Hazard analysis critical control points (HACCPs) and verification studies at shellfish depuration plants in the USA Analyse HACCP et contrôles dans des stations de purification des coquillages aux États-Unis

SANTO A. FURFARI¹, DIANE J. KELLEY-REITZ¹, MARTIN DOWGERT² 1. Northeast Technical Services Unit, Shellfish Sanitation Branch, Food and Drug Administration, CBC Base S-26, North Kingstown, RI, USA, 02852 2. Food and Drug Administration, Northeast Region, Montvale Ave., Stoneham, MA, USA, 02180.

Abstract

This article describes the requirements of the Manual of Operations, Part II of the National Shellfish Sanitation Program, for conducting verification studies at depuration plants for molluscan shellfish. This article also describes the effect of the Hazard Analysis Critical Control Points (HACCPs) on such studies, and how to plan studies on new or existing plants.

Methods are described for analyzing the various facets of the physical plant, such as sea water systems, tank construction, and other pertinent facilities. Of equal importance, methods are described for investigating and analyzing the various critical control points of the operation of the plant.

Studies at a soft clam depuration plant are used as a model for this article. The most important items are (1) development of the zero-hour upper limit of fecal coliform bacteria in the clams, (2) attainment of final product criteria, (3) development of mid-cycle criteria, (4) flow rate of sea water, (5) tank loading, and (6) sea water parameters. A model is presented of the Scheduled Depuration Process, the operational specifications for the soft clam depuration plant.

Keywords: Depuration, HACCP, Verification Studies.

Résumé

Cette communication décrit les exigences prescrites par le Manuel d'exploitation 2^e partie publié par le National Shellfish Sanitation Program, pour la réalisation d'études de contrôle dans les stations de purification des coquillages. Elle présente par ailleurs l'impact des analyses HACCP (Hazard Analysis Critical Control Points) sur ces études ainsi que la façon dont sont prévues les études dans des stations nouvelles ou existantes.

Nous décrivons des méthodes permettant d'analyser les différents aspects d'une station, tels que les circuits d'eau de mer, la conception des réservoirs, et autres installations pertinentes. Nous présentons également une description des méthodes destinées à étudier et à analyser les divers points critiques de contrôle existant dans l'exploitation d'une station.

Cet article utilise comme modèle des études réalisées dans une station de purification de clams Mya arenaria. Les éléments essentiels en sont les suivants : (1) détermination du seuil supérieur au temps zéro des coliformes fécaux dans les clams, (2) réalisation des cri186 PURIFICATION DES COQUILLAGES

tères de qualité produits, (3) détermination de critères à mi-cycle, (4) débit d'eau de mer, (5) chargement des bassins et (6) paramètres de l'eau de mer. Nous présentons le modèle du « Schedule Control Purification Process » qui comporte les spécifications d'exploitation d'une station de purification de clams.

Mots-clés : Purification, HACCP, études de contrôle.

INTRODUCTION

The National Shellfish Sanitation Program (NSSP) requires that the controlled purification of molluscan shellfish be based on the results of a comprehensive study of the effectiveness of the depuration process at a particular plant. A depuration plant cannot be immediately placed into commercial operation. The various operations must first be verified through a start-up testing program to assure that NSSP requirements are satisfied. These requirements are given the NSSP Manual of Operations (FDA, 1990b). In general, this testing program must address the range of variables that could be encountered during typical operations. A typical plant and its operations have critical control points (CCPs), which are identified by a procedure known as Hazard Analysis Critical Control Points (HACCPs). These findings are used as the starting point in the design of the verification studies.

Although the Manual of Operations (FDA, 1990b) provides general requirements for study design, there are no details on how studies should be set up, how to design sampling programs, or how to carry out the studies. Ultimately, a Scheduled Depuration Process (SDP) must be developed for a particular plant based on verification studies. The NSSP currently does not distinguish which kinds of microbiological hazards are critical to depuration. The verification studies described here apply to bacterial depuration and not the viral or parasitic pathogens. The purpose of this paper is to demonstrate how to define the CCPs, how to design and complete verification studies, and, subsequently, how to develop the SDP.

