Processing Mussels
-The HACCP Way

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Preface

In January 1994 the U.S. Food and Drug Administration (FDA) published a “Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products” in the Federal Register. FDA published their final rule, “Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products,” on December 18, 1995 with an implementation date of December 18, 1997. In the introduction to the final rule, FDA stated “The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control that can be used by processors to ensure the safety of their products to consumers. FDA is issuing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.”

This publication is intended to provide mussel processors with information on the HACCP concept and on developing HACCP Plans for mussel processing. The information in this publication should be used only as a guide. Written HACCP Plans must be species, plant, and process specific. They must reflect the actual processing and handling conditions found in each seafood plant.

Robert Price
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Hazard Analysis Critical Control Point (HACCP) Concept

**What is HACCP?**

HACCP (pronounced “HASSIP”) is a difficult name for a simple and effective way to ensure food safety. HACCP stands for the “Hazard Analysis and Critical Control Point” system. It allows you to predict potential risks to food safety and to prevent them before they happen. By using the HACCP approach to food safety, you will no longer have to rely solely on routine inspections to spot and control potential food safety hazards.

**How Will HACCP Help You?**

Food safety is key to good business. Selling unsafe foods can cause illness, lost sales, and lost customers. Keeping foods safe means jobs, good business, and happy customers.

You probably already know that mussels may cause illness. As a mussel processor, you must understand the importance of food safety. And you know that it is your responsibility to provide safe foods. The HACCP system is the best way to keep foods safe.

The HACCP system has other benefits as well. HACCP focuses only on critical areas, and thus saves time. HACCP makes inspections more useful by concentrating only on potential problems. Once you identify problems, you can easily correct them.

Records produced for the HACCP system also have benefits. Tracking food temperatures and other data lets employees become interested in food safety. This interest can lead to better food handling, improved food quality, and improved pride in their work.

**Is HACCP New?**

In the 1960s, the Pillsbury Company developed HACCP for foods as a part of its effort to produce foods for the space program. You can imagine how serious it would be if astronauts got food poisoning in space. So Pillsbury developed a system to predict and prevent food safety problems during food processing and handling.

Pillsbury’s system identified potential problems with food safety in advance and set up methods to control each possible hazard. The company kept records to make sure the controls worked. With this HACCP safety system, Pillsbury made safe foods. Testing the foods for safety was unnecessary. The HACCP system prevented food safety problems.

Today, many food companies use the HACCP system to make sure their products are safe. The U.S. Food and Drug Administration (FDA), Department of Agriculture, and Department of Commerce all encourage HACCP safety plans for food processing. This includes processing of aquacultured mussels.
THE SEVEN STEPS IN HACCP

The major goal of any HACCP system is to prevent food safety problems from occurring. A HACCP food safety system has seven basic steps. Each step is necessary for the overall program to work. The seven steps are these:

1. Identify potential food safety hazards (conduct a Hazard Analysis)
2. Determine where and when to prevent problems (determine Critical Control Points)
3. Set limits to control potential problems (establish Critical Limits)
4. Set up methods to monitor limits (establish Monitoring Procedures)
5. Set up procedures to handle control problems (define Corrective Actions)
6. Use record keeping to check that controls work (establish a Record-Keeping system)
7. Verify that the HACCP system works properly (establish Verification Procedures)

Let’s examine each step in turn.

Step 1. Identify potential food safety hazards (Hazard Analysis).

Hazard. A Hazard is any food property that may cause an unacceptable health risk to your customers. Hazards may be biological, chemical, or physical.

- Biological hazards include the presence of harmful bacteria, viruses, or other microorganisms
- Chemical hazards include natural toxins, heavy metals, drug residues, and improperly used pesticides, cleaning compounds, and food or color additives
- Physical hazards include foreign objects that may cause illness or injury - for example, metal, glass, plastic, and wood

Hazard Analysis (HA). Recall that the first two letters in HACCP stand for “Hazard Analysis.” When you do a HA, you determine the potential food safety risks that are reasonably likely to occur at each processing stage. A HA also includes identifying preventive measures that can control those risks.

Food safety hazards can originate within and outside the processing plant, and can include hazards that can occur before, during, and after harvest. A hazard that is reasonably likely to occur is one that a processor would control because there is a reasonable possibility that the hazard would occur without controls.

Each food-processing operation has its own unique potential food safety hazards. These hazards may vary from product to product and from plant to plant. Figure 1 gives examples of improper practices that may cause potential food safety hazards.

Step 2 Determine where and when to prevent problems (Critical Control Points).

In addition to determining major potential hazards, you need to identify at what point in the food-processing operation these hazards can be controlled best.

A Critical Control Point (CCP) is a step in the product handling process where controls will reduce or eliminate hazards. CCPs should be designed to control food safety hazards that could be introduced:
In the processing plant environment; and
Outside the processing plant environment, including hazards that occur before, during, and after harvest.
Examples of CCPs might include:
- Receiving
- Chilling and cold storage
- Thawing, mixing ingredients, and other food-handling stages
- Shipping

So HACCP systems include two major ideas: Hazard Analysis (HA) and Critical Control Points (CCP).

**Step 3. Set limits to control potential safety problems (Critical Limits).**

Once you identify CCPs, you must determine Critical Limits that will reduce or eliminate potential hazards. Examples of critical limits might include:
- Purchasing specifications
- Chilling and cold storage times and temperatures
- Handling practices

*Figure 2* gives examples of some specific critical limits to reduce or eliminate potential safety hazards.

**Step 4. Set up methods to monitor limits (Monitoring Procedures).**

Now that you have established limits for potential hazards, you must set up methods to be sure they are followed. These methods should include the procedure that will be used to monitor each CCP, and how frequently the CCPs will be monitored. Typical Monitoring Procedures may include:
- Visual observations (watching worker practices, inspecting raw materials)
- Sensory evaluations (smelling for off-odors, looking for off-colors, or feeling for texture)
- Chemical measurements (pH or acidity, viscosity, salt content, or water activity)
- Physical measurements (time and temperature)
- Microbiological measurements (coliforms, fecal coliforms, *E. coli*)

*Note*: Microbiological testing is seldom effective for monitoring CCPs due to its time-consuming nature (NACMCF 1992), but may be required by some regulatory agencies.

**Step 5. Set up procedures to handle control problems (Corrective Actions).**

Food safety problems can occur when HACCP limits are not met. You must set up procedures to deal immediately with such failures. These procedures are called Corrective Actions. Corrective actions ensure that:
- No product enters commerce that is unsafe; and
- The cause of the deviation is corrected.

Corrective actions need to be established for each critical limit at each CCP.
Examples of corrective actions might include:

- Rejecting products not meeting buying specifications
- Adjusting a cooler's thermostat to get the proper temperature
- Modifying food-handling procedures
- Discarding products

**Step 6. Use record keeping to check that controls work (Record-Keeping System).**

Monitoring results must be recorded for review by management. Record keeping is an essential part of the HACCP system. These records indicate to management and government inspectors that you properly evaluated, handled, and processed foods and ingredients.

