|-----------------|--|---|---|---|------------------------|
| RECEIVING | Natural Toxins | Yes | Areas of harvest have not been implicated in or suspected 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 in 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 |

| Processing Step | Potential Hazard | Could the Potential Hazard be Significant | Judgement for Significance | Preventive Measure(s) | Critical Control Point |
|----------------------|------------------------------------|---|---|--|------------------------|
| RECEIVING | Decomposition | No | Production governed by TQA plan and sanitation program monitors handling and storage conditions | Production TQA, time-temperature storage records, sanitation program | No |
| | Parasites | No | No implicated or suspected occurrence of health significance from area of harvest | Not Applicable | No |
| | Food and Color Additives | No | No additives used in processing | Not Applicable | No |
| | Physical (e.g. metal, glass, wood) | No | Initial product whole shellstock or certified shucked meats | 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 chemicals). | 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-temperature charts. | No |

| Processing Step | Potential Hazard | Could the Potential Hazard be Significant | Judgement for Significance | Preventive Measure(s) | Critical Control Point |
|----------------------|----------------------------|---|---|--|------------------------|
| PRODUCT COLD STORAGE | 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 | Natural Toxins | No | Not introduced or enhanced in processing | Not Applicable | No |
| | 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 chemicals). | No |
| | Pesticides | No | Not introduced or enhanced in processing | Sanitation Plan | 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 |

| Processing Step | Potential Hazard | Could the Potential Hazard be Significant | Judgement for Significance | Preventive Measure(s) | Critical Control Point |
|-------------------------------|--------------------------|---|---|---|------------------------|
| PROCESS-ING | Physical | Yes | Possible inclusion of grit and shell fragments in shucked meat | Sanitation program with cleansing and skimming procedures | 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-plant chemicals) | 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 problem | Sanitation Program and time-temperature 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 | |
| SHIPPING | Natural Toxins | No | Not introduced or enhanced during shipping | Assure proper ID and certification records | No |

| Processing Step | Potential Hazard | Could the Potential Hazard be Significant | Judgement for Significance | Preventive Measure(s) | Critical Control Point |
|-----------------|--------------------------|--|--|--|------------------------|
| SHIPPING | Microbial Contamination | Yes | Cross-contamination and/or if product is thermally abused | Sanitation Program 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 Program | 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 |
| | 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 | |

SPECIAL NOTICE

Proposed harvest Time-Temperature controls have been accounted for in the TQA program (see page 3.)

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 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 | 45° F (7.2° C) for Shellstock for no more than 4 hrs. (*) 40° F (4.4° C) for Shucked meats for no more than 4 hrs | Continuous Time-Temperature chart recorders for refrigeration 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 |

* Current Florida State regulation requires 45° F, but other states might require lower maximum storage temperature. Shellstock from harvest should be handled according to TQA program to prevent temperature abuse. After receiving, shellstock should not be exposed to temperatures higher than specified for more than 4 hrs.

** Shellstock and shucked meats are stored separately.

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 an annual evaluation of the company's HACCP Plan. Plan verification is based on an annual company review aligned with licensing and periodic DEP inspections.

HACCP Records

The following records will be completed in monitoring the HACCP program

Receiving (source)

- Form 1. HACCP Shellstock/Shucked Meat Harvest and Purchase Records/Harvest Surveyor Reports (CAR)
- Form 2. Harvester's Tags and Trip Ticket
- Form 3. Dealer's Tag*

* 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.

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.

