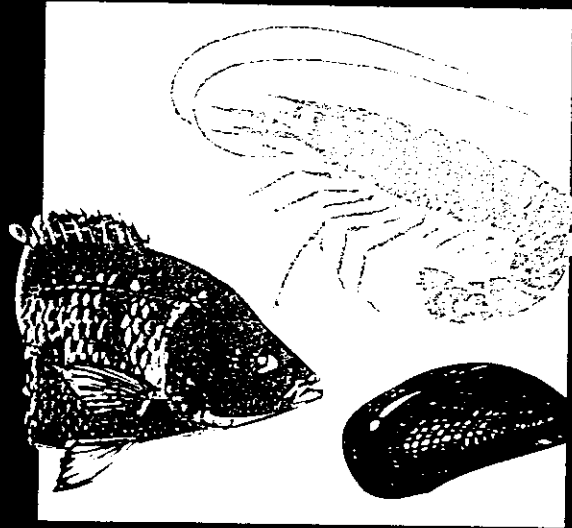


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INFORMATION

World Aquaculture Society
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 Bothell, WA 98021 USA
 Tel: +1-425-485-6682 Fax: +1-425-483-6319
 e-mail: worldaqua@aol.com

CEJEM - Promoções e Treinamento Ltda.
 R. Gal Americano Freire, 394 S/ 403 - Boa Viagem
 51021-120 Recife - Pernambuco - Brasil
 Fone: 55-81-465-8594 Fax: 55-81-325-5015
 e-mail: cejem@neothec.com.br

HACCP PROGRAMS - IMPLEMENTATION AND OPERATIONAL CRITERIA

**Steve Otwell, PhD
Aquatic Food Products Program
Food Science & Human Nutrition Department
University of Florida
Gainesville, Florida 32611
otwell@gnv.ifas.ufl.edu**

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HACCP PROGRAMS - IMPLEMENTATION AND OPERATIONAL CRITERIA

INTRODUCTION

Seafood remains the safest source of muscle protein eaten in the world and aquacultured products can offer further assurances through the routine controls used for farmed production and the closely related processing operations. Aquaculture has the advantage of farmed production that requires daily monitoring and the harvests that can be predicted to better coincide with processing methods and schedules. This scheme also allows for more immediate market access. For these reasons, aquacultured production and processing can easily incorporate the basic HACCP requirements that are currently in regulatory vogue.

HACCP (Hazard Analysis and Critical Control Points) is not a new concept, but it is a new regulatory requirement recently established for seafood and aquacultured products in the United States and the European Economic Community (EEC). Other countries and international firms are adopting similar programs and requirements are beginning to involve more foods. The basic intent is to prevent and control potential food safety problems. A properly designed HACCP program is becoming necessary to provide records that evidence a firm's efforts to maintain food safety. This evidence is becoming more crucial with the increasing globalization of aquaculture commerce.

HACCP

There are numerous sources to explain the basic principles for HACCP and the related regulations (Table 1). As with any new program, experience will dictate changes and additions to the regulations, but the basic HACCP principles will remain the same. The 7 basic steps for developing a program generate two essential documents that can be used to evidence a

HACCP program for a particular firm (examples, Table 2 and 3);

7 Basic Steps

1. Hazard Analysis
2. Identify Critical Control Points(CCPs)
3. Set Critical Limits
4. Establish Monitoring for CCPs
5. Establish Corrective Actions
6. Conduct Verifications
7. Maintain Records

2 Essential Documents

1. Hazard Analysis Worksheet
2. HACCP Plan

These essential documents can be no more than 3 to 4 pages, but they identify any Critical Control Points (CCPs) and records that will be maintained to evidence the daily activities of the firm.

Typical CCPs for aquacultured products concern the conditions of the products when harvested (Table 4). Previous culture practices could introduce substances through the feeds or water conditions that can be considered potentially harmful if in the final edible product form. The designated CCPs to monitor for these substances may vary according to the production scheme, but should be coordinated with the processing operations to generate the proper evidence that confirms the products are safe for consumption. Product 'receiving' at the processing operation is the most common CCP for aquacultured products. The producer must provide some evidence either in terms of production records or final product analysis that confirms the proper use of any chemical substances introduced through feeds or direct applications, and confirms the general water quality during production.

Additional CCPs will depend on the type and extent of product processing. There are differing definitions for processing, but all handling steps should initially be considered as potential CCPs. In the United States, where HACCP requirements are focused on the processing sector, the practice of bleeding, washing, and icing of otherwise unprocessed products by the aquaculture producer is considered an integral part of harvesting and getting the product to market, and is, therefore, not considered to be processing. However, heading,

gutting, or packaging of the products performed by the aquaculture producer is considered processing, and these procedures must be covered under the HACCP regulations.

