# Example
# SSOP Plan and Sanitation Control Records

## Introduction

As mentioned in the introductory chapter, a complete food safety program includes both HACCP and accompanying sanitation control procedures. Similar to documenting procedures in a HACCP plan, sanitation standard operating procedures (SSOP) outline how a firm will maintain sanitary control within the plant.

Although a written SSOP plan is not required by the FDA, it is recommended to explain the in-plant procedures the firm will follow to control, monitor and correct the key sanitation conditions and practices covered in the previous chapter of this manual. SSOP plans are recommended because they:

- describe the sanitary procedures to be used in the plant;
- provide the schedule for the sanitation procedures;
- provide a training tool for employees;
- identify trends and prevent re-occurring problems;
- ensure that everyone, from management to production workers, understands acceptable sanitation practices;
- provide the foundation to support a routine monitoring program;
- encourage prior planning to ensure that corrrections are taken when necessary;
- demonstrate commitment to buyers and inspectors; and
- lead to improved sanitary practices and conditions in the plant.

Like HACCP plans, SSOP should be specific to each plant. SSOP should describe the plant's procedures associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them. Plants can choose to develop **informal** or **formal** SSOP plans. **Informal** SSOP may simply outline the frequency and procedures to be followed to control, monitor and correct deficiencies for a specific task or sanitation concern. The Model SSOP Plan on the following pages illustrates an informal SSOP. **Formal** SSOP are written to follow a standard format, so each SSOP is developed to contain standard information. Prior to developing a **formal** SSOP plan, firms would design a standard format to use for each individual SSOP. The standard format may include some or all of the following sections:

- purpose or objective of the SSOP;
- scope or relevance of the SSOP (e.g., preparation of hand dip stations in RTE product packing room);
- responsibility (e.g., the individual or job description responsible for implementing and/or monitoring the procedures in the SSOP);
- materials and equipment (e.g., listing any special tools or equipment needed to carry out the task and/or monitoring activity);
- procedures (documentation of the procedures necessary to carry out the SSOP);
- frequencies (how often the procedure in the SSOP will be used);
- documentation of changes (records why changes were made to SSOP and documents version numbers so the most recent version is being used); and
- approval section (e.g., signatures of acceptance by plant management).

There is no right or wrong way to write an SSOP, the important point to remember is that the SSOP should be easy to use and follow. An SSOP plan that is not followed will not be beneficial to the firm. The two most important aspects of any type of SSOP -- either informal or formal -- is that: 1) enough detail is provided for someone to carry out the task in question, and 2) the procedures listed accurately reflect the activities that are being conducted. An SSOP with too much detail may be counter-productive because strict adherence to the procedures may be difficult to achieve every time and it is likely to be informally modified over time. Likewise, an SSOP without enough detailed information will not be useful for a plant because the user will need to "fill in the blanks" to figure out how to complete a task.

If a company chooses to develop an SSOP plan, it will support the required sanitation control monitoring, record keeping, and correction activities. However, some firms may find the prospect of writing an SSOP plan to be overwhelming, even though the SSOP plan will prove to be very worthwhile in the long run. An easy way to start writing SSOP is to think through each sanitation operation that is being conducted in the plant and document how it is conducted, where it is being conducted, and who is responsible for conducting the operation. In addition, think through how the sanitation control procedure will be monitored, recorded and corrected if there is a deviation. Simply writing down the sanitation procedures that are currently being conducted in the plant is the first step to developing an SSOP plan.

The following example is one approach that can be used to develop an SSOP plan and accompanying sanitation control records. As explained in all previous chapters, proper monitoring for sanitary conditions and practices requires employee training and understanding of the appropriate procedures. The details necessary for training are usually too lengthy and could be redundant for placement on the sanitation monitoring forms. Brief descriptions of the monitoring requirements help to reduce the amount of paper involved and serve as simple reminders for the actual sanitation monitoring procedures.

