Development of a HACCP-based program for a private shellfish purification facility

Mise au point d'un programme basé sur l'analyse HACCP dans une installation privée de purification de coquillages

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Abstract

A HACCP-based program is developed for the Spinney Creek Oyster Company (SCOC) Shellfish Purification Facility under a pilot program funded and implemented by the New England Fisheries Development Association (NEFDA). The SCOC Facility, which includes a government approved in-house coliform laboratory, is fully licensed for oysters and clams under State of Maine and NSSP regulations. SCOC's business is producing value-added, quality-assured shellfish for premium, health conscious markets. To accomplish this, SCOC uses shellfish harvested from approved waters which is an important distinction from other purification plants which process shellfish originating from restricted waters.

It was necessary to create a flow chart of the various steps involved in the processing including receiving, wet and dry storage, controlled purification, packing, and shipping. Receiving (trucks), controlled purification, and packing were determined to be the critical control points. For each of these critical control points, the potential hazard/defects were identified, critical limits were established, preventative measures and monitoring schemes were implemented, and corrective actions were delineated. A designated HACCP employee is responsible for implementing this program.

The Scheduled Controlled Purification Process (SCPP) for the SCOC plant is included with the HACCP documents. The SCPP contains important background information, a description of the SCOC facility, and the Standard Operating Procedure (SOP). Also included in this HACCP Plan were the complaint and recall procedures, plant sanitation SOP and HACCP Plan, and the qualifications of the designated HACCP employee.

The public health risks and benefits are evaluted for the SCOC quality assurance program and the implementation of the HACCP-based program. The public health risks and benefits will be compared to the standard practices in the US commercial shellfish industry where shellfish purification and HACCP-base inspection programs are not implemented.

The SCOC HACCP Plan has been developed for submission to the Federal government for participation in a joint FDA (Food and Drug Administration)/NOAA (National Oceanic and Atmospheric Agency) voluntary HACCP-based Inspection Program.

Résumé

Un programme fondé sur l'analyse HACCP a été mis au point pour la station de purification de coquillages de la société Spinney Creek Oyster Company (SCOC) dans le cadre d'un programme pilote financé et réalisé par la New England Fisheries Development

Association (NEFDA). La station de la SCOC, qui comporte un laboratoire d'analyse de coliformes homologué par l'État, est certifiée en vertu de la réglementation de l'État du Maine et de la NSSP. La SCOC produit des coquillages à forte valeur ajoutée et conformes aux normes de qualité, destinés à des marchés haut de gamme et très sensibles à la qualité sanitaire. A ces fins, la SCOC commercialise des coquillages récoltés en eaux certifiées salubres, ce qui la distingue des autres stations de purification traitant des coquillages provenant d'eaux exploitées sous certaines réserves.

Un organigramme a été établi définissant les différentes étapes du traitement, à savoir réception, conservation en eau et à sec, purification contrôlée, conditionnement et expédition. La réception (camions), la purification contrôlée et le conditionnement ont été identifiés comme points critiques de contrôle. Pour chacun de ces points critiques de contrôle, les risques/défauts potentiels ont été identifiés, des seuils critiques établis, des mesures de préventions et des plans de suivi mis en place et des actions correctives définies. Un employé responsable de l'analyse HACCP est chargé de mettre en place ce programme.

Le procédé SCPP (Scheduled Controlled Purification Process) utilisé pour la station SCOC fait partie de la documentation HACCP. Le SCPP contient des informations de base importantes, une description des installations SCOC, et la procédure standard d'exploitation (SOP). Ce plan HACCP contient également les procédures de plaintes et de retour, les plans d'assainissement SOP et HACCP ainsi que les qualifications de l'employé chargé de l'HACCP.

Les risques de santé publique et les avantages sont évalués en fonction du programme assurance-qualité de la SCOC et de la mise en place du programme HACCP. Ces risques et avantages seront ensuite comparés aux pratiques usuelles de l'industrie conchylicole aux-États-Unis qui ne mettent pas encore en œuvre de programmes de contrôle basés sur l'HACCP.

Le plan HACCP mis en place par la SCOC sera soumis à l'approbation du Gouvernement Fédéral dans le cadre d'un programme conjoint de contrôle volontaire basé sur l'HACCP, mené par la Food and Drug Administration et l'agence NOAA (National Oceanic and Atmospheric Agency).