OYSTERS

PACKED IN
FLORIDA BY _____

FL _____

LA _____

TX _____

AL _____

WA _____

ORIGINAL SS CERT # _____

HARVEST DATE _____

HARVESTED FROM _____

PACKAGE CONTAINS _____

_____ LB BOX _____ LB BAG

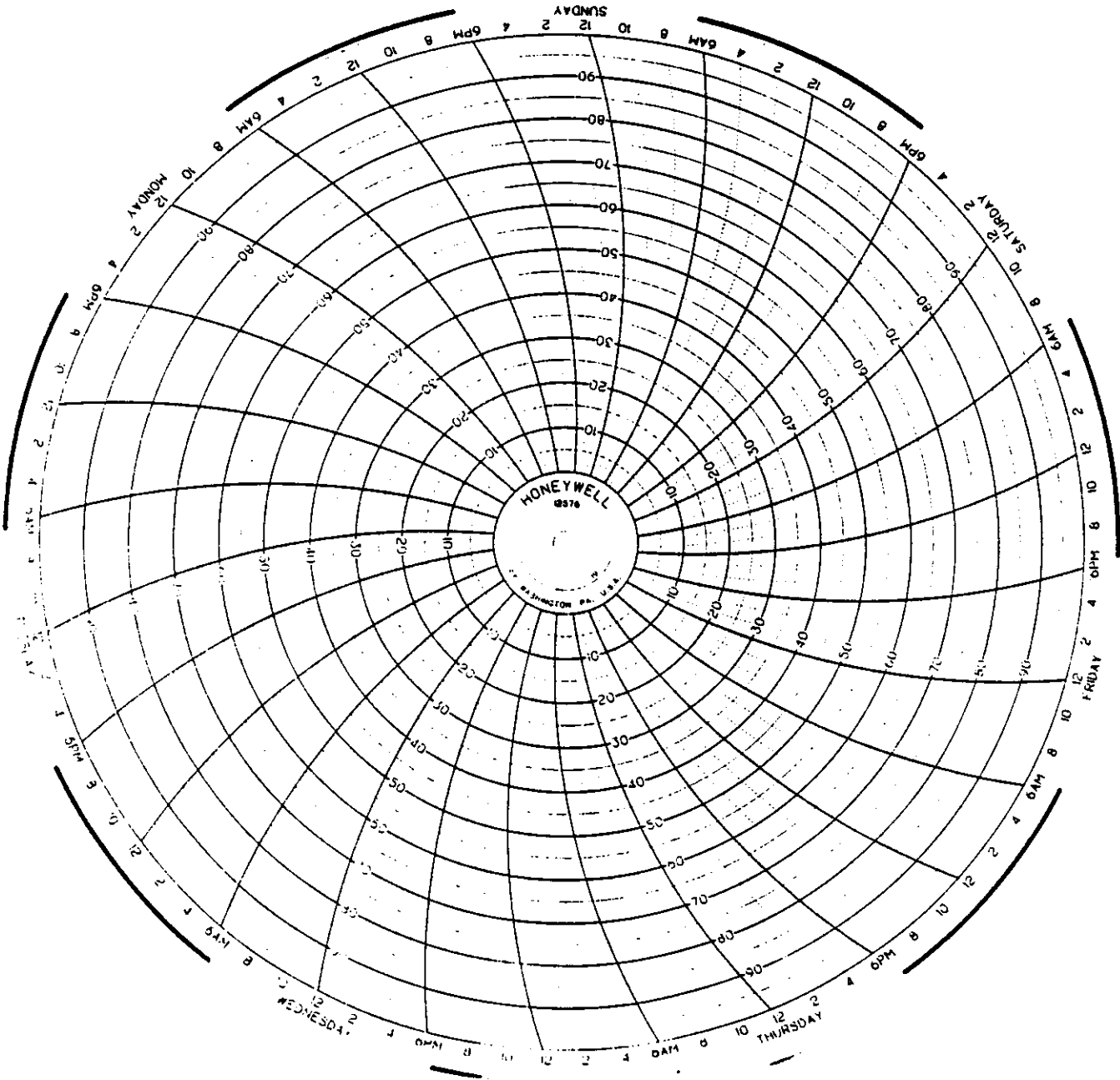
Cert. # _____ Wholesale # _____

**THIS TAG IS REQUIRED TO BE ATTACHED
UNTIL CONTAINER IS EMPTY AND
THEREAFTER KEPT ON FILE FOR 90 DAYS**



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 OYSTER PROCESSING

Standard Sanitary Operating Procedures

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

This program 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 Part 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 area 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 shells and other waste should be removed promptly 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 rodent 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 a contaminated product.
- (cont) No worker will be allowed into the processing area without any previous training in sanitation and food

- handling practices and the HACCP program.
(cont) No personnel will be allowed inside the processing area without hair covering

Operations - Receiving

Daily Activities.

- (cont) Control personnel and equipment (carts, pallets, shovels, etc.) traffic to avoid transporting mud, and possible contaminants to shucking and packing areas.
(per) Dry clean area, wash and sanitize [cleaner and sanitizer: (insert types)]
(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) Control personnel, equipment and product traffic to reduce the possibility of cross-contamination.
(cont) Inspect for proper product segregation and product inventory rotation.
(per) Dry clean the area to remove any debris or waste from floor.

Weekly 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

Daily 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 shut-down [sanitizer: _____]

Operations - Washing, Culling and Boxing area

Daily Activities.

- (per) Rinse area and equipment
- (per) Clean with a general purpose cleaner using a low pressure spray followed by rinse and sanitizer [cleaner: _____].

Weekly Activities.

- (per) Dry clean storage room (packing material and containers).

Operations - Shucking Room

Daily Activities.

- (per) Dry clean, rinse, wash and sanitize all equipment, utensils and surfaces (floor, foot stools, paper towel holders, sinks, tables) in the area at the beginning and at the end of the work day and before every brake [cleaner and sanitizer: _____].
- (per) Clean and sanitize shucking bowls/containers after each use and at the end of the work day, then rinse, wash and sanitize the same at the end of the day. Store properly [sanitizer: _____]
- (per) Product distribution and waste transport belts should be rinsed during every brake (approximately every 4 hrs) and washed at the end of the day [sanitizer: _____]

Operations - Packing Room

Daily Activity.