HACCP records include documenting:

- Monitoring at CCPs
- Corrective actions taken
- Calibration of process-monitoring instruments
- End-product and in-process testing

**Step 7. Verify that the HACCP system works properly (Verification Procedures).**

Management must verify that the HACCP plan is controlling food safety hazards that are likely to occur, and that the plan is being correctly implemented. Verification includes:

- An in-depth audit of the entire HACCP system at least once a year.
  Additional audits should be conducted whenever there are new products, new recipes, or new processes. Each of these requires a new HACCP plan.
- A daily record review that ensures: 1) controls were working, 2) proper information was recorded, 3) proper corrective actions were taken, if needed, and 4) workers handled foods properly. If records indicate potential problems, investigate immediately and document findings.
- A routine review of consumer complaints to determine if they relate to CCPs, or reveal unidentified CCPs.
- Calibration of process-monitoring equipment.
- Periodic end-product or in-process testing, if desired.

HACCP systems should cover all foods. For most foods, this requires only common sense and a knowledge of basic food-handling practices. For multi-ingredient foods, you may need technical assistance to develop a HACCP system.

**HACCP and Sanitation**

HACCP is an effective food safety management tool only when good sanitation practices are already in place. Without proper sanitation, HACCP cannot effectively manage and improve food safety.

Sanitation practices should be based on standard sanitation operating procedures, the FDA's GMP regulations, and on other applicable state and federal regulations including the FDA's Food Code 1995, and the National Shellfish Sanitation Program (NSSP) Manual of Operations.
FIGURE 1. EXAMPLES OF PRACTICES THAT INCREASE POTENTIAL FOOD SAFETY HAZARDS.

Cross-Contamination
- Storage of raw food with ready-to-eat food
- Employee practices leading to cross-contamination, such as handling raw and cooked product without washing and sanitizing hands (gloves) between products
- Failure to properly clean equipment
- Failure to adequately protect food from contamination, such as storing raw food above cooked food in refrigeration units
- Improper storage of refuse

Improper Cold Storage
- Food stored at improper temperatures
- Coolers without thermometers
- Poor cooling practices; overloading refrigeration units
- Storage of food in improperly labeled containers

Other Hazards
- Improper or inadequate cleaning and sanitation practices
- Poor food-handling practices
- Use of utensils or food-contact surfaces made from improper materials
- Inadequate documentation and record keeping
- Improper storage of chemicals and personal items
FIGURE 2. **EXAMPLES OF CRITICAL LIMITS TO REDUCE OR ELIMINATE POTENTIAL HAZARDS AT CCPs.**

**CCP: Receiving**
- Potentially hazardous food at or below 40°F (4.4°C)
- Molluscan shellfish at or below 50°F (10°C)
- No evidence of spoilage, abuse, foreign objects, or contamination in food

**CCP: Chilling and Cold Storage**
- Do not leave potentially hazardous food at room temperature
- Do not overload or stack containers in coolers

**CCP: Food Handling** - Covered by Sanitation Standard Operating Procedures (SSOPs) and the FDA’s Good Manufacturing Practices (GMPs)
- Use proper hand-washing techniques
- Use proper dish-washing and sanitizing techniques
- Cover and protect open cuts and scratches
  - Use clean and sanitized equipment and utensils
- Stay home when sick

**CCP: Shipping**
- Potentially hazardous food at or below 40°F (4.4°C)
- Molluscan shellfish at or below 50°F (10°C)
INTRODUCTION

Developing a HACCP Plan for Live Mussel Processing should begin and continue as a “team effort.” A successful HACCP program requires commitment from all levels of company management and a thorough understanding of mussel handling and processing.

HACCP Resources

Several resources are available for assisting mussel processors in developing HACCP plans. These include:

- The FDA's seafood HACCP regulation (FDA, 1995).
- The FDA's draft Fish and Fishery Products Hazards and Controls Guide (FDA, 1994).
- HACCP manuals (NFI and National Marine Fisheries Service).

Step 1: Hazard Analysis

Potential food safety hazards will depend on the species processed, harvest areas, product types, processing and handling methods, product distribution, intended use, and eventual consumers of the mussels. Each product, process, and plant may have different food safety hazards.

HACCP Team. The first step in conducting a HA is to assemble a HACCP team. Ideally, the HACCP team will include people knowledgeable about food safety, mussel harvesting, handling, processing and distribution procedures, and upper management. Depending on the size of the firm, the HACCP team could include 1, 2, or more than 20 individuals. HACCP training for the team may be necessary.

If sufficient technical expertise is not available within the firm, outside technical assistance may be helpful in developing HACCP plans. If outside technical assistance is used, the firm’s personnel should fully understand how and why the plan was developed.

A HACCP organizational chart is useful to define personnel with HACCP responsibilities within the firm. Figure 3 gives an example of a HACCP organizational chart and includes specific HACCP responsibilities for plant personnel.

Describe the Food and the Method of its Distribution. The second step in a HA is to describe the food and the method of its distribution. A separate HACCP plan must be developed for each food product being processed.
A description of the food must include recipes, formulations, additives, and processing aids used. The HACCP team should also consider the potential for abuse in distribution and by the consumer. For mussels, this description may include:

**Raw materials:**
Live mussels (*Modiolus* spp., *Mytilus* spp., and/or *Perna canaliculus*)

**Harvested:**
[Harvest Location(s)]

**Aquaculture drugs used:**
None

**Received:**
Directly from firm’s lease, facility, or harvester

**Finished product:**
Live mussels

**Food additives, ingredients, processing aids:**
None

**Shipping:**
Refrigerated trucks or iced in nonrefrigerated trucks

**Identify the Intended Use and Consumers of the Food** The third step in the HA is to identify the intended use and consumers of the food. The intended use of the food should be based upon the normal use by consumers.

**Intended use:**
Product is intended to be consumed live, steamed, or fully cooked

**Intended consumers:**
General public

**Develop a Flow Diagram which Describes the Process.** The fourth step in the HA is to develop a clear, simple flow diagram that describes the steps in the process. A flow diagram indicating all processing and handling steps from receiving through shipping is helpful in identifying potential food safety hazards. The amount of detail in flow diagrams can vary, but more detail assures a comprehensive HA. The flow diagram must cover all the steps in the process from receiving through shipping, and should include a narrative description of each step. Figure 4 is a flow diagram for a mussel processing system.

**Verify the Flow Diagram.** The fifth step in the hazard analysis is for the HACCP team to inspect the processing operation to verify the accuracy and completeness of the flow diagram. The diagram should be modified, if necessary, following the inspection.

**Conduct a Hazard Analysis.** The HACCP team next conducts a HA and identifies the steps in the process where potentially significant hazards can occur. Potential hazards are limited to safety issues and must be differentiated from quality concerns. The team must use their experience and knowledge to focus on the more probable and suspected safety hazards. Hazards which are of low risk and not reasonably likely to occur should not be considered.

The HACCP team must then consider what control measures exist which can be applied for each hazard. Control measures are physical, chemical, or other factors which will eliminate or minimize an identified hazard. More than one control measure may be required to control a specific hazard. More than one hazard may be controlled by a specified control measure.