# Sanitation Standard Operating Procedures (SSOP) Plan

The model SSOP Plan in Table 1 addresses the sanitation concerns for a fictional seafood company processing a cooked ready-to-eat seafood product. The SSOP sections are based on the eight FDA key sanitation conditions. This information could be further explained and strengthened by Sanitation Control Guides as provided with each previous chapter. Although the approaches may differ, sanitation procedures, monitoring requirements, and necessary corrections all emphasize the importance of a written SSOP plan to support and explain the monitoring requirements and necessary corrections.

SSOP plans will vary from facility to facility because each facility and process is designed differently. This SSOP plan is for illustrative purposes and does not constitute a recommendation by the Seafood HACCP Alliance. The use of trade names does not constitute endorsement by the Seafood HACCP Alliance for any specific product.

# Developing Sanitation Control Records

Monitoring forms for Sanitation Control Records are generated from the written SSOP plan. These monitoring control forms provide records for each FDA key sanitation condition. The "Daily Sanitation Records" (Table 2) and the "Periodic Sanitation Records" (Table 3) are based on the SSOP plan in Table 1. Outline numbers and letters in the monitoring forms correspond to specific sections of the SSOP plan.

**Table 1. Model SSOP Plan**

# Sanitation Standard Operating Procedure

1. **Safety of Processing Water and Ice** (FDA Key Sanitation Condition No. 1)

   **Controls and Monitoring:**

   a. All water used in the plant is from a reliable municipal water system. Municipal water bills indicate that the water source is safe. **Monitoring Frequency: Annually.**

   b. The water system in the plant was designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. Copies of building inspection reports indicate that the plumbing system is properly constructed. **Frequency: When plumbing is installed or modified.**

   c. All water faucets and fixtures inside and outside the plant have antisiphoning devices installed. Water faucets and fixtures are inspected for the presence of antisiphoning devices. **Monitoring Frequency: Daily before processing.**

   **Corrections:**

   a. In the event of municipal water treatment failure, the plant will stop production, determine when the failure occurred, and hold products produced during the failure until product safety can be assured. Production will resume only when water meets state and federal water quality standards.

   b. Corrections will be made to the plumbing system, if necessary, to correct problems. Production will resume only when water meets state and federal water quality standards.

   c. Water faucets and fixtures without antisiphoning devices will not be used until antisiphoning devices have been installed.

   **Records:**

   a. Municipal water bill and periodic sanitation record.

   b. Building plumbing inspection report and periodic sanitation record.

   c. Daily Sanitation Control Record

2. **Condition and Cleanliness of Food Contact Surfaces, Including Utensils, Gloves, and Outer Garments** (FDA Key Sanitation Condition No. 2)

**Controls and Monitoring:**

a. Food contact surfaces are adequately cleanable (do not have cracks, cavities, crevices, overlapping joints, mineral scale, etc. that are not possible to adequately clean and sanitize). The sanitation supervisor inspects food-contact surfaces to determine if they are adequately cleanable. **Monitoring Frequency: Daily**

b. Food-contact surfaces are cleaned and sanitized:

1) Before operations begin, food-contact surfaces are rinsed with cold water and sanitized with a 100 ppm sodium hypochlorite sanitizer. The sanitation supervisor inspects food-contact surfaces to determine if they are sanitized. **Monitoring Frequency: Before operations begin.**

2) During breaks, major solids are physically removed from floors, equipment, and food-contact surfaces. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120°F) water. All surfaces and floors are rinsed with cold water. Check sanitizers and food contact surfaces. Food-contact surfaces are sanitized with a 100 ppm sodium hypochlorite sanitizer solution. Floors are sanitized with a 400 ppm quaternary ammonium chloride sanitizer. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner, rinsed in hot water (190°F), soaked in a 100-ppm sodium hypochlorite sanitizer for at least 10 minutes, and rinsed in hot water (190°F) prior to use. The sanitation supervisor checks sanitizers before use and inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the 4 and 8-hour breaks.**

3) At the end of daily operations, major solids are physically removed from floors, equipment, and food-contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120°F) water. All surfaces and floors are rinsed with cold water. Floors and walls are sprayed with a 400 ppm quaternary ammonium chloride sanitizer solution. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner in warm (120°F) water, rinsed in hot water (190°F), soaked in a 100 ppm sodium hypochlorite sanitizer for at least 10 minutes, and air dried. The sanitation supervisor inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the end of operations.**

c. Workers wear clean gloves and outer garments.

