A HACCP PROGRAM FOR RAW, CULTURED PENAEID SHRIMP

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ABSTRACT

Shrimp continues to represent one of the safest forms of muscle protein consumed in the world, yet as for all seafoods, they will be subject to additional regulatory scrutiny through increasing use of Hazard Analysis and Critical Control Point (HACCP) programs for product safety. This example of a HACCP plan for cultured penaeid shrimp is recommended for consideration by producers, processors and importers of raw, fresh and frozen, shell-on or peeled shrimp tails. For this product form the primary critical control point is product receiving with a distinct critical limit for sulfite residuals. This plan is complimented by reference to appropriate Total Quality Assurance (TQA) programs to guide production practices and a sanitation control plan for in plant operations. Completion and implementation of these plans remains a company responsibility with additional and new record keeping requirements. The anticipated benefits are compliance for international commerce, less regulatory scrutiny per firm, consumer/buyer confidence and market access.

INTRODUCTION

Shrimp continues to represent one of the safest forms of muscle protein consumed in the world. Amongst seafoods, it is possibly the least problematic product in terms of reported illnesses per volume consumed. This situation was recently evidenced in the United States by the National Fisheries Institute NFI 1989). National Academy of Sciences (NAS 1991). and FDA's Fish and Fishery Products Hazard and Control Guide (FDA 1994-draft) and HACCP proposal (FR 1994). Collectively, these publications list a variety of potential health hazards that could be associated with shrimp consumption. but actual reported illnesses or outbreaks are rare and usually involve mishandling or cross-contamination in retail/food service settings or home. No doubt, shrimp are comparatively much safer than fish or chicken which have been estimated to cause 1 illness per 5,000,000 or 25,000 servings, respectively (Otwell 1989).

Despite this safety record, shrimp and all other seafoods will continue to be subject to increasing scrutiny for product safety and quality. The motivating factors include more health conscious consumers and increasing competition for international commerce. This situation involves all aquatic food products, be they harvested, cultured or fabricated. The current, dominant regulatory response is hazard analysis and critical control point surveillance. HACCP regulatory programs exist in Canada, they are being formulated and demanded about the European Union, and they were recently proposed as a mandatory program in the United States (FR 1994).

This brief HACCP plan for raw aquacultured shrimp illustrates some of the basic HACCP concepts and offers one initial approach for commercial and regulatory experience. Typical shrimp aquaculture and related raw product processing operations should not have difficulty with the implementation of basic HACCP programs. Initial confusion can be resolved with proper training to understand the basic principles and program expectations. Likewise, the perceived nuisance for extra monitoring and record keeping can progress to better plant management and employee commitments.

HACCP CONCEPT

HACCP is not a new concept. As a preventative maintenance program it has been used by various technical operations and food processing facilities for well over 30 years (NAS 1985, FR 1994). It simply involves a pre-planning procedure to fully outline an operation, noting potential hazards that could occur and identifying control points to prevent, minimize or correct hazards. Record keeping is an essential part of the program to monitor for practice. consequences and trends. In most instances shrimp processing firms have intuitively practiced HACCP activity, but they have lacked the specified monitoring and record keeping procedures.

As introduced, HACCP was a management style adopted by individual company decisions. but the U.S. FDA's recent proposal (FR 1994) would make HACCP a mandatory requirement for all seafood processors and domestic importers. FDA's mandatory HACCP proposal is based on the basic principles best outlined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF 1992). This selected committee recommended use of 7 steps in planning and monitoring the HACCP program (Table 1). FDA's initial HACCP proposal deleted steps for corrective action and verification. Interpretation and use of these HACCP principles can differ by firm, regulatory agency and country. For example in the United States. FDA's proposed program mandates the "shalls" for HACCP plans with steps for seafood safety, while recommending the "shoulds" for the various attributes of product quality and product integrity (economic fraud). The "shalls" are the enforceable part of FDA's HACCP program. In contrast, another federal agency. the Na-

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C.L. Browdy and J.S. Hopkins. editors. Swimming through troubled water, Proceedings of the special session on shrimp farming. Aquaculture '95. World Aquaculture Society. Baton Rouge. Louisiana. USA.