Methods

Initial planning

Initially, the plant develops a generalized operating plan, which is necessary from a business point of view. After the operating plan for product flow and process control are established, the HACCPs are used to identify potential problems. Then there are four steps that must be performed. One must, in order, (1) provide a detailed flow chart of the plant's operations, (2) use HACCPs to identify and evaluate CCPs, (3) plan and conduct verification studies, and (4) develop the SDP. After the results of the verification studies are analyzed, an initial SDP can be developed for temporary use while routine data are collected, and additional verification data can be used to modify the SDP into a final document.

Plant design

There are no standard plant designs in the United States. A depuration plant may be built with almost any configuration of tanks, tank sizes, and sea water systems (treatment and plumbing). However, principles for plant construction and depuration processes have been established that are effective and sanitary. There are also different requirements for various species of shellfish. The limitations on operating characteristics include tank loading, the depth of shellfish packed in baskets, the flow rate, and sea water temperature, salinity, and dissolved oxygen (FDA, 1990b). HACCP-based verification studies provide the operational limitations of these factors.

To exemplify the procedures, we will use experiences from a commercial soft clam (Mya arenaria) purification plant in the northeast United States. During 1991, in-depth verification studies were done at this plant for the purpose of developing a modern SDP. The operational flow chart (figure 1) for this plant has two parts: one for clam handling and the other for the sea water system. The plant comprises nine (9) concrete tanks arranged in a single row with common walls. Each tank has its own recirculating pump and ultraviolet (UV) treatment unit. The tanks are 5.2 m long, 1.5 m wide, and 1.5 m deep. The soft clams are delivered to the plant in stackable plastic baskets 55 cm long, 25 cm wide, and 20 cm deep. The baskets are placed on plastic pallets six deep (3 across and 2 wide) for a total of 36 baskets per pallet. A maximum of 3 pallets are allowed per tank for a total of 108 baskets or 86 bushels (approximately 2.3 metric tons). The source of the sea water is a salt water well about 40 m deep located about 800 m from the plant. The well water is free of coliform bacteria. Nearly constant temperature (10-12°C) and salinity (32 parts per thousand) persist all year. When the tanks are about half-filled with the well water, the recirculating pumps are turned on. The water is taken from a single inlet at the end of the tank about 30 cm from the bottom. The water is then sprayed across the width of the tank through holes in a plastic pipe lying on top of the tank wall. Supplemental aeration is provided by 15 small air stones located along one side of the tank at about mid-depth. More details of this plant are given in Appendix A.

Incoming shellfish quality control

The sanitary quality of the incoming shellfish is controlled by proper classification of the harvest areas designated for depuration. Commercial depuration, using a minimum of 2 days residence in tanks, imposes severe limitations on incoming quality. These limitations are offset by the specification that only areas meeting the restricted classification can be used as a source of shellfish, which is the primary CCP. After the maximum microbiological level has been determined, the depuration process is optimized to obtain the safest product in the shortest period of time, which ensures the economic feasibility of the operation.

The NSSP Manual of Operations (FDA, 1990a) specifies that restricted areas for depuration have a median or geometric mean most probable number (MPN) of 700 total coliforms/100 ml or an 88 fecal coliform (FC) MPN/100 ml in the water. Other requirements for variability are also specified. However, the maximum microbiological level in the shellfish must be derived from the verification studies. This maximum fecal coliform level must be reduced during the depuration process to acceptable specified levels given in the NSSP Manual of Operations (FDA, 1990b).