1) Workers working with raw and cooked product wear clean gloves, clean outer garments, waterproof aprons, and waterproof boots. Waterproof aprons are cleaned and sanitized twice each day, at the midday break and at the end of the shift.

2) Administrative personnel wear smocks and waterproof boots when in processing areas. Smocks are laundered in-house as needed.

3) Maintenance workers wear gray uniforms and waterproof boots. Uniforms are laundered in-house as needed.

4) Production supervisors monitor the use of gloves and the cleanliness of workers' outer garments. **Monitoring Frequency: Before operations and after each break.**

**Corrections:**

a. Food-contact surfaces that are not adequately cleanable are repaired or replaced.

b. Adjust sanitizer concentration. Food-contact surfaces that are not clean are cleaned and sanitized.

c. Gloves that become a potential source of contamination are cleaned and sanitized or replaced. Outer garments that become a potential source of contamination are cleaned and sanitized or replaced.

**Records:**

a-c. Daily Sanitation Control Record

**3. Prevention of Cross-Contamination** (FDA Key Sanitation Condition No. 3)

**Controls and Monitoring:**

a. Production supervisors have received basic food sanitation training. Plant manager schedules basic food sanitation courses for new production supervisors. **Monitoring Frequency: When production supervisors are hired.**

b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).

1) Workers wear hairnets, headbands, caps, beard covers, or other effective hair restraints and do not wear jewelry or other objects that might fall into the product, equipment, or containers.

2) Workers wear disposable gloves and replace them as needed.

3) Workers wash their hands and gloves thoroughly and sanitize them before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated.

4) Clothing and personal belongings are not stored in production areas.

5) Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas.

6) Workers wear color-coded aprons (blue in raw product areas and white in cooked product areas) and are not allowed to enter or pass through other processing areas.

7) Workers sanitize their boots in boot baths containing 800-ppm quaternary ammonium chloride sanitizer solution before entering processing areas.

8) Production supervisors monitor employee practices. **Monitoring Frequency: Before operations and every four hours during production.**

c. Boot sanitizing solutions are checked every four hours during production. Sanitation supervisor checks boot sanitizing solutions. **Monitoring Frequency: Before operations and every four hours during production.**

d. Plant grounds are in a condition that protects against contamination of food. Sanitation supervisor inspects plant grounds. **Monitoring Frequency: Daily before operations.**

e. Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste. **Monitoring Frequency: Every 4 hours.**

f. Floors are sloped to facilitate drainage. Processing area floors are inspected for adequate drainage. **Monitoring Frequency: Daily before operations.**

g. Plant buildings are maintained in good repair. Raw-product processing and cooked-product processing areas are separated. Coolers, including the evaporators, are cleaned annually, or more often if needed. Nonfood-contact surfaces in processing and packaging areas are cleaned daily at the end of the shift. Raw and cooked products are physically separated in coolers. Packaging materials are protected from contamination during storage. Sanitation supervisor inspects plant. **Monitoring Frequency: Daily before operations.**

h. Cleaning and sanitizing equipment is color-coded for specific plant areas: blue for raw-product processing areas, white for cooked-product processing areas, and yellow for toilet facilities and general plant cleaning. Sanitation supervisor observes that proper equipment is used. **Monitoring Frequency: At each cleanup period.**

**Corrections:**

a. New production supervisors receive basic sanitation instruction.

b. Workers correct deficiencies in hair restraint use, jewelry use, glove use, hand washing, personal belonging storage, eating and drinking in processing areas, and boot sanitizing before working with raw or cooked products.

c. Boot sanitizing solution is changed.

d. Sanitation supervisor initiates correction of potentially contaminating condition.

e. Waste is removed

f. Floors with standing water will have the drains unplugged, or, if necessary, consultations will be held with plumbing or general contractors and corrections will be made to correct floor drainage problems.

g. Sanitation supervisor initiates correction of potentially contaminating condition including assessment of product quality.

h. Sanitation equipment that is being used in the wrong plant area is cleaned and sanitized and exchanged for correct equipment. Sanitation supervisor initiates correction of potentially contaminating condition.