Table 1. Seven basic principles or steps for a HACCP program (NACMCF, 1992).

Steps	Procedure
1	Conduct a hazard analysis to determine potential safety problems associated with the seafood processing operations from production through final product commerce.
2	Identify critical control points (CCP) in processing
3	Establish critical limits (CL) for each CCP.
4	Establish monitoring requirements for each CCP and CL.
5	Establish corrective actions to be taken when monitoring indicates a deviation from the CL.
6	Establish effective recordkeeping procedures.
7	Establish a HACCP verification procedure.

tional Marine Fisheries Service in the U.S. Department of Commerce has established a voluntary, fee-for-services HACCP program that addresses both product safety and quality through all 7 basic steps (FR 1985). Both federal programs are good, but they should be distinguished. FDA is the primary food safety regulatory authority in the U.S. governing all domestic seafood production, processing and importing. They are complimented by the voluntary NMFS program which is often used by buyers and sellers to assure quality and safety in purchase. Further explanation of the respective programs is beyond the intent of this text, but additional information can be obtained from their headquarters;

U.S. FDA-Office
of Seafoods
200 C Street, SW
Washington, DC 20204

National Marine
Fisheries Service
1335 East West Highway
Silver Spring Metro
Center Bldg., Rm 6140
Silver Spring, MD 20910

In brief, aquacultured shrimp imported and/or processed in the U.S. will be subject to FDA's proposed mandatory HACCP requirements. The final rule is expected in summer 1995, and compliance will follow through 1996 and 1997. Many firms are not waiting for a final rule. They reason that experience with HACCP implementation before the expected compliance dates could offer marketing advantages. Canada and some European nations are currently requesting evidence for HACCP practice. As proposed (FR 1994),U.S. importers would be required to have on file the HACCP plans of each of its foreign processors. Proof for a valid and equivalent HACCP program could involve a variety of methods, including active participation by the respective foreign authorities (Table 2). Obviously, the time for HACCP planning has arrived.

Table 2. A condensed version of FDA's proposed HACCP obligations for U.S. based importers of fishery products (FR,1994)

1. Importers shall have their own HACCP plans for products while in their control.
2. Importers shall have HACCP plans on file for each of its foreign processors.
3. Importers shall take actions to ensure the products imported were produced under the HACCP plan on file and subject to FDA specified sanitation controls. Such steps may include, but would not be limited to:
   a. Obtain foreign processors HACCP records
   b. Obtain 'certification' from foreign government authorities that the processor compiles with HACCP
   c. Regularly inspect the processors operations for HACCP compliance.
   d. Periodic end product testing.
   e. Other measures ...
4. Importers receive product from a country with an active memorandum of understanding (MCU) with FDA per HACCP.
5. Importers encourage foreign processors to obtain HACCP training per FDA specifications.

HACCP PLAN

Raw penaeid shrimp, as the primary product form for most cultured shrimp, is used to illustrate a possible HACCP plan following the basic principles in Table 1. The final product form is frozen, shell-on shrimp with or without heads. This example only features product safety in compliance with FDA's mandatory proposal (FR 1994). The plan will be an actual written document that identifies the firm, products of concern, potential hazards, critical control points, critical limits, monitoring procedures and associated records. Establishing a plan is a company responsibility. FDA does not plan any pre-approval process. Compliance will rely on company performance evidenced through routine regulatory activity.

The HACCP document along with progressive records would represent a firm's HACCP program. The document should list the firm's address (location), telecommunications and key per-

sonnel (i.e. owners, plant managers, HACCP coordinator, etc.). HACCP plans and records will require signatures denoting maintenance by the responsible persons identified in the plan. Likewise, each firm should employ at least one individual who has successfully completed a prescribed course of HACCP instruction. The educational requirements are being addressed by a recently formed 'Seafood HACCP Alliance for Education and Training' initially funded by the National Sea Grant College Program (1994). This project involves a partnership of FDA, state agencies, industry and academic expertise. The specific training requirements are expected to be released with FDA's final HACCP rule.