- (per) Dry clean and rinse equipments and utensils (cleansing 'blowing' tanks and packing, grading and skimming tables) after every run.
- (per) Dry clean area.
- (per) Clean [cleaner: _____], brush scrub to remove soil, rinse and sanitize area and utensils [sanitizer: _____]
- (per) Sanitize all containers to be used during the workday

Operations - Finished Product Cooler and Freezers

Daily Activity.

- (cont) Control personnel, product and equipment traffic to avoid cross-contamination.
- (per) Dry clean area.

Weekly Activity.

- (per) Clean [cleaner: _____], followed by rinse and sanitation [sanitizer: _____]

Monthly Activity.

(per) Clean drip pan of refrigeration unit with non-corrosive sanitizer [sanitizer: _____]

Annual Activity.

(per) Clean refrigeration coils with a brush using a general purpose cleaner and sanitizer [sanitizer: _____]

Operations - Shipping area

Daily Activity.

(cont) Control personnel traffic frequenting this area.

(per) Dry clean area.

(per) Clean [cleaner: _____] and sanitize area and utensils.

Monthly 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 sanitize [sanitizer: _____]

(*) 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 monitor continuous and periodic Standard Sanitary Operating Procedures. The following forms are recommended for such monitoring 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-1 -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 1258 (4-23) UTM-USA

| NAME | | REGULAR TIME | | EXTRA TIME | | TOTAL | |
|--------|------|--------------|------|------------|------|----------|------|
| IN | OUT | IN | OUT | IN | OUT | IN | OUT |
| AM | NOON | PM | NOON | AM | NOON | PM | NOON |
| MONDAY | | TUESDAY | | WEDNESDAY | | THURSDAY | |
| THIS | | SIDE | | OUT | | SATURDAY | |
| S | | S | | S | | SUNDAY | |
| TOTAL | | TOTAL | | TOTAL | | TOTAL | |

Form A-2 -Time/Procedure check 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 supervisor 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 be 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; knives, 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 properly 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. | |

Processing Supervisor - Daily Sanitation Record

"Continuous Items"

CAR

| | |
|--|--|
| Control all personnel traffic. Only authorized personnel in processing plant operation area. | |
| OTHER: | |

Packing Room Supervisor - Daily Sanitation Record

"Continuous Items"

CAR

| | |
|--|--|
| Control all personnel traffic. Only authorized personnel in processing plant operation area. | |
| OTHER: | |

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

Records will be kept by the assigned individuals to indicate that the 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 a CAR (Corrective Action Record) form will be attached.

Plant Manager - Periodic SOP's

| "Periodic Items"(D=Daily Time; W=Weekly Time & Day) | Time & CAR |
|--|------------|
| Conduct Pre-operation review for general plant condition and sanitation, including workers. | D= |
| Clean and sanitize shucking area and surfaces that contact product; tables, drains, floor, walls, utensils and equipment; At least once daily and/or before each break and at the end of operations. | D= D= |
| Clean and sanitize the cooler/refrigeration storage, daily for dry clean and weekly for full cleaning and sanitization. | D= W= |
| Clean and sanitize washroom areas and facilities. | D= |
| Inspect and clean as necessary all waste disposal areas and completely clean and wash waste containers. | D= W= |
| Inspect plant premises for clutter and general filth that may attract pests; clean and remove excess weeds, vegetation, waste, etc. | W= |
| Inspect all areas for presence of insects and/or rodents and implement rodent control program. | W= |
| Inspect lighting and ventilation for proper operation or possible product contamination. | W= |
| Inspect all chemical storage for segregation from processing area and possible leakage or spills. | D= |
| OTHER: | |

Sanitation Supervisor: _____ Date: _____

HACCP Record Manager: _____ Date: _____

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 daily and/or before each break and at the end of operations. | D= D= |
| Clean and sanitize packing supplies room. Dry clean daily and clean and sanitize weekly. | D= W= |
| Inspect packing supplies room for presence of insects and/or rodents and implement rodent control program. | W= |
| Clean and sanitize all utensils used during the workday; knives, gloves, aprons, etc. | D= |
| OTHER: | |

Area Supervisor: _____

Date: _____

HACCP Record Manager: _____

Date: _____

Packing Room Supervisor - Periodic SOP's

"Periodic Items"(D=Daily Time; W=Weekly Time & Day)

Time & CAR

| | |
|--|----------|
| Clean and sanitize packing room area and surfaces that contact product; tables, drains, floor, walls, utensils and equipment; At least once daily and/or before each break and at the of operations. | D= D= |
| Clean and sanitize all containers to be use during the workday. | D= |
| Clean and sanitize packing supplies room. Dry clean daily and clean and sanitize weekly. | D= 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; knives, gloves, aprons, etc. | D= |
| OTHER: | |

Area Supervisor: _____

Date: _____

HACCP Record Manager: _____

Date: _____

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 Company, Inc.'s Seafood Oyster 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.