**Records:**

a. Periodic Sanitation Control Record or training record

b-h. Daily Sanitation Control Record

**4. Hand Washing/Sanitizing, and Toilet Facilities** (FDA Key Sanitation Condition No. 4)

**Controls and Monitoring:**

a. Toilet facilities are provided off the workers' dressing room, physically separated from processing areas. Toilet facilities have self-closing doors, are maintained in good repair, and are cleaned and sanitized daily at the end of operations. Sanitation supervisor inspects the toilet facilities and hand washing facilities. **Monitoring Frequency: Daily before operations and every 4 hours during operations.**

b. Handwashing/sanitizing facilities are provided in raw and cooked processing areas and in the toilet facility. Hand washing facilities have: hot and cold running water with foot activated valves; liquid sanitizing hand soap; hand sanitizer solutions that are changed every 4 hours during production; sanitary towel service; signs directing workers to wash their hands and gloves thoroughly. Hands should be washed and sanitized before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated. Sanitation supervisor inspects the hand washing facilities and checks hand sanitizer strength. **Monitoring Frequency: Daily before operations and every 4 hours during operations**.

**Corrections:**

a. Sanitation supervisor initiates cleaning of dirty toilet facilities and correction of any potentially contaminating condition. Repairs are made as needed.

b. Sanitation supervisor restocks facilities or adjusts sanitizers.

**Records:**

a-b. Daily Sanitation Control Record

**5. Protection of Food, Food-Packaging Material, and Food-Contact Surfaces from Adulteration** (FDA Key Sanitation Condition No. 5)

**Controls and Monitoring:**

a. Cleaning compounds, sanitizers, and lubricants used in processing and packaging areas are approved for use in food plants. Receiving manager checks invoices at receiving before food-grade chemicals are stored. **Monitoring Frequency: When cleaning compounds, sanitizers, and lubricants are received.**

b. Food-grade and non-food-grade chemicals and lubricants are stored separately outside processing and packaging areas. Sanitation supervisor inspects chemical storage areas. **Monitoring Frequency: Daily before operations.**

c. Food, food-packaging materials and food-contact surfaces are protected from adulteration from biological, chemical and physical contaminants. Safety-type light fixtures are used in processing and packaging areas. Sanitation supervisor inspects processing and packaging areas. **Monitoring Frequency: Daily before operations and every 4 hours.**

d. Equipment is in good repair with no loose or missing metal parts. Sanitation supervisor inspects processing and packaging equipment. **Monitoring Frequency: Daily before operations.**

e. Drip or condensate does not contaminate food or packaging materials. **Monitoring Frequency: Pre-op and at 4 and 8-hour breaks.**

**Corrections:**

a. Unapproved chemicals are returned or used in non-processing areas.

b. Improperly stored chemicals are moved to the correct storage area.

c. Safety of the product is examined.

d. Repairs are made as needed.

e. Sanitation supervisor corrects any condensation problems.