CLAM FLOW

SEAWATER SYSTEM

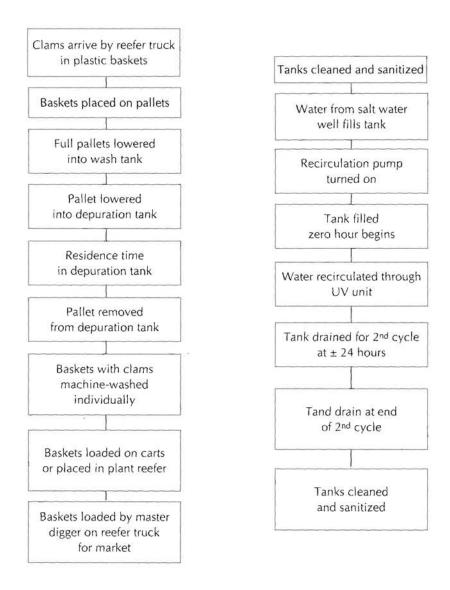


Figure 1: Clam and seawater system flow chart

Basic HACCP procedures

The HACCP approach is a two-step process, according to the National Marine Fisheries Service (NMFS, 1990). The first step relates to consumer risk and the second relates to process and quality control.

The first step of the HACCP process requires a description of the end-use product. The intent of depuration is to reduce the microbiological hazard of molluscan bivalves. Consumers frequently eat molluscs raw or partially cooked. The hazard level for raw molluscan bivalves from restricted areas without upper limits of bacterial contamination can be high.

The second step is multifaceted and includes (1) knowing the total operation, (2) evaluating hazards involved with the depuration, (3) controlling the CCPs, (4) monitoring the process, (5) defining the verification procedures, and (6) defining preventive measures.

Critical control points

The definition of a CCP is "a specific operational step of a food manufacturing process, the failure of which may automatically result in an unacceptable consumer health or economic risk" (NMFS, 1990). There are two CCP types (table I) for depuration: the first applies to any scenario and the second may or may not apply to a particular plant because of local circumstances and requirements.

The first CCP in any plant is the shellfish source. The area where the shellfish are harvested must meet restricted area criteria, and the maximum fecal coliform

Table I: Depuration plant critical control points (CCPs)

)	pe I. Universal CCPs
	Restricted areas for source of shellfish
	Maximum zero-hour fecal coliform levels
	Washing before and after depuration
	Culling before and after depuration
	Residence time in depuration (minimum 48 hours)
	Sea water suitable for shellfish activity
	Sanitary tank surfaces
	Attainment of end-product criteria
	Laboratory quality assurance
1	
)	pe II. Local CCPs Handling and storage before depuration Species dependence for basket depth Species dependence for tank loading
,	pe II. Local CCPs Handling and storage before depuration Species dependence for basket depth
,	pe II. Local CCPs Handling and storage before depuration Species dependence for basket depth Species dependence for tank loading Flow rate of sea water and dissolved oxygen

Source: FDA, 1990b.

value in the shellfish meats before depuration must be within a range that can be treated to meet the end-product criteria. Washing of shellfish is a CCP because the mud and detritus on the shells may contain pathogenic microorganisms, which should not be allowed to enter the sea water system. Dead and broken shellfish should be discarded because they cannot depurate. At this depuration plant, muddy and broken clams are a persistent problem during preliminary preparation.

Many years ago, the minimum residence time recommended for depuration was 48 hours, to ensure the elimination of viruses. Although the hazard of viral contamination in shellfish from restricted areas with only low to moderate pollution levels is expected to be low, depuration cannot be taken for granted, and 48 hours is now an NSSP requirement.

Cleaning and sanitizing tank surfaces and pipes is a CCP because certain organisms such as *Vibrio* spp. may be transmitted to the shellfish in the tank water. Furthermore, cleaning and sanitizing food-contact surfaces (such as tanks and pipes) are necessary for any food-handling establishment. The potential for recontamination of shellfish in the depuration system must be minimized by inplant sanitation. The disinfection of the recirculating seawater is a CCP because as depuration takes place there is a real chance of water contamination. The UV light treatment system assures that the microbes will not return to the tank. The intensity requirements for UV light depend on whether the system is flowthrough or recirculating.