A useful reference is the FDA’s draft Fish and Fishery Products Hazards and Controls Guide (FDA, 1994). The guide lists the following species-related potential safety hazards for aquacultured mussels (*Modiolus* spp., *Mytilus* spp., and *Perna canaliculus*).

### Chemical Contamination
Contamination of raw material at receipt
with pesticides, radioactivity, toxic elements, and industrial chemicals derived from the harvest area.

#3: Natural Toxins. Contamination of raw material at receipt with natural toxins, derived from the harvest area. For mussels, potential toxins include: 3a, Paralytic Shellfish Poisoning; 3b, Neurotoxic Shellfish Poisoning; 3c, Diarrhetic Shellfish Poisoning; and 3d, Amnesic Shellfish Poisoning.

#7: Food and Color Additives. Contamination of raw material at receipt with unapproved or excessive levels of approved food or color additives.

#9: Aquaculture Drugs. Contamination of raw material at receipt with violative levels of animal drugs.

#10: Pathogens. Contamination of raw shellfish with pathogenic microorganisms, derived from the harvest/growing area.

The FDA’s draft Fish and Fishery Products Hazards and Controls Guide also lists the following process-related potential safety hazards for mussels:

#3b: Temperature abuse during raw material storage (pathogens). Microbiological growth resulting from time temperature abuse during refrigerated storage of raw material fish or fishery product (excluding live crustaceans) and microbiologically sensitive nonfish or fishery product raw materials.

#8b: Temperature abuse during processing (pathogens). Microbiological growth resulting from time/temperature abuse during processing of raw molluscan shellfish.

#13b: Temperature abuse during final cooling (pathogens). Microbiological growth resulting from time/temperature abuse during final cooling or freezing.

#14b: Temperature abuse during finished product storage (pathogens). Microbiological growth resulting from time/temperature abuse during refrigerated, finished product storage.

#15b: Temperature abuse during shipping (pathogens). Microbiological growth resulting from time/temperature abuse during refrigerated, finished product shipping.

#16: Metal Inclusion. Introduction of metal fragments into the product resulting from metal-to-metal contact, especially in mechanical cutting and blending operations.

#17: Food and color additives. Food and color additives may exceed permitted limits.

Safety Hazards that are Reasonably Likely to Occur and Must Be Controlled. Once potential safety hazards have been identified, the HACCP team must examine each safety hazard to determine if it is reasonably likely to occur and must be controlled in a HACCP plan. The team should use its experience and knowledge of food safety and mussel processing to distinguish between “possible” and “reasonable” safety hazards. In the 1995 seafood HACCP regulation, the FDA defines “reasonably likely to occur” as: “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 absence of those controls.”
The HACCP team should document their thought processes on a brief form or “HA worksheet.” This approach encourages thorough plan considerations and serves to justify the final HACCP plan. Any safety hazard that is reasonably likely to occur must be controlled through specific control measures at a critical control point. Hazards that are unlikely to occur should have an explanation for the team’s decision.

*Figure 5* is an example of a HA worksheet using the potential hazards identified for mussels in the FDA's draft Fish and Fishery Products Hazards and Controls Guide (FDA, 1994). Specific potential safety hazards may vary with harvest locations, products, processing methods, and plants.

**Step 2: Determine Critical Control Points**

A CCP is a step in the product-handling process where controls will reduce or eliminate hazards. In addition to determining major potential hazards, you will need to identify at what point in the food-processing operation each hazard can best be controlled. There must be a CCP for each identified food safety hazard that is reasonably likely to occur. A CCP is usually a specific processing procedure or handling step that can be easily monitored to ensure compliance with the HACCP program.

Identifying Critical Control Points. Identifying CCPs can be a difficult part in developing the HACCP plan. The selection of CCPs requires knowledge of the food safety hazards and of the processing procedures used. *Figure 6* is a decision tree that is useful in determining which processing steps are CCPs.

It is common to identify too many CCPs because the HACCP team may have difficulty distinguishing between product safety and quality concerns. In most mussel processing plants, there are only two or three CCPs: receiving, refrigerated storage, and shipping (if the processor distributes the mussels).

**Critical Control Points in Mussel Processing.** *Figure 7* gives the CCPs identified for the reasonably likely safety hazards in mussel processing.

**Step 3: Establish Critical Limits**

Each CCP must have a Critical Limit that can be monitored to ensure control of the food safety hazard. A critical limit is defined as a criterion that must be met for each control measure associated with a CCP. Critical limits may be set for control measures such as:

- Temperature
- Time
- Physical dimensions
- Humidity
- Moisture level
- Water activity ($a_w$)
- PH
- Titratable acidity
- Salt concentration
- Available chlorine
- Viscosity
- Preservatives
The critical limits must comply with existing federal, state, and local regulations; tolerances; and action levels. The mussel processor is responsible for validating that critical limits will control the identified hazard.

**Critical Limits for Hazards Associated with Mussel Processing** Figure 8 gives recommended critical limits for the hazards reasonably likely to occur in mussel processing (FDA, 1994).

**Step 4: Establish Monitoring Procedures**

Monitoring at CCPs involves observations or measurements to ensure the CCPs are in control and that critical limits are not exceeded. Monitoring can be continuous (temperature recorders) or periodic (shellfish tags, temperature logs). The monitoring methods and frequency must be adequate to accurately reflect trends and any deviations from critical limits that could cause a food hazard.

**Monitoring Procedures for Mussel Processing.** Figure 9 gives recommended monitoring procedures for the identified CCPs in mussel processing (FDA, 1994).

**Step 5: Define Corrective Actions**

Plans of actions or procedures should be predetermined if monitoring indicates a critical limit is exceeded and a CCP has failed to control a potential hazard. Corrective actions can involve holding or isolating product until a safety analysis can be conducted. The results may indicate the product is safe, or that the product must be treated, reprocessed, rejected, or destroyed.

All corrective actions require a written record indicating the reason for the corrective action and the final disposition of the product. A HACCP program without any recorded corrective action records is ideal and not probable.

**Corrective Actions for Mussel Processing.** Figure 10 gives recommended corrective actions for mussel processing CCPs (FDA, 1994).

**Step 6: Record Keeping**

Records of control measures are an essential part of a HACCP program. The firm uses records to ensure the HACCP program is working on a day-to-day basis, and for regulatory review. HACCP records give a continuous “view” of the firm’s practices and commitment to food safety. HACCP records can include:

- The HACCP plan and original development documents which specify the records to be maintained
- CCP monitoring records
- Corrective action records
- Employee training records

In most cases, HACCP programs do not require firms to generate new records. Existing shellfish tags, bills of lading, and invoices may satisfy most record-keeping requirements. In some cases, modifications of existing records or new records may be needed.