**Records:**

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

**6. Labeling, Storage, and Use of Toxic Compounds** (FDA Key Sanitation Condition No. 6)

**Controls and Monitoring:**

a. All toxic compounds used in the plant are labeled with the manufacturer's name, use instructions, and the appropriate EPA approval, or have documentation with the necessary information. Receiving manager verifies that this information is present before toxic compounds are stored. **Monitoring Frequency: When toxic compounds are received.**

b. Cleaning compounds, sanitizing agents, lubricants, pesticide chemicals, and other toxic compounds are properly labeled and stored in a closed and locked cage in dry storage outside processing and packaging areas and separately from food-grade chemical, food-grade lubricant, and packaging material storage. Only authorized personnel have access to the cage. Sanitation supervisor checks cage for cleanliness and container leakage. **Monitoring Frequency: Daily before operations.**

c. All manufacturers' instructions and recommendations are followed. Only authorized personnel fill small working containers, such as containers of hand sanitizing compounds. These containers are properly marked with the common name of the chemical and are not stored in any way that may cause the chemical to fall or drip onto food or food-packaging materials. Sanitation supervisor verifies proper procedures and labeling. **Monitoring Frequency: Daily before operations.**

**Corrections:**

a. Toxic compounds without proper information are placed on hold until information is obtained. Toxic compounds without documentation are returned to the supplier.

b. Improperly stored chemicals are moved to the correct storage area. Leaking containers are resealed or replaced as necessary. Storage cage will be cleaned by the next working day.

c. Misuse of toxic compounds results in disciplinary action or retraining. Potentially contaminated food is discarded or destroyed. Improper labeling of working containers is corrected.

**Records:**

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

**7. Employee Health** (FDA Key Sanitation Condition No. 7)

**Controls and Monitoring:**

a. Workers report to their immediate supervisor any health condition that might result in food contamination. Supervisors report suspected health problems to the plant manager. The plant manager decides if a potential food contamination situation exists. **Monitoring Frequency: Daily before operations.**

b. Supervisors check for infected lesions that might contaminate food. **Monitoring Frequency: Daily before operations.**

**Corrections:**

a. Workers who represent a potential risk are sent home or reassigned to non-food-contact jobs.

b. Cover lesion with impermeable bandage, reassign, or send worker home.

**Records:**

a-b. Daily Sanitation Control Record

**8. Pests** (FDA Key Sanitation Condition No. 8)

**Controls and Monitoring:**

a. A pest management firm treats the outside of the building. They also inspect the interior of the building and treat as necessary with appropriate chemicals. **Monitoring Frequency: Every other month.**

b. Plant grounds and interior areas are kept free of litter, waste, and other conditions that might attract pests. Outer plant doors are kept closed, processing areas are screened with plastic curtains, and electric bug-killing devices are located outside entrances to processing areas. No pets are allowed in the plant. Supervisors report any pest problems to the plant manager. The sanitation supervisor inspects for the presence of pests. **Monitoring Frequency: Daily before operations.**

**Corrections:**

a. Conditions that may cause pest problems are corrected.

b. The pest management firm is notified of any pest problem and treats the problem. Pest treatments are more frequent if problems are identified.

**Records:**

a. Periodic Sanitation Control Record

b. Daily Sanitation Control Record

## Table 2.

| Daily Sanitation Control Record | Date: | | | |
|---|---|---|---|---|
| **Firm:** | Mark S/U | | | |
| **Address:** | | | | |
| **Products being processed: (?)** | Pre-Op | 4-Hour | 8-Hour | Post-Op |
| **Condition** | Time: | Time: | Time: | Time: |
| **1. Safety of Water and Ice:** | | | | |
| c. Water faucets and fixtures have anti-siphoning devices. | | | | |
| **2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments:** | | | | |
| a. Equipment and utensils are adequately cleanable. | | | | |
| b. Sanitation strength (ppm)/food contact surfaces and utensils are clean and sanitized. | | | | |
| c. Gloves/garments contacting food are clean and sanitary. | | | | |
| **3. Prevention of cross-contamination:** | | | | |
| b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing). | | | | |
| c. Boot sanitizer strength is adequate (ppm). | | | | |
| d. Plant grounds are in good condition. | | | | |
| e. Waste is removed from processing areas. | | | | |
| f. Floors have adequate drainage. | | | | |
| g. Plant buildings in good repair. | | | | |
| Raw and cooked-product processing areas separated. | | | | |
| No drip over food or packaging materials. | | | | |
| Safety-type lighting used. | | | | |
| Coolers and evaporators are clean. | | | | |
| Non-food-contact surfaces are clean. | | | | |
| Cooked and raw products physically separated in coolers. | | | | |
| Packaging materials protected from contaminants. | | | | |
| h. Proper color-coded sanitation equipment is used. | | | | |