Step 1. Hazard Analysis

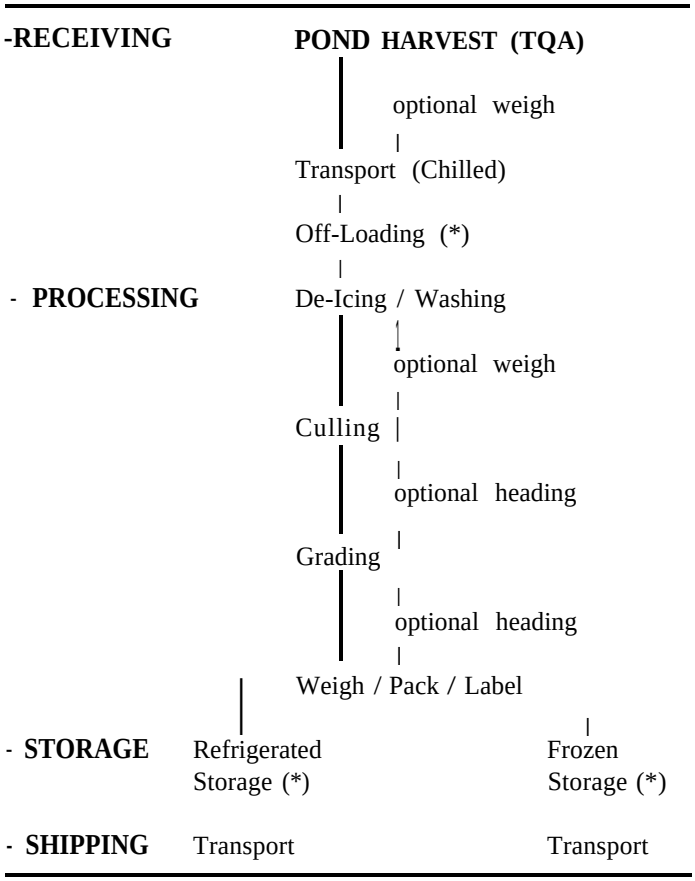
The FDA does not require an illustrated flow-diagram of the production and processing operations. This approach is helpful for identifying potential hazards and critical control points. The process in Figure 1 yields fresh or frozen raw shrimp with shell-on. Options include heading. Mindful of potential health hazards, the firm must list possible and reasonable problems that could occur in this process. FDA has drafted a Hazards and Controls Guide to help identify potential problems (FDA 1994-draft). For raw aquacultured shrimp this guide lists three potential hazards: 1) chemical contamination; i.e. pesticides, industrial chemicals, etc., 2) food and color additives, and 3) aquaculture drugs.

Many other concerns such as temperature abuse in processing, microbial contamination, decomposition and filth should also be considered as hazards. The first draft of FDA's Hazards and Controls Guide (FDA 1994) does not list *Salmonella*, *Vibrio* or *Listeria* as hazards on raw cultured shrimp for critical control point monitoring in raw cultured shrimp processing. These potential bacterial pathogens would still be subject to regulatory scrutiny through import sampling. FDA reasons these pathogens are destroyed by cooking and can be prevented by proper sanitation control procedures. For this reason FDA's initial mandatory HACCP proposal requires a written sanitary control plan with appropriate monitoring. This mandate is basically record keeping for traditional GMP's ("good manufacturing practices", CFR 1986). The primary safety hazards are addressed by critical control procedures. The distinction between critical control points and sanitary control plans is more obvious in daily practice and proposed record keeping procedures.

Step 2. Critical Control Points

Table 3 is the part of a typical HACCP plan that identifies the critical control points (step 2) and progresses through the setting of critical limits to listing of the records to be kept. By reviewing the flow-diagram it should be obvious that prevention of the three potential product safety hazards can all be controlled

RAW FRESH/FROZEN CULTURED PENAEID SHRIMP
Production / Processing Flow - Diagram



(TQA)-subject to total quality assurance plan
(*) - critical control point.

Figure 1. Flow - diagram for processing raw cultured penaeid shrimp to produce fresh and frozen shell-on product.

or monitored at harvest and receiving. It is best to prevent or eliminate these problems before they enter processing. If these problems are discovered during or after processing, then corrective actions and possible rejection can be more difficult, less likely and more costly. Critical control points are located at any point where hazards need to be either prevented, eliminated or reduced to acceptable levels. All significant hazards identified in step 1 must be addressed by an effective critical control point. Identifying and locating these points requires an understanding of basic food safety and the processing operations. For this reason, training is a mandatory part of FDA's proposal.