**Mussel HACCP Records.** For most mussel processors, only receiving and temperature-monitoring records are required.

Receiving records are properly completed harvester shellfish tags from licensed harvesters or bills of lading from certified processors. Receiving records should include at least:

- Date of harvest
• Location of harvest by state and site
• Type and quantity of shellfish
• Harvester number assigned by a SCA, or harvester’s name, or harvester’s vessel registration number

Temperature-monitoring records should include:
• Daily recorder thermometer charts, computerized temperature data storage, or daily temperature logs
• Record of calibration for thermometers, which specifies the date, standard used, method used, results, and person performing the test
• Record of accuracy checks for the temperature recorders that specify the time, date, temperatures shown by both devices before adjustment, corrective action taken, and person performing the accuracy check
• Records showing the sufficiency of ice

All HACCP records should be signed or initialed and dated by the person making the record entry

**Step 7: Verification**

Processors must 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 procedures include a reassessment of the adequacy of the HACCP plan, ongoing verification activities, and a routine records review.

**Reassessment of the HACCP Plan.** A reassessment of the adequacy of the HACCP plan is needed whenever any changes occur that could affect the HA or alter the HACCP plan. This audit should be conducted at least annually, and whenever there are changes in:

• Raw materials or sources of raw materials
• Product formulation
• Processing methods or systems
• Finished product shipping systems
• The intended use or consumers of the finished product

A reassessment also should be conducted when new or unexpected potential food safety hazards are identified. The reassessment must be performed by someone who has been trained in the application of HACCP principles. The HACCP plan should be modified whenever an audit reveals that the plan no longer controls identified hazards.

**Ongoing Verification Activities.** Ongoing verification activities should include:

• A review of consumer complaints that relate to the performance of CCPs or reveal the existence of unidentified CCPs
• The calibration of process-monitoring instruments
• Optional periodic end-product or in-process testing

**Records Review.** A records review should include a review of the records that document:

• The monitoring of critical control points

This review is to ensure that the records are complete and to verify that they document values that are within the critical limits. This review must occur within 1 week after the records are made.
• The taking of corrective actions

This review is to ensure that the records are complete and to verify that appropriate corrective actions were taken. This review must occur within 1 week after the records are made.

• The calibrating of any process control instruments used at CCPs and the performing of any periodic end-product or in-process testing that is part of the processors verification activities

This review is to ensure that the records are complete, and that these activities followed the processors written procedures. These reviews should occur within a reasonable time after the records are made.

After being reviewed, all HACCP records should be signed and dated by someone trained in the application of HACCP principles.
**HACCP Responsibilities**

**President**
Owner, treasurer, and primary person responsible for all plant activity, products, personnel, and business liaison. Primary authority for design and operation of the HACCP program. Responsible for budget and operational expenses. Member of the HACCP team.

**Vice President**
Co-owner and secretary. Responsible for day-to-day operation of HACCP program.

**Office Manager**
Responsible for plant sales records. Reviews, accepts, and signs HACCP records. Responsible for firm’s public relations.

**Plant Manager**
Responsible for day-to-day plant operations and plant sanitation program. Monitors routine plant inspection, sanitation, and HACCP record keeping. Responsible for receiving, processing, and shipping product, and personnel training.

**Shellstock Supervisor**
Responsible for shellstock grading, packing, shipping, and receiving. Keeps HACCP production records.

**Harvest Supervisor**
Responsible for ensuring all products received are in compliance with NSSP and state regulations.

**Remaining Staff**
Responsible for handling and packing product according to the HACCP plan and GMPs. *Trained in HACCP principles.*
Live Shellstock (*Modiolus* spp., *Mytilus* spp., and/or *Perna canaliculus*) are received directly from harvester in tagged bags. The mussels are harvested from approved waters. No aquaculture drugs are used.

Mussels are either processed immediately or stored dry in mechanically refrigerated coolers which are maintained below 50°F (10°C).

Mussels are declumped mechanically or by hand.

Mussels are washed with clean water.

Dead and broken mussels are removed by hand. Mussels are hand graded by size. No food additives, ingredients, or processing aids are used.

Mussels are placed in bags, and the bags are tagged.

Mussels are stored dry in mechanically refrigerated coolers which are maintained below 50°F (10°C).

Live mussels are shipped in refrigerated trucks and held below 50°F (10°C) during shipping.
FIGURE 5. HAZARD ANALYSIS Worksheet

<table>
<thead>
<tr>
<th>Ingredient/Processing Step</th>
<th>Potential Hazard Introduced or Controlled</th>
<th>Is the Potential Hazard Reasonably Likely to Occur?</th>
<th>Justification for Inclusion or Exclusion as a Significant Hazard (Consider the likelihood that the hazard would be introduced, or intensified, or a hazard from a previous step can be controlled)</th>
<th>Preventive Measure(s) for the Significant Hazard from Column 3 (Existing plus additional, if needed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Chemical Contamination</td>
<td>Yes</td>
<td>Contamination with pesticides, toxic elements, radioactivity, and industrial chemicals has not occurred in the harvest area, but is a potential hazard.</td>
<td>Approved waters, proper product identification.</td>
</tr>
<tr>
<td></td>
<td>Natural Toxins</td>
<td>Yes</td>
<td>Natural toxins have occurred in the harvest area and are reasonably likely to occur again.</td>
<td>Approved waters, proper product identification, (batch certification, if required).</td>
</tr>
<tr>
<td></td>
<td>Food and Color Additives</td>
<td>No</td>
<td>No food or color additives are used.</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Aquaculture Drugs</td>
<td>No</td>
<td>No aquaculture drugs are used.</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Pathogens</td>
<td>Yes</td>
<td>Pathogens may occasionally occur in the harvest area.</td>
<td>Approved waters, proper product identification</td>
</tr>
<tr>
<td>Raw Material Storage</td>
<td>Pathogen Growth</td>
<td>Yes</td>
<td>Temperature abuse may occur during raw material storage.</td>
<td>Proper storage temperature.</td>
</tr>
<tr>
<td>Declumping</td>
<td>Metal Inclusion</td>
<td>No</td>
<td>Metal inclusion is not a potential problem in manual processing and is not reasonably likely to occur during mechanical processing.</td>
<td>N/A</td>
</tr>
<tr>
<td>Washing</td>
<td>Pathogen Growth</td>
<td>No</td>
<td>Exposure to temperatures above 50°F (10°C) is minimal. Total exposure to temperatures above 50°F (10°C) is evaluated at finished product storage.</td>
<td>N/A</td>
</tr>
<tr>
<td>Culling/Grading</td>
<td>Pathogen Growth</td>
<td>No</td>
<td>Exposure to temperatures above 50°F (10°C) is minimal. Total exposure to temperatures above 50°F (10°C) is evaluated at finished product storage.</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Food and Color Additives</td>
<td>No</td>
<td>No food or color additives are used.</td>
<td>N/A</td>
</tr>
<tr>
<td>Packaging/Labeling</td>
<td>Pathogen Growth</td>
<td>No</td>
<td>Exposure to temperatures above 50°F (10°C) is minimal. Total exposure to temperatures above 50°F (10°C) is evaluated at finished product storage.</td>
<td>N/A</td>
</tr>
<tr>
<td>Final Product Cooling/Storage</td>
<td>Pathogen Growth</td>
<td>Yes</td>
<td>Temperature abuse is unlikely to occur during final product cooling. Temperature abuse may occur during finished product storage. Total exposure to temperatures above 50°F (10°C) can be evaluated at this step.</td>
<td>Proper storage temperature, limited exposure to temperatures above 50°F (10°C)</td>
</tr>
<tr>
<td>Shipping</td>
<td>Pathogen Growth</td>
<td>Yes</td>
<td>Temperature abuse may occur during shipping.</td>
<td>Proper storage temperature</td>
</tr>
</tbody>
</table>
FIGURE 6. CCP DECISION TREE.