In most instances, basic processing for sale as raw, fresh or frozen, aquacultured products destined for cooking prior to consumption do not require CCPs, but rely on essential sanitation procedures and good manufacturing practices to prevent cross-contamination and any temperature abuse that would degrade the quality of the products. The distinction is loss of product quality rather than food safety. For this reason, daily monitoring and records for sanitation procedures and routine time-temperature management should be an integral prerequisite for the HACCP program. A daily record for Standard Operating Procedures (SOPs) is further evidence for a proper HACCP program.

More CCPs are expected with more extensive processing that can involve product cooking, smoking, fabrication, special packaging (i.e., vacuum packaging) and other value-added procedures, because the final products usually include ready-to-eat items that require no further cooking before consumption. Aquacultured products are not unique relative to further processing. The advanced processing steps introduce more food safety concerns.

SANITATION

The importance of sanitation as a pre-requisite to HACCP warrants special consideration. Sanitary practices must be evidenced even in the absence of any CCPs. Use of sanitation SOPs is an easy approach to documenting a company's daily practices in processing (Table 5). These sanitation SOPs should be custom to each processing scheme and routine. Properly designed they can be used in an internal on-the-job training program while generating the records to evidence the firm's sanitation efforts. In the United States there are 8 key sanitation categories of concern in seafood processing (Table 5). The first and primary concern will always be the quality of the water used in processing. The water must be

free of various chemical and microbial impurities that could contaminate the products (Table 6)
All production and processing operations should maintain periodic (at least annual) evaluations of the water used to handle and process the cultured products.

REGULATORY REQUIREMENTS

The recent regulatory requirements for HACCP and related sanitation pre-requisites have been dominated by the mandates issued by the United States and the EEC. Both requirements are based on "equivalence" for domestic and international commerce. They differ in their approaches and regulatory language, but they both require 'evidence' for sanitation in processing and food safety controls through CCPs. The FDA mandates an entire HACCP program with hazard analysis and HACCP plans, while the EEC directive 91/493 requires processors to conduct 'own checks' with CCP monitoring, verifications and records. The evidence, as explained in this article, can suffice both programs and most domestic situations, but there are some distinct features that must be considered for the respective countries (Table 7). The United States mandate, administered by the U.S. Food and Drug Administration (FDA), initially relies on evidence provided by the importers of incoming products. Although the FDA has drafted provisions for more future reliance based on the recognized authorities in the country of product origin, this option will require significant time to secure the necessary country-to-country confidence. In contrast, the EEC directives initially rely on approval of the country of product origin. EEC approval depends on specific committee reviews of individual country documents and country site visits to confirm the competence of a recognized authority to provide evidence that the seafood and aquacultured products are safe and fit for consumption. The necessary evidence includes inspection scrutiny for properly identified and monitored CCPs and sanitation. Each batch of seafood or aquacultured product shipped to Europe must be accompanied by a Health Certificate which is linked to product and process

inspections by the competent authority in each country. A 'batch' is defined as the quantity of fishery products obtained under practically identical circumstances.

In addition to the HACCP requirements, each national program expects the processing firms to maintain evidence for sanitation. The EEC directives 91/492 (live bivalve mollusk) and 91/493 (fishery products) specify extensive concerns in production, processing, storage and transportation. The FDA relies on the Good Manufacturing Practices (GMPs; Code of Federal Regulations Chapter 21, Part 110) available in the Seafood HACCP Training manual (Table 1). These documents are similar in addressing the water use, facilities, operations and personnel health.

The final evidence for compliance rest with the inspection of products on arrival in the importing nation. The EEC has introduced the use of Border Inspection Posts (BIPs) to verify that fishery products imported into the European Community comply with the community regulations. Their regulations include visual inspections, organoleptic (sensory) evaluations and product sampling if necessary. Similarly, the U.S. FDA will maintain their traditional port inspections linked with releases by the U.S. Customs Offices for product entry into the United States. In both cases the final products can be subjected to further sampling and analysis. Thus HACCP mandates do not replace existing regulations, but are in addition to traditional requirements.