Step 3. Critical Limits

In many instances, the critical limits or permissible levels for certain processing conditions, various chemical residues and microbial concerns have been established by previous regula-

Table 3. Raw cultured Penaeid Shrimp HACCP Plan: Steps 2 through 6.

Safety Hazards	Critical Control Points	Critical Limits	Monitoring	Corrective Action	Record
1. Chemical Contamination	Product receiving from pond	TQA	Specific analysis as necessary if deviation from TQA	Reject product with contamination or unapproved chemicals	TQA & any analytical work, NUOCA
2. Food Additives	Product receiving from pond	Preservative: bisulfite residual, 100 ppm edible portion	Residual screening, periodic and as needed, 3 steps: a. Sulfite test strips b. Malachite green test c. M-W verification (AOAC process) outside lab	Reject product over 100 ppm sulfite residual on edible portion	Progressive test results per pond harvest
3. Aquaculture Drugs	Product receiving from ponds	TQA	Specific analysis as necessary if deviation from TQA	Reject product improperly treated or containing illegal drug residuals	TQA and analytical results, NUOCA
4. Temperature Abuse	Storage - Refrigerator - Freezer	below 40°F (4.4°C) below 0°F (-18°C)	Continuous Time - Temperature Charts (optional periodic monitoring)	Examine for acceptable product and reduce product temperature	Time - Temperature chart or Periodic Records. Periodic Calibrations

TQA - Total Quality Assurance program for culture production
NUOCA - Notice of Unusual Occurrence and Corrective Actions

tions (FDA 1994-draft), but other hazards may require special consideration. Without previous approvals, established use or designated action levels. processors should consider zero critical limits for certain pesticides and drugs. For example there is a zero tolerance for chloramphenicol in aquacultured shrimp. With the tendency for introduction of new pesticides and antibiotics through water and feed, shrimp processors should monitor on the side of caution. Additional information on legal drugs and pesticides for aquaculture use can be obtained through the FDA Center for Veterinary Medicine, Office of New Drug Evaluations in Rockville, Maryland and the FDA Office of Seafoods in Washington. DC. Their roles and activities are explained in a useful publication produced by the USDA (1992). Critical limits must be set as the guidelines for critical control point compliance. Effectiveness and acceptance of a HACCP plan rest with current and appropriate critical limits.

Step 4. Monitoring

The HACCP plan should list the actual procedures to be used in monitoring the critical control points to assure the shrimp stay within the stated critical limits. Routine pesticide and drug analysis is not practical for most shrimp processing firms. As a preventative measure some aquaculture operations have drafted a total quality assurance (TQA) plan for the entire production procedure (Table 4a). The TQA specifies how and when all approved chemicals are used, throughout all stages of pond production. Any deviations should be justified and recorded. Unintentional deviations may require water and product analysis by an appropriate lab to assure compliance with the critical limits as a declaration of the companies commitment to product safety before processing. Good TQA examples can be obtained from the Catfish Farmers of America (1993) and the US Trout Farmers Association (1994). Their programs feature standards for farm management practices, water quality. broodstocks, feeds and feeding, and animal health, including use of medication. All TQA participants agree to maintain records for medication and chemical applications. Their agreements are a voluntary pledge that can be substantiated with a 'verifier' with appropriate professional experience. These records can supplement a processors' HACCP records.

Routine procedures for field and process plant application do exist for monitoring of sulfite residuals on the edible portion of shrimp. Sodium bisulfite and metabisulfite have been used to control 'blackspot' or melanosis on penaeid shrimp since the early 1950's. These reducing agents retard the natural polyphenoloxidase enzymes that create the black surface pig-

Table 4a. Total Quality Assurance (TQA) record for cultured shrimp production. This example is based on the recommended Total Quality Assurance programs by the Catfish Farmers of America (1992) and US Trout Farmers Association (1994).