Q1. Do control measure(s) exist for the identified hazard?

- Yes
- No

Modify step, process or product

Is control at this step necessary for safety?

- Yes
- No

Not a CCP → Stop*

Q2. Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?

- No

Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable level(s)?

- Yes
- No

Not a CCP → Stop*

Q4. Will a subsequent step eliminate identified hazard(s) or reduce the likely occurrence to an acceptable level?

- Yes
- No

Not a CCP → Stop*

* Proceed to next step in the process flow diagram.
**FIGURE 7.** CCPs IN MUSSEL PROCESSING.

<table>
<thead>
<tr>
<th>Hazard</th>
<th>CCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical contamination</td>
<td>Receiving</td>
</tr>
<tr>
<td>Natural toxins</td>
<td>Receiving</td>
</tr>
<tr>
<td>Pathogens</td>
<td>Receiving</td>
</tr>
<tr>
<td>Temperature abuse: raw material storage</td>
<td>Raw material storage</td>
</tr>
<tr>
<td>Temperature abuse: finished product storage</td>
<td>Finished product storage</td>
</tr>
<tr>
<td>Temperature abuse: shipping</td>
<td>Shipping</td>
</tr>
</tbody>
</table>

**FIGURE 8.** CRITICAL LIMITS FOR MUSSEL PROCESSING STEPS.

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>Critical Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Accept no mussels harvested from areas closed due to chemical contamination.</td>
</tr>
<tr>
<td></td>
<td>Accept no mussels harvested from areas closed due to contamination with natural toxins. If required, obtain certification that each batch is toxin-free.</td>
</tr>
<tr>
<td></td>
<td>Accept no mussels harvested from areas closed due to contamination with pathogens.</td>
</tr>
<tr>
<td>Raw Material Storage</td>
<td>Temperatures should not exceed 50°F (10°C) in refrigerators used to store in-shell, raw, mussels.</td>
</tr>
<tr>
<td></td>
<td><strong>Total exposure to temperatures above 50°F (10°C) shall not exceed 4 hours.</strong></td>
</tr>
<tr>
<td>Finished Product Storage</td>
<td>Temperatures should not exceed 50°F (10°C) in refrigerators used to store in-shell, raw, mussels.</td>
</tr>
<tr>
<td></td>
<td><strong>Total exposure to temperatures above 50°F (10°C) shall not exceed 4 hours.</strong></td>
</tr>
<tr>
<td>Shipping</td>
<td>Temperatures should not exceed 50°F (10°C) in containers used to distribute in-shell, raw, mussels.</td>
</tr>
<tr>
<td></td>
<td><strong>Total exposure to temperatures above 50°F (10°C) shall not exceed 4 hours.</strong></td>
</tr>
</tbody>
</table>
FIGURE 9. MONITORING PROCEDURES FOR MUSSEL PROCESSING.

<table>
<thead>
<tr>
<th>CCP</th>
<th>Monitoring Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>For each lot or batch, determine the harvest area. Before accepting shellfish from a new area and as often after that as necessary to assure accuracy, find out whether each harvest area is closed due to chemical contamination, natural toxins, or pathogens. If required, obtain certification that each batch is toxin-free.</td>
</tr>
<tr>
<td>Raw Material Storage</td>
<td>Equip each refrigerator with a temperature-indicating device (thermometer) or maintain a temperature log that notes temperatures with sufficient frequency to achieve control, at least once each production day. Equip each refrigerator with a temperature-recording device, a high-temperature alarm, or a maximum-indicating thermometer.</td>
</tr>
<tr>
<td>Finished Product Storage</td>
<td>Equip each refrigerator with a temperature-indicating device (thermometer) or maintain a temperature log that notes temperatures with sufficient frequency to achieve control, at least once each production day. Equip each refrigerator with a temperature-recording device, a high-temperature alarm or a maximum-indicating thermometer.</td>
</tr>
<tr>
<td>Shipping</td>
<td>Monitoring procedures may include the use of: temperature-indicating and recording devices, maximum-indicating thermometers, high-temperature alarms, temperature or ice checks during shipping, receiving checks for internal and ambient temperature or sufficiency of ice, and standardized and validated icing procedures.</td>
</tr>
</tbody>
</table>
FIGURE 10. CORRECTIVE ACTIONS FOR MUSSEL PROCESSING

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>Hazard</th>
<th>Critical Limits</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Chemical Contamination</td>
<td>Accept no mussels harvested from areas closed due to chemical contamination.</td>
<td>Reject products that fail to meet the critical limit.</td>
</tr>
<tr>
<td></td>
<td>Natural Toxins</td>
<td>Accept no mussels harvested from areas closed due to contamination with natural toxins.</td>
<td>Reject products that fail to meet the critical limit.</td>
</tr>
<tr>
<td></td>
<td>Pathogens</td>
<td>Accept no mussels harvested from areas closed due to contamination with pathogens.</td>
<td>Reject products that fail to meet the critical limit.</td>
</tr>
<tr>
<td>Raw Material Storage</td>
<td>Pathogen Growth</td>
<td>Storage temperatures should not exceed 50°F (10°C).</td>
<td>Adjust thermostat.</td>
</tr>
<tr>
<td>Finished Product Storage</td>
<td>Pathogen Growth</td>
<td>Storage temperatures should not exceed 50°F (10°C).</td>
<td>Adjust thermostat.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total exposure to temperatures above 50°F (10°C) shall not exceed 4 hours.</td>
<td>Destroy product.</td>
</tr>
<tr>
<td>Shipping</td>
<td>Pathogen Growth</td>
<td>Storage temperatures should not exceed 50°F (10°C).</td>
<td>Adjust thermostat.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total exposure to temperatures above 50°F (10°C) shall not exceed 4 hours.</td>
<td>Destroy product.</td>
</tr>
</tbody>
</table>
Model HACCP Plan for Mussel Processing

1. PRODUCT DESCRIPTION

Aquatic product raw material: Mussels (Modiolus spp., Mytilus spp., and/or Perna canaliculus)
Raw material harvest area: [Harvest Location(s)]
Raw materials received: Directly from firm’s lease, facility, or harvester
Finished product: Live mussels
Aquaculture drugs, food additives, ingredients, processing aids: None
Shipping: Refrigerated trucks or iced in nonrefrigerated trucks
Intended use: Product is intended to be consumed live, steamed, or fully cooked
Intended consumers: General public

2. FLOW DIAGRAM AND NARRATIVE FOR MUSSEL PROCESSING

See figure 4.