INTRODUCTION

Questions about seafood safety and decreased consumer confidence in seafood over the past decade has moved the U.S. seafood industry towards HACCP-based (Hazard Analysis Critical Control Points) seafood inspection. A FDA/NOAA Voluntary Seafood Inspection Program for domestic processors of fin fish is in the final stages of completion and should be offered to the industry in 1992. The FDA/NOAA pilot and program for the shellfish plants are still in the development stages.

The U.S. shellfish industry suffers economically because of a high incidence of food-borne illness relative to other fisheries and the subsequent plunging consumer confidence. The U.S. shellfish industry bases shellfish sanitation on the quality of the growing waters instead of the depuration basis used by some European countries, New Zealand, and Australia. In an effort to regain consumer confidence, Spinney Creek Shellfish, Ins. (SCS) has developed a quality assurance program combining the strength of the European and the U.S. shellfish sanitation approaches. The SCS Half Shell Safety Program®, specifies that:

1. All Spinney Creek Shellfish originate from growing areas classified as approved or conditionally approved,

2. All Spinney Creek Shellfish are microbiologically cleansed in our depuration system for a minimum of 48 hours, and

3 - All lots of Spinney Creek Shellfish are tested for stringent end-point fecal coliform standards.

Program development

SCS has developed a HACCP-based program for its depuration facility under a pilot program funded and implemented by the New England Fisheries Development Association. This HACCP-bases program is utilised by SCS to provide quality assurance for the operation of the plant. The program is distinct from, but complimentary to the components of the SCS Half Shell Safety Program, which provide enhanced product quality assurance. The HACCP Plan parallels the Plant (SOP) Standard Operating Procedure. The SCS HACCP plan is not a substitute for the plant GMP's (Good Manufacturing Practices Guidelines) or other State of Maine Regulations affecting the depuration and handling of the shellfish.

In developing the SCS HACCP program, it was necessary to first create a flow chart of the various steps or control points involved in shellfish processing from the plant SOP. The control points include receiving, wet and refrigerated (dry) storage, depuration, packing, and shipping (figure 1). Operation of the quality assurance laboratory and sampling procedures are excluded as control points in the HACCP plan development. A separate, internal quality assurance program for the laboratory exists which is prerequisite for laboratory certification.

The relationships between the various control points were analysed and critical control points were identified. For each of the critical control points, the potential hazard/defects were identified, critical limits established, preventive

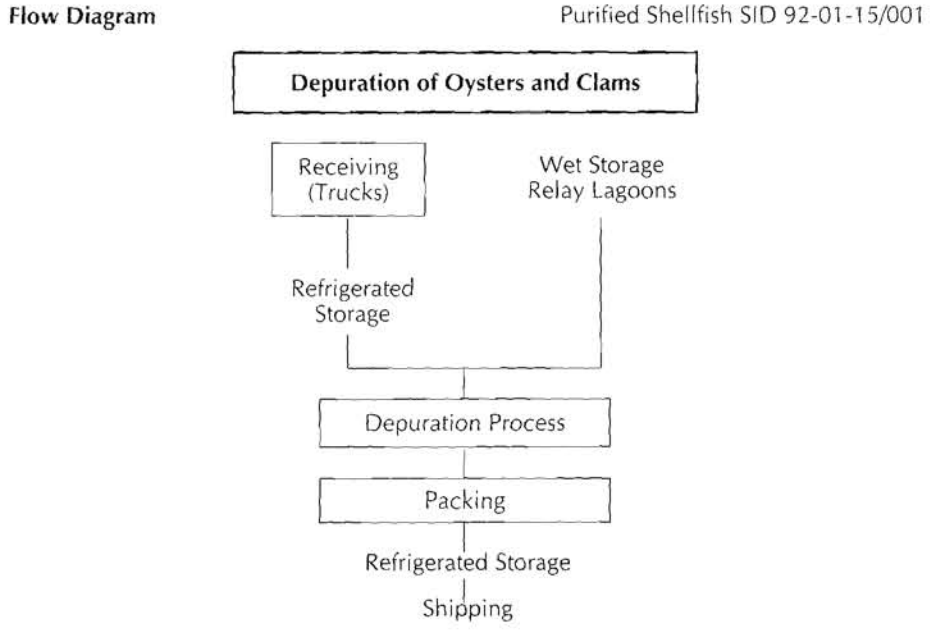

Figure 1: Flow chart of the various steps or control points involved in shellfish processing. Critical control points are shown in boxes

measures and monitoring schemes developed, and corrective actions delineated. Figure 2 shows the critical control point at receiving (trucks). Microbial contamination is a potential hazard if the shellfish were not harvested from growing waters classified as approved or conditionally approved. These growing area classifications give basic protection from the harvest of shellfish containing high levels of contamination which might not readily depurate in the allotted time. Economic fraud is the second potential hazard at the receiving point. Although economic fraud is not a public health concern, it is being included in the FDA/NOAA voluntary inspection programs. Time abuse is the third potential hazard at the receiving point. For the depuration process to be viable, the shellfish must be alive and unstressed.