Water Quality

Date and Time for Test	Pond	Water Analysis and Reason for Analysis	Product Analysis and Reason	Sampling Plan	Results

Medication and Chemical Application Record

Date and Time for chemical use	Pond	Diagnosis (reason for treatment)	Treatment (drug or chemical used)	Rate / dose	Applicator	Date of last dose	Time of last dose	Withdrawal period expiration (date and time)

ments. Likewise, bisulfites help bleach the pigments thereby imparting a brighter, clean appearance. These actions result in sulfite residuals, both free and bound, on the shell and muscle tissue. Previous studies have concluded the original sanctioned sulfite procedure for shrimp (1.25% bisulfite dip for 1 minute; Camber *et al.* 1957) would leave less than 100 ppm (parts per million) on the edible portion of penaeid shrimp (Finne and Miget 1985). This work substantiated FDA's regulatory action level of 100 ppm (FR 1985 and 1988). Other countries have established sulfite residual action levels ranging from 0 to 60 ppm. Since the original sanctioned procedures were for on-vessel use, commercial practice with sulfiting agents has changed and weaker treatments can offer effective controls for cultured shrimp. The need for action levels still remains due to adverse sulfite-induced allergic-type reactions that can occur most commonly with certain asthmatic consumers. Although there are limited investigations or reported illnesses implicating sulfites as the causative agent on shrimp, the action levels are easily and often enforced.

A three phase test procedure can be used for monitoring sulfite residuals on shrimp (Table -4b). Phase one is a sulfite test paper check that only indicates distinct problems or suspect product. Commercially available sulfite test strips cannot accurately measure parts per million (ppm) on edible shrimp meat, but they can reflect a general level of concern based on the intensity of color changes when touched to the meat surface. The second phase is a malachite-green procedure (DeVries 1985) that can be adjusted to measure acceptance or rejection about a set sulfite residual level. This procedure only requires a blender, balance and pre-mixed dye. Preliminary trials are required to determine the ratio of blended meat to dye that responds to a set residual limit. For an official or FDA recognized analysis, processors must finally rely on the recognized Monier-Williams procedure (AOAC 1990). This procedure requires equipment and expertise beyond the practical capability of most operations.

Step 5. Corrective Action

FDA's proposed HACCP program only recommends firms to pre-consider possible corrective actions in the event that a critical limit is exceeded. Pre-documented corrective action procedures are not required, but recommended. Actions can range from product rejection to various methods of adjustment or reconditioning to assure the product complies with the critical limits. All corrective actions should be recorded with subsequent monitoring to assure the product is in compliance. Specified corrective actions are a probable addition for FDA's final rule.

Step 6. Records

Each critical control point and related monitoring procedure will be accompanied by an actual record of activity (Tables 4a-d). The records may be continuous, i.e., temperature charts for refrigeration, or periodic, i.e., daily lot sampling. The records are the most essential part of the HACCP program. They represent the firm's commitment to product safety, and they can be used to judge company performance. If the HACCP document identifies a certain record, then this form should be available for regulatory review. As proposed by FDA, a company's HACCP performance will be linked with a regulatory ranking for further surveillance. An incentive for accurate and thorough records that reflect on the actual operations and product will be less regulatory scrutiny for the processing firm and/or importer.

If possible all existing records should be considered for direct or modified use as HACCP records so as to minimize the

Table 4b. Typical recording form for critical control point monitoring for sulfite residuals on raw cultured penaeid shrimp.

Raw Cultured Penaeid Shrimp HACCP plan
Records

1. Receiving

Date	Pond*	Sample	Sulfite Residuals			Action
			Test Strip	Malachite Green	M - W	

Key to Positive Results:

Test Strip Ratings: 1. <l00 ppm (pink), 2. Suspect, 3. >I00 ppm (brick red)
Malachite Green Score: 1. <l00 ppm, 2. Suspect, 3. >I00 ppm
M - W (official procedure, Monier-Williams, AOAC, 1990): Average ppm for three tests /outside lab. (list name)

*Sampling.- Random accumulative sample, as product is received at the processing plant. Sample initial, med and latter portion of off-loading. Total sample size 20 - 30 lbs. Subsamples for each test procedure: test strip - 6 samples; MG - 6 samples; M - W.3 samples. Samples taken per pond harvest with or without sulfite treatments.

amount of record keeping. For example, an invoice or record of incoming product could also identify checks for sulfite residuals. Combining records can be useful, but it should not compromise confidential production information. FDA's proposed regulatory concerns rest primarily with product safety. All HACCP records must be maintained or filed for one to two years if the products are fresh or frozen, respectively.