3. POTENTIAL HAZARDS

- Chemical contamination
- Natural toxins
- Food and color additives
- Aquaculture drugs
- Pathogens
- Temperature abuse during raw material storage
- Temperature abuse during processing
- Temperature abuse during final cooling
- Temperature abuse during finished product storage
- Temperature abuse during shipping
- Metal inclusion

4. HAZARD ANALYSIS WORKSHEET

See figure 5.
5. **HACCP PLAN FORM**

   *See figure 11.* Hazards and control measures are based on information from the FDA's draft Fish and Fishery Products Hazards and Controls Guide (FDA, 1994).

6. **EXAMPLES OF MONITORING FORMS AND RECORDS**

   *Figures 12-16* are examples of monitoring records that could be used in mussel processing (shellfish tag, recording thermometer chart, temperature log, temperature recorder accuracy check, and thermometer calibration).
**FIGURE 11. HACCP PLAN FORM FOR MUSSELS.**

<table>
<thead>
<tr>
<th>(CCP)</th>
<th>Hazard</th>
<th>Critical Limits of the Preventive Measures</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Chemical contamination</td>
<td>Mussels must not be harvested from areas closed due to chemical contamination</td>
<td>Shellfish tag</td>
</tr>
<tr>
<td></td>
<td>Natural toxins</td>
<td>Mussels must not be harvested from areas closed due to contamination with natural toxins</td>
<td>Certificate</td>
</tr>
<tr>
<td></td>
<td>Pathogens</td>
<td>Mussels must be certified toxin-free (if required by a SCA).</td>
<td>Shellfish tag</td>
</tr>
<tr>
<td>Raw material</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature recorder</td>
</tr>
<tr>
<td>storage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature recorder</td>
</tr>
<tr>
<td>product storage</td>
<td></td>
<td>Total exposure of mussels to temperatures above 50°F (10°C) does not exceed 4 hours</td>
<td>Temperature recorder</td>
</tr>
<tr>
<td>Shipping</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature log</td>
</tr>
</tbody>
</table>

Reviewed by: ___________________________  Date: _______________
FIGURE 12. **EXAMPLE OF INFORMATION FOR A SHELLFISH TAG.**

Date of harvest

Location of harvest (state and site)

Type and quantity of shellfish

Harvester number assigned by a SCA

or harvester’s name,

or harvester’s vessel registration number

This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days.

Reviewed by: ___________________________ Date: ____________
FIGURE 13  EXAMPLE OF A DAILY RECORDER THERMOMETER CHART.
FIGURE 14 EXAMPLE OF A TEMPERATURE LOG.

Temperature Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Thermometer Temperature (°F or ºC)</th>
<th>Thermometer Functioning Properly (?)</th>
<th>Corrective Action Taken</th>
<th>Initials</th>
</tr>
</thead>
</table>

Reviewed by: ___________________________ Date: __________

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FIGURE 15. EXAMPLE OF A RECORD OF ACCURACY CHECKS FOR TEMPERATURE RECORDERS.

Record of Accuracy Checks for Temperature Recorders

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Thermometer Temperature ($^\circ$F or °C)</th>
<th>Thermometer Recorder Temperature ($^\circ$F or °C)</th>
<th>Thermometer Functioning Properly Temp (°)</th>
<th>Corrective Action Taken</th>
<th>Initials</th>
</tr>
</thead>
</table>

Reviewed by: ___________________________ Date: __________
FIGURE 16. EXAMPLE OF A THERMOMETER CALIBRATION RECORD.

**Thermometer Calibration Record**

<table>
<thead>
<tr>
<th>Date</th>
<th>Standard Used</th>
<th>Method Used</th>
<th>Results</th>
<th>Person Performing Test</th>
</tr>
</thead>
</table>

Reviewed by: ___________________________ Date: __________
A HACCP Approach for Managing Quality

QUALITY FACTORS

QUALITY MANAGEMENT ANALYSIS CAN FOLLOW THE SAME BASIC procedures as those used for the HA in the HACCP plan. Only nonsafety-related quality factors are considered in developing a quality plan.

Potential Nonsafety Species-Related Aquacultured Mussel Quality Factors. The following potential nonsafety species-related quality factors for mussels are from the FDA’s draft Fish and Fishery Products Hazards and Controls Guide (FDA, 1994):

#4: Filth. Contamination of raw material at receipt with filth, extraneous materials, and noxious substances.
#5: Decomposition. Decomposition of raw material.
#8: Parasites. Parasites in species disposed to them.

Potential Nonsafety Process-Related Quality Factors for Live Mussels. The following potential nonsafety process-related quality factors for live mussels are taken from the FDA’s draft Fish and Fishery Products Hazards and Controls Guide:

#2: Processing of dead mollusks. Dead mollusks decompose rapidly.
#3c: Temperature abuse during raw material storage (Decomposition). Decomposition resulting from time temperature abuse during refrigerated storage of raw material fish or fishery product (excluding live crustaceans) and microbiologically sensitive nonfish or fishery product raw materials.
#9c: Temperature abuse during processing of noncooked products (Decomposition). Decomposition resulting from time temperature abuse during processing of noncooked products.
#13c: Temperature abuse during final cooling (Decomposition). Decomposition resulting from time/temperature abuse during final cooling or freezing.
#14c: Temperature abuse during finished product storage (Decomposition). Decomposition resulting from time temperature abuse during refrigerated, finished product storage.
#15c: Temperature abuse during shipping (Decomposition). Decomposition resulting from time temperature abuse during refrigerated, finished product shipping.
#18: Short weight. Short weight, addition of water, standard of fill, and overglazing.
#19: Species substitution. Misrepresentation of mollusk species.
#20: Grade size misrepresentation. Inaccurate grade size labeling.
QUALITY MANAGEMENT ANALYSIS

Figure 17 gives an example of a quality management analysis for mussel processing.

QUALITY MANAGEMENT POINT IDENTIFICATION

Figure 18 lists quality management points for potential quality problems identified in mussel processing (FDA, 1994). QMPs for quality factors can vary with processing plants, species processed, and handling and processing methods. Additional controls than those given here may be necessary for specific processing and handling procedures.
<table>
<thead>
<tr>
<th>Ingredient/Processing Step</th>
<th>Potential Quality Factor Introduced or Controlled</th>
<th>Is the Quality Factor Reasonably Likely to Occur?</th>
<th>Justification for Inclusion or Exclusion as a Significant Quality Factor</th>
<th>Preventive Measure(s) for the Quality Factor from Column 3</th>
<th>QMP (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Filth</td>
<td>Yes</td>
<td>Contamination with rodent, bird, or insect filth, trash, and nonmarine debris may occur.</td>
<td>Visual examination</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No</td>
<td>Dead mollusks are culled out during processing.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Parasites</td>
<td>No</td>
<td>Parasites are not reasonably likely to occur.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Processing of dead mollusks</td>
<td>No</td>
<td>Dead mollusks are culled out during processing.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>Yes</td>
<td>Temperature abuse may occur during raw material storage.</td>
<td>Proper storage temperature</td>
<td>Yes</td>
</tr>
<tr>
<td>Raw Material Storage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No</td>
<td>Time is minimal. Decomposition is not reasonably likely to occur.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td>Declumping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No</td>
<td>Time is minimal. Decomposition is not reasonably likely to occur.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culling/Grading</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No</td>
<td>Time is minimal. Decomposition is not reasonably likely to occur.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processing of dead mollusks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging/labeling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade size misrepresentation</td>
<td>Yes</td>
<td>Grade size misrepresentation may occur.</td>
<td>Check grade size</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No</td>
<td>Time is minimal. Decomposition is not reasonably likely to occur.</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Product/ Cooling/ Storage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>Yes</td>
<td>Temperature abuse may occur.</td>
<td>Proper storage temperature</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Figure 18. QMPS in Mussel Processing.**