**Table 2. (Continued )**

| **Daily Sanitation Control Record** | **Date:** | | | |
|---|---|---|---|---|
| **Firm:** | Mark S/U | | | |
| **Address:** | | | | |
| **Products being processed: (?)** | Pre-Op | 4-Hour | 8-Hour | Post-Op |
| **Condition** | Time: | Time: | Time: | Time: |
| **4. Hand Washing Sanitizing, and Toilet Facilities:** | | | | |
| a. Toilets facilities are clean, sanitary and in good repair. | | | | |
| b. Hand sanitizer strength (ppm)/hand washing and sanitizing supplies. | | | | |
| **5. Adulteration:** | | | | |
| b. Food-grade chemicals identified and stored properly. | | | | |
| c. Food, food-packaging materials and food-contact surfaces are protected from adulteration. | | | | |
| d. Equipment is in good repair. | | | | |
| e. Drip and surface condensate. | | | | |
| **6. Toxic compounds:** | | | | |
| b. Toxic compounds identified and stored properly. | | | | |
| c. Proper containers and procedures are used. | | | | |
| **7. Employee Health:** | | | | |
| a. Employee health conditions are acceptable. | | | | |
| b. Employees do not have infected lesions. | | | | |
| **8. Pests:** | | | | |
| No pests in plant. | | | | |
| **Comments & Corrections:** | | | | |
| | | | | |
| | | | | |
| Report by: | | | | |
| S = Satisfactory / U = Unsatisfactory | | | | |

## Table 3.

| Periodic Sanitation Control Record | | | Date: |
|---|---|---|---|
| **Firm Name:**<br><br>**Firm Address:** | | | |
| **Condition** | **S** | **U** | **Comments/Corrections** |
| **1. Safety of Water and Ice:** | | | |
| a. Municipal water bill (annually). | | | |
| b. Building plumbing inspection report (when plumbing is modified). | | | |
| **3. Prevention of cross-contamination:** | | | |
| a. Production supervisors have received basic food sanitation training (when hired). | | | **Name(s):** |
| **5. Adulteration:** | | | |
| a. Invoices for food-grade chemicals checked before chemicals are stored (when received). | | | |
| **6. Toxic compounds:** | | | |
| a. Labels or documents for toxic compounds checked before compounds stored (when received). | | | |
| **8. Pests:** | | | |
| a. Pest management firm's report is satisfactory (every other month). | | | |
| **Comments and Corrections:** | | | |
| | | | |
| | | | |
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| | | | |
| | | | |
| **Report by:**<br>S = Satisfactory / U = Unsatisfactory | | | |

## Table 4. Chemicals Approved for Use in Plant

| Chemical | Strength | Dilution |
|---|---|---|
| **Chlorinated Alkaline Cleaner**<br>Brand: Clean-Up Now<br>Usage: Equipment, food-contact surfaces, utensils, toilet facilities | | 1/4 cup concentrate to 6 gallons water (26 mL concentrate to 10 L water) |
| **Liquid Sanitizing Hand Soap**<br>Brand: L-Sanitizer<br>Usage: Hand washing facilities | | Undiluted |
| **Sodium Hypochlorite Sanitizer**<br>Brand: Hypo-Sanitizer<br>Usage: Food contact surfaces | 100 ppm | 1/4 cup concentrate to 13 gallons water (12 mL concentrate to 10 L water) |
| **Quaternary Ammonium Sanitizer**<br>Brand: QA-Sanitizer<br>Usage: Floors<br>Usage: Boot sanitizing baths | 400 ppm<br>800 ppm | 1/4 cup concentrate to 4 gallons water (39 mL concentrate to 10 L water)<br>1/4 cup concentrate to 2 gallons water (7.75 mL concentrate to 10 L water) |
| **Iodine Sanitizer**<br>Brand: I-Sanitizer<br>Usage: Hand sanitizing solutions | 25 ppm | 1/4 cup concentrate to 26 gallons water (6 mL concentrate to 10 L water) |
| **Lubricants**<br>Brand: Wizard Grease<br>Usage: Food processing equipment<br>Brand: White Grease<br>Usage: Non-food processing areas | | |