RECOMMENDATIONS

HACCP and the related sanitation requirements are real and necessary for international aquaculture commerce. The best approach to compliance is to prepare a program that generates evidence for daily practice in monitoring proper CCPs and performing the basic sanitation procedures and good manufacturing practices, including time-temperature management. The following recommendations are intended for individual aquaculture

processing operations:

1. Draft a letter for distribution to any buyers or inspection authorities that confirms the company is committed to food safety through implementation of a HACCP program and accompanying sanitation SOPs.
 - a. Include copies of the companies hazard analysis worksheets, basic HACCP plan and blank sanitation check sheets (only 2 to 4 sheets).
 - b. Explain how the HACCP records can be accessed on request.
2. Maintain complete and accurate HACCP records for all CCP monitoring, corrective actions, and verifications.
3. Maintain records that support the HACCP program (i.e., water quality analysis, any test results for potential contaminants or food additives, certificates for approved drug use, etc.)
4. Maintain an active training program for the company administration and staff concerning HACCP and sanitation SOPs.

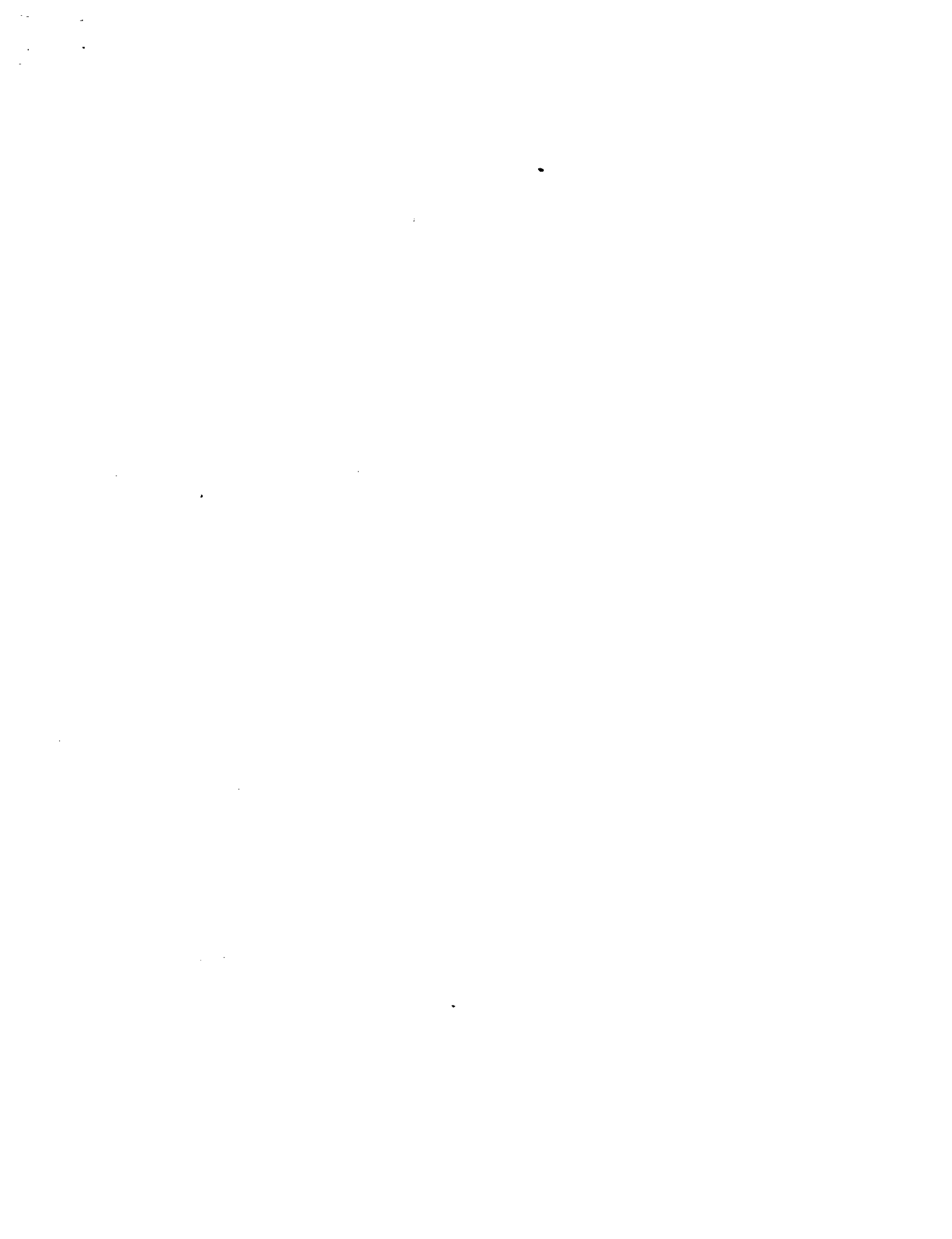


Table 2 Typical parts for a Hazard Analysis Worksheet used to identify potential food safety problems or hazards for any food handling or processing operation. Each column should be completed for each processing step.