The HACCP calls for monitoring of the depuration process

In the soft clam plant (table II), and for most others, four CCPs are identified for routine monitoring: (1) the bacteriological quality of the incoming shellfish, (2) the microbiological level in the shellfish after depuration, (3) the physical, chemical, and bacteriological quality of the water used for depuration, and (4) the effectiveness of the UV disinfection system.

The plant operations described by this HACCP procedure are being specified before the verification studies. However, there needs to be a starting point, and initial procedures can be designed on the basis of previous experience. The initial or tentative plant criteria are given to provide a reasonable approach to plant operation and to provide a list of the items to be verified.

Verification studies: General considerations

As mentioned previously, the SDP is based on results of verification studies of the tentative operational parameters of the plant and the depuration process. Most of the process variables in depuration plant operations (table III) are CCPs because they enable the plant to operate as intended. Microbiological testing of water and shellfish is essential for providing the data necessary for establishing the controls of the plant. Such testing also demonstrates that the microbiological criteria of the NSSP for water and shellfish are met.

Verification studies are similar to scientific investigations and may include statistical sampling plans. If season affects the quality of the incoming shellfish

Critical Control point	Evaluation and requirement	Critical limit/prevention
Harvest area classification	Area must meet NSSPa restricted area.	Accept only clams from areas meeting criteria
Maximum zero hour	Reject clams with >1 600 fecal coliforms/100 g	Maintain zero-hour sampling program.
Depuration time: minimum 48 hours	Depuration of high zero-jour fecal coliform levels require minimum of 48 hours	Use zero-hour levels to determine if >48 hours is required.
Ultraviolet (UV) effectiveness	UV disinfection for recirculating system is critical for effective depuration	Sample UV effluent daily and maintain log of UV lamps.
Tank loading	Tank loading > 0.23 cubic meters per bushel may cause low DO.	Do not exceed tank loading of 108 baskets per tank.
Dissolved oxygen (DO)	Clams do not depurate with low DO.	Provide supplemental aeration.
Tank, drain and clean	At 24 hours, detritus from clam activity accumulates.	Drain tanks and hose down to remove detritus.
Clams, wash and cull	Contaminated mud may be on shells of incoming clams.	Wash clams and cull out dead and broken clams.
Final product	Specific requirements for each species.	Use final product criteria.

Table II: Model hazard analysis critical control points (HACCPs) for a soft clam depuration plant

NSSP: National Shellfish Sanitation Program.

or the rate of purification, then verification may take as long as a year to complete. If this is the case, then the first year of operation is probationary. The NSSP does not provide any guidelines, and each plant is a unique case in study design. Because the objective of verification studies is to develop the SDP, monitoring and sampling can be intensive and costly at the start up. A model verification study outline for the soft clam plant is given in table IV.

Verification studies test the ability of the plant to consistently reduce fecal coliform indicator bacteria from a known initial level to an acceptable level in the final product. The NSSP does not provide a maximum initial level for any species of shellfish, although it does provide final product levels that must be met for oyster, hard clams, and soft clams. Parameters such as the water quality, water flow rates, and plant and tank loading, which all affect the quality of the final product, should be carefully monitored and recorded.

The NSSP (FDA, 1990b) specifies two requirements that must be attained for depuration: the maintenance of 50% dissolved oxygen (DO) saturation and the

	Verification study method		
Process variable	Microbiological sampling	Physical or chemical tests	
Shellfish			
Species	x		
Area	x		
Mid-cycle fecal level	X X X X X		
Initial fecal level	X		
Final product level	х		
Process water	5		
Temperature		х	
Salinity	1	X	
Turbidity		X X X X X X	
рH	2	X	
Dissolved oxygen		X	
Flow rate		X	
Shellfish handling			
Wash	х	х	
Cull	03	X	
Basketing	X X		
Time in tanks	Х		
Treatment of process water	х	х	
Season	х	х	