<table>
<thead>
<tr>
<th>Quality Factor</th>
<th>QMP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species-Related Quality Factors:</strong></td>
<td></td>
</tr>
<tr>
<td>#4: Filth</td>
<td>Receiving</td>
</tr>
<tr>
<td>#5: Decomposition</td>
<td>Receiving</td>
</tr>
<tr>
<td>#8: Parasites</td>
<td>Receiving, storing, or processing</td>
</tr>
<tr>
<td><strong>Process-Related Quality Factors:</strong></td>
<td></td>
</tr>
<tr>
<td>#2: Processing of dead mollusks</td>
<td>Culling</td>
</tr>
<tr>
<td>#3c: Temperature abuse during raw material storage (Decomposition)</td>
<td>Raw material storage</td>
</tr>
<tr>
<td>#9c: Temperature abuse during processing of noncooked products (Decomposition)</td>
<td>Processing</td>
</tr>
<tr>
<td>#13c: Temperature abuse during final cooling (Decomposition)</td>
<td>Final product cooling</td>
</tr>
<tr>
<td>#14c: Temperature abuse during finished product storage (Decomposition)</td>
<td>Finished product storage</td>
</tr>
<tr>
<td>#15c: Temperature abuse during shipping (Decomposition)</td>
<td>Shipping</td>
</tr>
<tr>
<td>#18: Short weight</td>
<td>Packaging</td>
</tr>
<tr>
<td>#19: Species substitution</td>
<td>Labeling</td>
</tr>
<tr>
<td>#20: Grade size misrepresentation</td>
<td>Grading</td>
</tr>
</tbody>
</table>
Model Quality Management Plan for Mussel Processing

1. **PRODUCT DESCRIPTION**

   **Aquatic product raw material:** Mussels (*Mytilus* spp.)
   
   **Raw material harvest area:** [Harvest Location(s)]
   
   **Raw materials received:** Directly from firm’s lease, facility, or harvester
   
   **Finished product:** Live mussels
   
   **Aquaculture drugs, food additives, ingredients, processing aids:** None
   
   **Shipping:** Refrigerated trucks or iced in nonrefrigerated trucks
   
   **Intended use:** Product is intended to be consumed live, steamed, or fully cooked
   
   **Intended consumers:** General public

2. **FLOW DIAGRAM AND NARRATIVE FOR MUSSEL PROCESSING**

   *See figure 4.*

3. **POTENTIAL QUALITY FACTORS**

   - Filth in raw materials
   - Decomposition of raw material
   - Parasites in raw materials
   - Processing of dead mollusks
   - Temperature abuse during raw material storage (Decomposition)
   - Temperature abuse during processing of noncooked products (Decomposition)
   - Temperature abuse during final cooling (Decomposition)
   - Temperature abuse during finished product storage (Decomposition)
   - Temperature abuse during shipping (Decomposition)
   - Short weight
   - Species substitution
   - Grade size misrepresentation
4. **Quality Analysis Worksheet**
   See figure 17.

5. **Quality Management Form for Mussels**
   See figure 19.

6. **Examples of Monitoring Forms and Records**
   Examples of quality management records could include a recorder thermometer chart (figure 13), a temperature log (figure 14), and a receiving log (figure 20).
**Figure 19. Quality Management Form for Mussels.**

<table>
<thead>
<tr>
<th>QMP</th>
<th>Quality Factor</th>
<th>Quality Limits</th>
<th>Monitoring</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Filth</td>
<td>No detectable visible filth</td>
<td>Mussels, Visual</td>
<td>Reject products that fail to meet critical limits</td>
</tr>
<tr>
<td></td>
<td>Decomposition</td>
<td>No odors of decomposition</td>
<td>Mussels, Visual</td>
<td>Reject products that fail to meet critical limits</td>
</tr>
<tr>
<td>Raw material storage</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature recorder</td>
<td>Adjust thermostat</td>
</tr>
<tr>
<td>Finished product storage</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature recorder</td>
<td>Adjust thermostat</td>
</tr>
<tr>
<td>Shipping</td>
<td>Pathogen growth</td>
<td>Storage temperatures do not exceed 50°F (10°C)</td>
<td>Temperature recorder</td>
<td>Destroy</td>
</tr>
</tbody>
</table>

**Records**
- Receiving record
- Recorder chart

**Verification**
- Daily record review
- Daily record review; thermometer calibration
- Daily record review; temperature calibration

Reviewed by: ___________________________ Date: __________
**FIGURE 20. EXAMPLE OF A RECEIVING LOG.**

<table>
<thead>
<tr>
<th>Product Received</th>
<th>Time</th>
<th>Filt OK (√)</th>
<th>Decomp. OK (√)</th>
<th>Comments</th>
<th>Initials</th>
</tr>
</thead>
</table>

Reviewed by: ___________________________ Date: ____________
**Sanitation Standard Operating Procedures**

Each processor should have a written sanitation standard operating procedure (SSOP) that is specific to each location where fish and fishery products are produced. These sanitation controls need not be included in the plant’s HACCP plan. Sanitation control records must document SSOP monitoring and corrective actions. The SSOP should address at least the following sanitation conditions and practices:

<table>
<thead>
<tr>
<th>Condition/Practice</th>
<th>Recommended Inspection Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Safety of the water that comes into contact with food or food-contact surfaces, or is used in the manufacture of ice.</td>
<td></td>
</tr>
<tr>
<td>- Water that directly comes into contact with a product or with food-contact surfaces, or is used in the manufacture of ice, is derived from a safe and sanitary source or is being treated to render it of safe and sanitary quality</td>
<td></td>
</tr>
<tr>
<td>- There are no cross-connections between the potable water system and any nonpotable system.</td>
<td></td>
</tr>
<tr>
<td>2. Condition and cleanliness of food-contact surfaces, including utensils, gloves, and outer garments.</td>
<td></td>
</tr>
<tr>
<td>- All food-contact surfaces of plant equipment and utensils, including equipment used for ice production and storage, are so designed and of such material and workmanship as to be easily cleanable, and are maintained in a sanitary condition. Such surfaces shall be constructed of nontoxic materials and designed to withstand the environment of its intended use and the action of the food, cleaning compounds, and sanitizing agents.</td>
<td></td>
</tr>
<tr>
<td>As necessary to ensure control (public water system is exempt)</td>
<td></td>
</tr>
<tr>
<td>As necessary to ensure control (when plumbing is changed)</td>
<td></td>
</tr>
<tr>
<td>As necessary to ensure control (when received, modified, or repaired)</td>
<td></td>
</tr>
</tbody>
</table>
### Condition/Practice

- All utensils and surfaces of equipment that contact food during processing are cleaned and sanitized with effective cleaning and sanitizing preparations with the following frequency:
  - Cleaned at the end of the day’s operations;
  - Cleaned and sanitized at least every 4 hours during the processing of cooked, ready-to-eat fishery products; and
  - Sanitized before the beginning of the day’s operations.