Processing ¹ Step	Potential ² Hazard	Are Hazards ³ Significant Yes/No	Justify Response ⁴ in column no. 3	Preventative ⁵ Measures	Is the Step ⁶ a CCP? Yes/No
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Key for the Columns:

1. The worksheet should be completed for each handling or processing step. Typical processing steps can include pre-harvest, receiving, gutting, washing, application of food additives, storage, etc.
2. List all food safety hazards that are reasonably likely to occur. They should include the biological (microbial), chemical (drugs, food additives or contaminants, and physical (metal fragments) hazards. For examples, use of antibiotics in production, potential microbial pathogens, sulfites to prevent discoloration, etc.
3. Is the listed hazard significant?
4. Justify your decision to designate the hazard as significant or not significant. Some responses may cite local evidence for previous occurrences or test results that indicate insignificance.
5. List the possible control measures that can be used to eliminate or reduce the hazard. Examples can be specific treatments or methods, monitoring records, letters of guarantee, time and temperature controls, or proper sanitation procedures.
6. Based on the listed responses determine if the processing step is a critical control point (CCP) necessary to eliminate or reduce the food safety hazard to an acceptable level.

NOTES: *All of the identified CCPs are carried over to the HACCP Plan (Table 3)

**There is no standard, required forms for the Hazard Analysis Worksheet, but any worksheet should include the items listed above.

Table 3. Typical parts for a HACCP Plan used to show how the identified Critical Control Points (CCPs) will be monitored and maintained in control of the specified food safety hazard. The columns below each CCP would be completed with the details for the respective procedure.

<u>PROCEDURES</u>	<u>CCP 1</u>	<u>CCP 2</u>	<u>CCP 3</u>
Significant Hazard	(list the food safety hazards for each CCP identified in the Hazard Analysis Worksheet)		
Critical Limit	(list the value to which a biological, chemical or physical hazard must be controlled for the CCP to be in compliance, i.e., proper approved drug use, specific residual levels or third party letters of guarantee)		
Monitoring			
What	(specify what will be monitored to assure the CCP remains in compliance, i.e., certificates for on-farm usage of approved drugs, analysis of the product, or third party certificate for drug use)		
How	(specify the documents, persons or tests used in monitoring)		
Freq.	(specify how frequently the monitoring will occur, i.e., each pond harvest, monthly, each lot, each batch, etc.)		
Who	(specify the person or persons that will do the actual monitoring)		
Corrective Actions	(list the actions that will be taken if the CCP is found out of compliance, i.e., segregate and further evaluate the product or reject the product)		
Verification	(list the procedures used to verify that the CCP is adequate and working, i.e., periodic product testing, review of monitoring records, visit and exam production procedures, etc.)		
Records	(List all records that will be maintained concerning the CCP)		

NOTE: **There is no standard, required form for the HACCP Plan, but any HACCP Plan form should include the items listed above.

Table 4. Possible Critical Control Points (CCPs) for an aquaculture operation. The selections are based on examples provided in the United States Food and Drug Administration, 'Fish & Fisheries Products Hazards & Control Guide listed in Table 1.

CCPs	Significant Hazard	Possible Controls or Preventative Measures
Pre-Harvest	Drugs	Review of on-farm drug use procedures through site visits, survey of the procedures, drug use records and any certificates for approved drug use status and recommended usage.
Receiving	Drugs	Presence of a certificate indicating proper use of an approved drug and product subject to analysis
Receiving	Drugs	Test results from lot in question for any prior drug usage
Receiving	Food Additive (sulfites)	Presence of a label or invoice declaring previous use to control black-spot on shrimp and product subject to analysis for residuals
Processing Treatment	Food Additive (sulfites)	Labeling to designate previous treatment and previous test results to verify residual levels for established process
Processing Treatment	Food Additives	Labeling to declare previous use and certification for approve food additive status for the intended application
Packaging	Food Additive (sulfites)	Proper label information on the containers prior to packaging

Table 5. Check sheet for daily Sanitation Standard Operating Procedures (SSOP). Adopted from examples in the national HACCP Training Manual provided by the Seafood HACCP Alliance training program list in Table 1. The check sheet is segregated by the eight (8) key categories for sanitation concerns as specified by the U.S. Food and Drug Administration.