Revised: 3/17/99
Reviewed by (Plant Manager): _____ Date: _____

# SSOP Record

1. Municipal water bills are reviewed and kept on file for two years.
2. Building plumbing inspection reports are reviewed and kept on file for two years.
3. Daily and Periodic Sanitation Reports are reviewed and kept on file for two years.
4. Invoices for food-grade chemicals and lubricants are reviewed and kept on file for two years.

# Appendix A
# Seafood HACCP Regulation

## Title 21 of the Code of Federal Regulations Part 123 - Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule (Dec. 18, 1995)

### Subpart A—General Provisions

**§ Sec. 123.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c) Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food safety hazard means any biological, chemical, or physical property that may cause a foodto be unsafe for human consumption.

(g) Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k) (1) Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) Shall is used to state mandatory requirements.

(o) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) Shellstock means raw, in-shell molluscan shellfish.

(q) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s) Smoked or smoke-flavored fishery products means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and
(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

**§ Sec. 123.5 Current good manufacturing practice.**

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

**§ Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan.**

(a) Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:
(1) Each location where fish and fishery products are processed by that processor; and
(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods to gether, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:
(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:
(i) Natural toxins;
(ii) Microbiological contamination;

(iii) Chemical contamination;
(iv) Pesticides;
(v) Drug residues;
(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
(viii) Unapproved use of direct or indirect food or color additives; and
(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:
(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with Sec.123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:
(i) Upon initial acceptance;
(ii) Upon any modification; and
(iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).

(e) Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of Clostridium botulinum toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

**§ Sec. 123.7 Corrective actions.**

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs(c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the recordkeeping requirements of Sec. 123.9.

**§ Sec. 123.8 Verification.**

(a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).

(2) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.

(d) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of Sec. 123.9.

**§ Sec. 123.9 Records.**

(a) General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;
(2) The date and time of the activity that the record reflects;
(3) The signature or initials of the person performing the operation; and
(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) Record retention.

(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.
(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.
(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) Public disclosure. (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

(f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

**§ Sec. 123.10 Training.**

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and

(c) Performing the record review required by Sec. 123.8(a)(3); The trained individual need not be an employee of the processor.

**§ Sec. 123.11 Sanitation control procedures.**

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
(6) Proper labeling, storage, and use of toxic compounds;
(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

**§ Sec. 123.12 Special requirements for imported products.**

This section sets forth specific requirements for imported fish and fishery products.

(a) Importer verification. Every importer of fish or fishery products shall either:
(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:
(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,
(ii) Affirmative steps that may include any of the following:
(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.

(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

## Subpart B—Smoked and Smoke-flavored Fishery Products

### § Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

### § Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by Clostridium botulinum for at least as long as the shelf life of the product under normal and moderate abuse conditions.

## Subpart C—Raw Molluscan Shellfish

### § Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

### § Sec. 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;
(2) The location of harvest by State and site;
(3) The quantity and type of shellfish;
(4) The date of receipt by the processor; and
(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;
(2) The quantity and type of shellfish; and
(3) The name and certification number of the packer or repacker of the product.

## Part 1240—Control of Communicable Diseases

2. The authority citation for 21 CFR part 1240 continues to read as follows:

AUTHORITY: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

**§ Sec. 1240.3 General definitions.**

(r) Molluscan shellfish. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

**§ Sec. 1240.60 Molluscan shellfish.**

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.