Table III: Depuration process variables for verification studies

Table IV: Model verification study for soft clam depuration plant

SEASONS Conduct fo	ur verification studies: spring, summer, fall, and winter.
	RO-HOUR LEVELS plicate samples for each depuration run over a wide range of harvest areas.
24-HOUR PRE Provide 24	DICTION hour or mid-cycle testing of depuration runs.
	EPTABILITY olicate 48-hour (final product) testing to determine acceptability product criteria are met.
	ILITY k: sample shellfish in all nine depuration tanks. c: sample shellfish from all locations within the tanks at 24 and 48 hours.
Provide ten Test tank w	TY PARAMETERS sperature and dissolve oxygen levels at the beginning and end of each cycle. ater at beginning and end of each cycle for total coliforms. from UV units.
	PEPURATION RUNS n, study at least eight depuration runs in a 2-week period.

end-product fecal coliform criteria. These parameters form the basis for evaluating the results of the verification studies.

Number of depuration trials

To derive sufficient data for analysis and final verification, one must complete several depuration trials. Statistical validity can not be proven because the NSSP does not specify the number of trials, the limits of statistical confidence, or the type of data manipulation. Several depuration trials will be required each season to determine the range of initial concentrations (zero-hour levels) of indicator bacteria. The high cost of microbiological testing and the need for special instruments for certain water-quality tests prevent industry from using sophisticated sampling plans.

Most depuration plants have several tanks, which are used in rotation. Because of the 48-hour minimum residence time, one trial is in the middle of a cycle when another trial is begun. On any given day, zero-hour shellfish are being treated in about half of the tanks. Therefore, to test the plant's routine capabilities, one should vary the size of the load in the plant's tanks to determine the effects on DO and fecal coliforms. During the rotation, each tank will have replicate trials and various loading rates. For the soft clam plant, three different shellfish harvesting areas were used during the studies. Lots from each area were placed in separate tanks, as needed. Because each tank had its own UV and recirculation, each day three depuration subtrials were completed. Thus, each season provided a total of 24 separate depuration trials for study and analysis. Therefore, only eight depuration runs were necessary for each season at this facility.

Results and discussion

Analysis of data

Analysis of data derived from verification studies usually presents a challenge because only a few depuration trials are made. Replication of samples within and between tanks is done sparingly because of the costs associated with microbiological testing. It is usually impossible to use sophisticated statistical tests because of the small number of samples. However, the objectives are specific: define the tank loading scheme, the sea water quality, and the flow rate that will maintain DO and reduce fecal coliform levels in the shellfish to meet end-product criteria.

Data from the trials are analyzed together first and then by season, area, and tank. The data are summarized to determine that DO levels are maintained and that end-product criteria are met. To evaluate the conditions that might prevent the criteria from being met, one must use statistical summaries and graphs.

Final product criteria

Attainment of final product criteria, as specified by NSSP (FDA, 1990b), is essential to proving that the process is effective. If the initial bacterial levels are not high enough, it will be difficult to prove that the plant can conform with levels near the maximum zero-hour. The final product criteria for soft shell clams include meeting a geometric mean value of 50 FC/100 g, and not more than 10% of the samples can exceed 130 FC/100 g for at least 10 consecutive depuration trials. A maximum of 170 FC/100 g in a single sample is also specified.

These statistics were used during the verification studies to determine if finalproduct criteria were met for the various conditions. These values serve as the prime criteria for development of the maximum zero-hour fecal coliform levels. If, for example, a final product MPN value is >170 FC/100 g, then the zerohour value was too high or the depuration conditions were not suitable. However, all of these criteria can be met in well-run depuration plants.