- Gloves and outer garments that contact food or food-contact surfaces are made of an impermeable material and are maintained in a clean and sanitary condition.

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.

- Employees’ hands, gloves, outer garments, utensils, and food-contact surfaces of equipment that come into contact with waste, the floor, or other insanitary objects, do not contact fish or fishery products without first being adequately cleaned and sanitized.

- Where applicable, employee’s hands, gloves, outer garments, utensils, and food-contact surfaces of equipment that come into contact with raw product shall not contact cooked product or ice used on cooked product, without first being adequately cleaned and sanitized.

- Unprotected cooked, ready-to-eat fishery products, smoked fishery products, raw molluscan shellfish, and raw fish and fishery products shall be physically separated from each other during refrigerated

<table>
<thead>
<tr>
<th>Condition/Practice</th>
<th>Recommended Inspection Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaned at the end of the day’s operations</td>
<td>Immediately after cleaning</td>
</tr>
<tr>
<td>Cleaned and sanitized at least every 4 hours during the processing of cooked, ready-to-eat fishery products</td>
<td>Immediately after cleaning and sanitizing</td>
</tr>
<tr>
<td>Sanitized before the beginning of the day’s operations</td>
<td>Immediately after sanitizing</td>
</tr>
<tr>
<td>Gloves and outer garments that contact food or food-contact surfaces are made of an impermeable material and are maintained in a clean and sanitary condition</td>
<td>At least daily</td>
</tr>
<tr>
<td>At least every 4 hours during processing</td>
<td></td>
</tr>
<tr>
<td>At least every 4 hours during processing</td>
<td></td>
</tr>
<tr>
<td>Daily during operations</td>
<td></td>
</tr>
</tbody>
</table>
4. Maintenance of hand washing, hand sanitizing, and toilet facilities.

- Hand washing and hand sanitizing facilities are:
  - Located in all processing areas in which good sanitary practice requires employees to wash and sanitize their hands; and
  - Equipped with hand-cleaning and effective sanitizing preparations and single-service towels or suitable hand-drying devices.
  - Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.

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.

- Food, food-contact surfaces, and food-packaging materials shall be protected from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments, or other chemical or physical contaminants.

- Food, food-contact surfaces, and food-packaging materials shall be protected from contaminants that may drip, drain, or be drawn into the food.

- Compressed gases that contact food or food-contact surfaces of equipment shall be filtered or treated in a way that ensures that they will not contaminate the food with unapproved indirect food additives or other chemical, physical, or microbiological contaminants.

6. Proper labeling, storage, and use of toxic compounds.

<table>
<thead>
<tr>
<th>Condition/Practice</th>
<th>Recommended Inspection Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>storage.</td>
<td></td>
</tr>
<tr>
<td>4. Maintenance of hand washing, hand sanitizing, and toilet facilities.</td>
<td>After construction or building modification</td>
</tr>
<tr>
<td>- Hand washing and hand sanitizing facilities are:</td>
<td>At least daily (hand sanitizer strength shall be checked and recorded at least every 4 hours during processing)</td>
</tr>
<tr>
<td>- Located in all processing areas in which good sanitary practice requires employees to wash and sanitize their hands; and</td>
<td>Daily before operations</td>
</tr>
<tr>
<td>- Equipped with hand-cleaning and effective sanitizing preparations and single-service towels or suitable hand-drying devices.</td>
<td>Daily during operations</td>
</tr>
<tr>
<td>- Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.</td>
<td>As necessary to ensure control</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>- Food, food-contact surfaces, and food-packaging materials shall be protected from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments, or other chemical or physical contaminants.</td>
<td></td>
</tr>
<tr>
<td>- Food, food-contact surfaces, and food-packaging materials shall be protected from contaminants that may drip, drain, or be drawn into the food.</td>
<td></td>
</tr>
<tr>
<td>- Compressed gases that contact food or food-contact surfaces of equipment shall be filtered or treated in a way that ensures that they will not contaminate the food with unapproved indirect food additives or other chemical, physical, or microbiological contaminants.</td>
<td></td>
</tr>
<tr>
<td>6. Proper labeling, storage, and use of toxic compounds.</td>
<td></td>
</tr>
</tbody>
</table>
**Condition/practice**

- Toxic compounds shall be identified, held, used, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- The plant is designed to minimize the risk of contamination of the food, food-contact surfaces, and food-packaging material.

7. Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials, and food-contact surfaces.

- Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion (including boils, sores, or infected wounds), or any other source of microbial contamination by which there is a reasonable possibility that food, food-contact surfaces, or food-packaging materials will become contaminated, shall be excluded from any operations that may be expected to result in such contamination until the condition is corrected.

8. Exclusion of pests from the food plant.

- No pests are in any area of a food plant.

Examples of sanitation reports are included as figures 21 and 22.
**Figure 21. Example of a Periodic/Annual Sanitation Report.**

**Periodic/Annual Sanitation Report**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
<th>Date</th>
<th>Initials</th>
<th>Comments/Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant water is from a safe source</td>
<td>Annually</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No cross-connections between potable and nonpotable water systems</td>
<td>When plumbing is changed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment and utensils easily cleanable</td>
<td>When received, modified, repaired</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand washing/sanitizing facilities properly located</td>
<td>After construction or building modification</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewed by: ___________________________ Date: _______________
### FIGURE 22. EXAMPLE OF A DAILY SANITATION REPORT.

Daily Sanitation Report

<table>
<thead>
<tr>
<th>Condition/Procedure</th>
<th>Date</th>
<th>Time</th>
<th>Sanitizer conc.</th>
<th>Equipment Condition/Corrective Actions</th>
<th>Init.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before start of operations:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food-contact surfaces and utensils sanitized</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toilets are sanitary and in good repair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toilets have hand-cleaning and sanitizing preparations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toilets have single-service towels or hand-drying device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food, food-contact surfaces, and packaging materials protected from adulteration/contaminants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxic compounds identified and stored properly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee health conditions are acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No pests in plant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Every 4 hours during processing operations:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gloves/garments contacting food are clean and sanitary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee practices do not result in cross-contamination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooked and raw products physically separated in storage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand sanitizer strength is adequate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Every 4 hours during processing of cooked, ready-to-eat products:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food-contact surfaces and utensils cleaned and sanitized</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>At end of day's operations:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food-contact surfaces and utensils cleaned</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FDA. 1994. Fish and Fishery Products Hazards and Controls Guide. Food and Drug Administration, Department of Health and Human Services, Washington, DC.