Product: Purified Shellfish — Purified Shellfish SID 92-01-15/001
STEP: Receiving (trucks) — **Critical**: Yes
CONTROL POINT: Receiving area

HAZARD/DEFECT:
1. Microbial contamination/consider defective if shellfish not harvested from approved growing areas.
2. Economic fraud/considered defective if the shellfish count does not agree with invoice and or if there is excessive breakage.
3. Time abuse/considered defective if the product is exposed to delays which would inhibit the depuration.

CRITICAL LIMITS:
1. Shell stock must be harvested from approved waters.
2. Count must agree with invoice. Breakage must be <7%.
3. Product must be received within 3 days of harvest date.

PREVENTIVE MEASURES:
1. Inspect incoming product for valid identification tags.
2. Inspect incoming product for specified count and breaking.
3. Verify harvest dates from identification tags.

MONITORING:
1. Inspect each incoming product containers for identification tag.
2. Duplicate samples incoming product for count and breakage.
3. Record harvest dates from identification tags.

CORRECTIVE ACTION:
1. Reject or dispose of product which is missing identification tag.
2. Notify vendor and adjust invoice or reject/return product.
3. Notify vendor and reject/return product.

RECORD NAME:
Receiving Log

COMPONENTS:
1. Log of dealer #, harvest area and quantity received for each harvest lot and actions.
2. Log of sample count and breakage for each harvest lot received and actions.
3. Log of harvest date for each harvest lot received and actions.

Figure 2: Listing of the potential hazard/defects, critical limits, preventive measures, monitoring schemes, and corrective actions at the receiving (trucks) critical control point.

Product: Purified Shellfish — Purified Shellfish SID 92-01-15/001
STEP: Depuration Process — **Critical:** Yes
CONTROL POINT: Depuration System

HAZARD/DEFECT:
1. Excessive microbial contamination of raw product/considered defective if microbial contamination of the raw product exceeds the zero-hour maximum rating of the system.
2. Contamination of process water/considered defective if detectable levels of coliform organisms are present.
3. Ineffective depuration/considered defective when the critical process variables of temperature (T), salinity (S), dissolved oxygen (DO), and flow rate fall outside of process specifications.
4. Incomplete depuration/considered defective if cycle time is less than 48 hours.

CRITICAL LIMITS:
1. Zero-hour maximums are 1,000 FC (fecal coliform organisms per 100 grams of shellfish meats) for oysters and 1000 FC for littleneck clams.
2. Process water must contain <1.8 coliform organisms per 100 ml sample.
3. T is 8-27°C. S range is 24-34ppt. DO must be >70% saturation. Flow rate must be >12 gal./min./tank.
4. Minimum depuration cycle must be 48 hours.

PREVENTATIVE MEASURES:
1. Use shellfish harvested from growing areas classified as approved or conditionally approved.
2. UV dissinfection units are inspected daily and the bulbs are replaced annually. Purification system is cleaned and sanitised at the end of each run.
   Raw process water is filtered to remove particulate prior to dissinfection.
   Shellfish are washed prior to loading to remove mud and detritus.
3. T can be modified by building heat in the winter and by aeration in the summer. S can be regulated by operation of the tide gate. 70% saturation (D0) can be maintained by aeration. A control valve regulates flow rate.
4. End cycle only after 48 hours of elapsed purification time.

MONITORING:
1. Periodic sampling of raw product from different growing areas. Additional sampling of raw product during periods of heavy rainfall.
2. Routine sampling of process water.
3. Routine sampling of variables T, S, flow rate, and inspection of aerators.
4. Record time and date of cycle start and end.

CORRECTIVE ACTION:
1. Raw product which exceeds the zero-hour maximum is removed from the purification system and is either returned to the growing area or disposed of.
2. Cleanse and sanitise system and check UV bulbs. Verify end-product quality standards for the process batch.
3. Suspend operation until process variables fall within specified ranges. Verify end-product quality standards for the process batch.
4. Continue cycle until 48 hours of purification time has elapsed, return product to growing area or dispose of.