Development of the zero-hour upper limit

The development of the zero-hour upper limit of fecal coliforms for any depuration plant requires consideration of at least the following factors: (1) the species of shellfish, (2) the season of year, (3) the end-product criteria, and (4) the residence time in depuration. In the same water, different species of shell-fish accumulate fecal coliform bacteria at different rates. Water temperature also influences the accumulation of fecal coliforms. Because season is the controlling factor for water temperature, possibly the salinity of the water, and, subsequently, the biology of the shellfish, each season could have a different zero-hour limit. A practical method for determining the maximum zero-hour level is to calculate the geometric means of (1) the final product values that do not meet the end-point criteria, (2) the mid-cycle (24-hour) values, and (3) the zero-hour values, and then plot them on logarithmic-scaled paper. The same can be done with the final-product values that do meet the end-product criteria. The zero-hour upper limit is then interpolated from a fitted line.

Another approach makes use of log-probability plotting paper. The zero-hour data and the end-product data are plotted, and then a vertical line is drawn from the end-product line at the NSSP criteria to the zero-hour line to estimate the value of maximum zero-hour. Establishing a final maximum zero-hour value may require data from one or more years of depuration trials.

Another method for determining the zero-hour upper limit is to categorize the zero-hour values into several groups, depending on the available data. For example, for the soft clam plant the groups <330 FC/100 g, 330-1000 FC/100 g, and >1000 FC/100 g were used. Statistical analyses, such as log-probability plotting, analyses of variance, and T-tests for geometric means, can be performed on the final product results associated with these groups. Although the verification studies are not usually planned with a statistical hypothesis *a priori* because of sampling restrictions, these types of statistical tests may be used to develop the levels of fecal coliforms that may be allowed.

Mid-cycle criteria

The NSSP allows the release of 48-hour depurated shellfish based on fecal coliform levels at an intermediate time, such as 24-hours. As a result, fresher shellfish may be released to the market without the 1- to 3-day wait for laboratory test results on the final product. This is especially advantageous if the laboratory method requires 24 hours. Verification studies can be used to arrive at these criteria.

To derive the mid-cycle criteria, one must use data from a large number of depuration trials at the zero-, 24- (mid-cycle), and 48-hour (final product) stage. Statistical tests are then used to derive the mid-cycle predictor values for the release. One approach uses plots of the geometric mean fecal coliform values at zero, 24, and 48 hours. When plotted on a graph, these values describe a rate or curve of depuration (decline in fecal coliform levels). One can then use two methods to interpolate the mid-cycle release value: draw a curve parallel to the rate curve such that it begins at the maximum allowable zero-hour value, and then determine that the final product level is met and read the mid-cycle value from the graph; or draw the curve such that the final product criteria are the key point and then determine if the zero-hour upper limit is reasonably met. The mid-cycle value can be estimated from the curve.

Flow rate, tank loading, and oxygen

To maintain sufficient DO, one must balance water flow rate (oxygen supply) and tank loading. If the DO level drops below 50% saturation, then rates of purification will be affected. The relationship between tank loading and flow rate has been well established; therefore, to meet NSSP requirements, one must merely demonstrate that adequate purification occurs and DO is maintained. For the two flow regimes used, flow-through and recirculation, different procedures are required to maintain DO. A flow-through system seldom requires ancillary aeration of water unless the source of sea water contains low DO, as with salt water wells. However, with recirculating sea water systems, supplemental aeration is usually required with the tank loadings allowed by the NSSP guidelines, especially in the warmer months. The CCPs in a flow-through system include DO levels in the initial sea water and the tank effluent.

The nine tanks at the plant under study did not maintain the same aeration configuration throughout the verification studies. Tanks with low flow rates and no supplemental aeration initially, did not maintain the recommended oxygen levels, especially during the warmer summer months. (The plant is not air conditioned and ambient air reached 29°C.) At the start of the verification studies, some of these tanks were allowed to contain only two pallets, while others were allowed three pallets. As supplemental aeration was added, all tanks maintained the required DO levels when loaded with three pallets.