SANITATION CONDITION & PRACTICE	Time ¹	Time ²	Time ³	Comments
	Pre-Op		Assigned	
1. Safety of Water				
a. City water (annual verification)				
b. No cross-contamination between potable & wastewater system				
2. Condition & cleanliness of food contact surfaces				
a. Processing equipment and utensils in suitable condition				
b. Equipment cleaned and sanitized before start-up				
1. Concentration of chlorine used for sanitizing (ppm)				
c. Product residuals removed from equipment during breaks				
d. Gloves and aprons in good repair				
3. Cross-Contamination				
a. Physical condition of plant and layout of equipment suitable to minimize contamination				
b. Employees' hands, gloves, equipment, and utensils that contact unsanitary objects are washed and sanitized before contacting product				
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities				
a. Adequate supplies				
b. Concentrations for proper hand dip stations				
c. Toilets are clean and properly functioning				

Key for Times:

1. The 'pre-op' is before daily operations begin
2. Interim times can be determined based on the schedule and volume of work
3. Times for certain routine checks can be assigned by week, month or year

Table 5. Continued as backside of previous portion

SANITATION CONDITION & PRACTICE	Time ¹	Time ²	Time ³	Comments
	Pre-Op		Assigned	
5. Protection from adulterations (lubricants, fuel, pesticides, cleaning and sanitizing agents, condensates, floor splash, etc.)				
a. Food products				
b. Food packaging materials				
c. Food contact surfaces				
6. Labeling, storage and use of toxic compounds				
a. Cleaning compounds labeled and stored properly				
b. Lubricants labeled and stored properly				
c. Pesticides labeled and stored properly				
7. Employee health conditions				
a. Employees show no signs of medical problems that could compromise product safety				
8. Exclusion of pests				
a. No evidence of pests in plant				

Comments:

Signature:

Date:

Reviewed signature:

Date:

Table 6. Excerpts from the water quality standards specified the European Economic Community Directive 80/778/EEC relating to the quality of water fit for human consumption. This example is not complete, but provides some indication of the pre-requisite sanitary requirements that must accompany an proper HACCP program.

Microbial Parameter	Volume for the sample (ml)	Maximum admissible concentration (MAC)	
		Membrane filter method	Multiple tube method (MPN)
Total coliforms	100	0	MPN < 1
Fecal coliforms	100	0	MPN < 1
Fecal streptococci	100	0	MPN < 1
Sulphite-reducing Clostridia	20	—	MPN < 1

Water intended for human consumption should not contain pathogenic organisms, i.e., salmonella, pathogenic staphylococci, fecal bacteriophages, enteroviruses, parasites, algae or other organisms such as animalcules

NOTE: The EEC Directive 80/778 listed additional microbial concerns and numerous chemical parameters, include concerns for odors and off-flavors.

Table 7. Condensed comparison of the current seafood and aquacultured product safety requirements mandated by the U. S. Food and Drug Administration and the European Economic Community (EEC).

	U. S. FDA	EEC
Authority	Food & Drug Administration	European Commission as established by the Member States of the European Community
Effective Date	December 18, 1997	Harmonization on July 1, 1998 with extension for certain countries until January 31, 1999
Requirements for Imported Products	Foreign processors must practice HACCP requirements equivalent to that required for domestic processors in the United States, per the Federal Code of Regulation Title 21, Part 123- Fish & Fishery Products	Equivalence to requirements for production and placing on the market of Community products in accordance with Directives 91/492/EEC and 91/493/EEC
Current Focus	United States importers must provide the evidence for equivalent compliance by the foreign processors	Countries must be approved for import to the EEC by recognition of competent authorities in the country to evidence compliance from production through processing
Evidence for Compliance	<p>If a Memorandum of Understanding (MOU) exist between the USA and another country, the importer does not need to take further action. Evidence relies on the country authority. No MOU's are currently in effect, but many are under consideration which may require considerable time</p> <p>In the absense of MOUs, domestic importers must provide the evidence for HACCP compliance. Two verification procedures are required:</p> <ol style="list-style-type: none"> 1) Product specifications must be drafted and applied to ensure the products are not injurious to health and have been processed in sanitary conditons, and 2) Affirmative steps must be taken to assure the products were processed under controls that meet the requirements of the HACCP regulations. Six optional affirmative procedures are listed for consideration. 	<p>A competent authority must be recognized by the EEC before a countries products can enter the European Community. The competence is based on an assigned committee review of the authorities documentation and a site visit to judge the authority and country situation.</p> <p>EEC directives imply recognition is possible for establishments in the absence of country approval, but the procedure is not clear and the potential demand for establishment reviews would overwhelm the Committees.</p>