Step 7. Verification

FDA's proposed mandatory HACCP proposal does not require a verification plan. Verification is considered a company responsibility to assure their HACCP plan is effective. Verification can involve periodic end-product testing, in-plant and outside audits, and annual plant reviews. Verifications can also include calibrations or checks on monitoring methods or devices. Any change or addition to the processing operations would require modification of the HACCP plan and verification. FDA's final HACCP rule will most likely include some verification requirement. The ultimate verification is an FDA HACCP inspection.

SANITATION CONTROL PLAN

In addition to the basic HACCP plan with critical control points for product safety, FDA has proposed that every processing firm should have a written sanitation control plan that includes adequate record keeping for performance. This requirement is one of the more controversial and debated parts of FDA's HACCP proposal. The requirement basically addresses all "good manufacturing practices" and emphasizes certain points for particular attention. Concerns range from cleanliness and sanitation of operations, equipment, surfaces, and clothing, etc. to personnel hygiene, pest control, time-temperature controls, etc. The expectations are reasonable, but tedious record keeping requirements have been questioned.

Assuming record keeping is required or generally accepted by a firm, these sanitation record keeping procedures could be segregated by plant operations managers and by time (Table 4c-d). Most sanitation procedures require 'continuous monitoring' which could be recorded by the actual 'begin and end' working time of an assigned employee (Table 4c). For the more routine periodic procedures, i.e. daily, weekly or monthly activities, may require actual logs to designate completion of procedures (Table 4d).

SUMMARY

Despite the safety record for consumption of cultured penaeid shrimp, as for all seafoods, further regulatory scrutiny is expected in the form of HACCP programs. The safety associated with raw cultured shrimp is evidenced by the simplicity of the HACCP plan for raw cultured shrimp. Following FDA's proposed HACCP mandate, firms can anticipate needs for TQA plans and monitoring for sulfite residuals and storage temperatures. In the United States the burden of proof for HACCP compliance is proposed to rest with the domestic importer. Processors should initiate HACCP planning to gain experience in advance of the final FDA rule expected in mid- 1995.

Table 4c. Partial example for a daily sanitation record for ‘continuous items’ to be controlled in a shrimp processing plant sanitary control plan. The record is structured by plant personnel responsible for items that require continuous attention. Deviations and corrections in procedures are recorded asNUOCA’s (notice of unusual occurrences and corrective actions) and compliance is denoted by the appropriate daily signature.

Any Shrimp Co., Inc.
Daily Sanitation Record

Continuous Items (From pre-operation review thru end of work day)	**NUOCA**
- 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.	
- 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.	

_____Date_____ _____Date_____
HACCP Record Manager Plant Manager

Table 4d. Partial example for a daily sanitation record for 'periodic' items to be controlled in a shrimp processing plant's sanitary control plan. The recorded is structured for the personnel responsible for certain items that require periodic attention at specified time. Deviations and corrections in procedures are recorded as NUOCA's (notice of unusual occurrence and corrective action) and daily compliance is denoted by the appropriate signature

Any Shrimp Co., Inc.
Daily Sanitation Record

"Periodic Items"(D=Daily Time; W=Weekly Time & Day)	**Time & NUOCA**
- Conduct Pre-operation review for general plant condition and sanitation. including workers. Listed time marks beginning for "continuous" records.	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 weekly. All waste containers should be clean and sanitize daily.	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 rodent 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:	

* D = time of day W = time of week

_____Date_____ _____Date_____
HACCP Record Manager Plant Manager

Processors should note that HACCP regulations are not intended to replace existing regulations. In reality. the proposed program is in addition to current regulations. Imported shrimp processed under a HACCP plan are still subject to product sampling and possible rejection. particularity for decomposition, filth, chemical contaminants, microbial content, improper labeling and various economic frauds. The advantage of an effective, recognized HACCP plan is proposed to be less regulatory scrutiny. HACCP is an honor system with the reward of product/firm confidence. This concept is new, evolving and a significant challenge for international seafood commerce.

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