CONCLUSION

SDP Development

On the basis of the HACCP and the verification studies, we developed a model SDP for the soft clam plant (Appendix A). The NSSP does not have minimum requirements for the content or format of an SDP, but specifications for the construction and operation are essential. With the SDP, a plant operator will be able to maintain uniform controls over the plant. Also, a sanitarian will be able to evaluate the operations of this plant during routine inspections. If problems arise with final-product fecal coliform or DO levels of the water, then data for water and shellfish can be compared to the norms established by the verification studies and specified in the SDP.

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APPENDIX A:

Model scheduled control purification lower case process (SDP) for a soft clam depuration plant

ITEM	EXAMPLE
SHELLFISH Species of shellfish	Soft shelled clams (Mya arenaria)
Source of shellfish	Areas to be designated by the State Shellfish Control Authority (SSCA).
Delivery of shellfish	Routes and times of harvest designated by the SSCA; refrigerated trucks; washed and culled at harvest site.
PLANT UNITS	
Number and types of tanks	Nine fiberglass concrete tanks
Dimensions	1.5 m wide, 1.5 m deep, 5.2 m long
Baskets	0.8 bushel; 25 cm wide, 55 cm long, 20 cm deep. Maximum depth of clams in baskets, 17 cm.
Tank loading	108 baskets (maximum), loaded on three plas- tic pallets; 36 baskets per pallet; six basket layers maximum.
Source of seawater	Salt water well; 40 m deep.
Parameters	Salinity, 32 ppt Temperature, 10°C
5 2	Undetectable coliform
Pretreatment of sea water	None
Flow type	Recirculation; minimum 2.5 l/sec; flow meters calibrated in 0.3 l/sec increments.
Ultraviolet (UV) treatment units	4 UV tubes (1 m); 3 l/sec capacity with turbi- dity <20 nephelometric turbidity units (NTU)
Aeration	1. Via spray from 4.6 m delivery pipe, mini- mum of 12 holes at 10 mm diameter.

Clam washing at delivery Clam washing after depuration	 Supplemental aeration by 15 air stones located mid-depth, along sides of the tank. Process water Maximum turbidity 20 NTU Undetectable coliform in UV effluent or tank water at end of cycle. Minimum DD 50% of saturation. Baskets loaded on pallets, dipped for mini- mum of 10 sec in agitated water in Tank 1. Individual baskets washed through mechanical
	washer.
OPERATIONAL	
Tank cleaning and sanitizing	Before pallets are loaded, each tank hosed with water from salt water well, sprayed with 200 ppm chlorine solution and rinsed.
Pallet cleansing	Each pallet hosed with well water before use in tanks. Sanitize weekly.
Microbiology of clams	Maximum zero hour levels: 1000 fecal coli- forms (FC)/100 g in summer and 1600 FC/ 100 g in spring, fall, and winter. Maximum mid-cycle levels: 300 FC/100 g in summer and 500 FC/100 g in spring, fall, and winter. Final product levels: maximum individual sample 170 FC/100 g; overall performance, geometric mean 50 FC/100 g and not more than 10% may exceed 130 FC/100 g.
Storage of clams	Clams for overnight storage, either before or after process, stored in 4°C coolers.
Clam lots	Clams from each harvest area to be depurated in a different tank (subject to delivery amounts).
Depuration cycles and time	The first cycle of depuration is a minimum of 18 hours ; lower case the tanks must be drai- ned and filled within 1 hour. The second cycle must be completed on the second day of depuration; minimum residence time, 48 hours. Clams must be processed for a third day if the maximum zero-hour values or the maxi- mum mid-cycle values are exceeded.
SAMPLING SCHEDULE	Sample zero-hour clams from each harvest area once for each depuration run. (A depura- tion run consists of all the clams that are deli- vered to the plant for depuration on a given day.) Sample mid-cycle clams if the zero-hour values are exceeded. Sample final product if either the zero-hour values or the mid-cycle limits are exceeded.
DATA ANALYSIS	Determine the overall plant depuration statis- tics each month.