RECORD NAME: Depuration Log

COMPONENTS:
1. Log of raw product quality (FC) and actions.
2. Log of process water quality and actions.
3. Log of critical process variables and actions.
4. Log of cycle start time and date and cycle end time and date and actions.

Figure 3: Listing of the potential hazard/defects, critical limits, preventive measures, monitoring schemes, and corrective actions at the depuration process critical control point

Figure 3 shows the critical control points at the purification system. Excessive microbial contamination is the first potential hazard at the purification system. Through comprehensive process verification studies, the zero-hour maximum levels of fecal coliforms which can be consistently depurated to end-point standards are determined (see critical limit 1). The second potential hazard is contamination of the process water which could result from a breakdown or inhibition of the disinfection system or contamination of the system plumbing. Ineffective purification can occur if the critical process variables of T, S, dissolved oxygen, and flow fall outside of the critical limits. Incomplete purification is the fourth potential hazard if the cycle time is less than 48 hours.

Packing is the third critical control point (figure 4). Contamination from dead, cracked, decomposing shellfish, or extraneous matter is the first potential hazard. Economic fraud is the second potential hazard when the count does not agree with product specifications. And finally the loss of recall ability is a potential hazard if the boxes are improperly identified.

Product: Purified Shellfish
Purified Shellfish SID 92-01-15/001
STEP: Packing **Critical**: Yes
CONTROL POINT: Packing area

HAZARD/DEFECT:
1. Contamination/considered defective if packaged product is not free of cracked, dead, or decomposed shellfish and/or extraneous matter.
2. Economic fraud/considered defective if the shellfish count does not conform to product specifications.
3. Loss of recall ability/considered defective if identification tag is missing.

CRITICAL LIMITS:
1. No detectable cracked, dead, or partially decomposed shellfish or extraneous matter.
2. Count must be equal to or greater than specification on box.
3. All boxes must have a valid identification tag.

PREVENTIVE MEASURES:
1. Thoroughly wash and cull shellfish before and after cycle. Inspect product in boxes before sealing. Employee training and hygiene.
2. Employee training on counting techniques.
3. All containers tagged before shipping.

MONITORING:
1. Inspect boxes for cracked, dead, and decomposed shellfish and/or extraneous matter.
2. Duplicate sample boxes for correct count.
3. Inspect boxes after packing and before shipping

CORRECTIVE ACTION:
1. If the contents are not properly washed, culled, and free of extraneous matter, the lot will be rewashed, reculled, and repacked.
2. If the contents are not properly counted, the lot will be repacked.
3. Affix proper identification to boxes.

RECORD NAME: Packing Log Book

COMPONENTS:
1. Log of Packing QC inspections and actions.
2. Log of sample counts and actions.
3. Log of lot #, shipping invoices, and actions.

Figure 4: Listing of the potential hazard/defects, critical limits, preventive measures, monitoring schemes, and corrective actions at the packing critical control point.

Receiving Log
Spinney Creek Shellfish, Inc. HACCP Program

Receiving Date	Dealer Name	Dealer Number	Harvest Area	Species	Quantity units	Sample 1 count/break	Sample 2 count/break
Problems: Action Taken:					Identification Tags Accounted for ____ Receiver Initials _____ Lots # _____		

Figure 5: Sample sheet from the Receiving Log

Depuration Log
Spinney Creek Shellfish, Inc. HACCP Program

Lot #	Raw Product Source/Quality	Module Number	Date In Time In	Date Out Time Out	Temp. °C	Sal. ppt	Aeration on	Flow gpm	Process water TC
	FC								
Problems: Action Taken:						End-point FC		Initials	

Figure 6: Sample sheet from the Depuration Log

Packing Log
Spinney Creek Shellfish, Inc. HACCP Program

Lot #	Packing Date	Detectable Cracked, Dead, or Decomposing Shellfish	Extraneous Materials	Sample 1 Count	Sample 2 Count
Problems: Action Taken:			All boxes Properly Identified ____ Initials ___		

Figure 7: Sample sheet from the Packing Log

In addition to the main body of the HACCP plan which has been presented in figures 2, 3 and 4, general information, an organisational chart, product descriptions, complaint and recall procedures, plant and plant sanitation SOP's, and designation and qualifications of the designated HACCP employee are included. The receiving log, purification log, and packing log are shown in figures 5, 6 and 7, respectively.