



**Facilities Inspection  
Manual**

## **Bulletin**

**TO:** All Holders of the Facilities Inspection Manual

**SUBJECT:** Guidance for Acceptable HACCP Controls for Live Molluscan Shellfish Processing Establishments

The purpose of this bulletin is to inform manual holders of the minimum expected HACCP controls for live molluscan shellfish processing establishments. This guidance document was developed to provide clear HACCP policies for all molluscan shellfish processing establishments, and to introduce new requirements for establishments that source shellfish from areas adjacent to wastewater treatment plants that are classified as conditional.

It is expected that improvements to this document will be forthcoming as a result of experience gained during implementation of conditional management in several key areas in Canada. Please note that this policy will be adjusted as necessary and finalized in 2009, when it will be published as appendix H of this manual.

### **1. Introduction**

This bulletin establishes the criteria for the development and implementation of an acceptable HACCP plan to control any health and safety hazards related to the processing of live molluscan shellfish. The criteria in this document serve to assist in the determination of compliance with the requirements of the Quality Management Program (QMP) Reference Standard, Section 5: The Hazard Analysis Critical Control Point (HACCP) Plan. Processors must review their HACCP controls and make changes necessary to ensure compliance with these criteria.

### **2. Scope**

This bulletin is applicable to all registered fish processing establishments that process live molluscan shellfish.

### **3. Requirements For HACCP Controls For The Processing Of Live Molluscan Shellfish**

The Canadian Shellfish Sanitation Program (as administered by the Canadian Food Inspection Agency, Environment Canada and Fisheries and Oceans Canada) provides the basis for determining which areas are acceptable for shellfish

harvesting. It is the responsibility of each registered shellfish processing establishment to use this information and any other control measures deemed necessary to ensure shellfish are safe for consumption. Any control measures developed must be clearly documented in each establishment's QMP.

As required by the Fish Inspection Regulations, an acceptable HACCP plan requires the appropriate application of the seven principles of HACCP by the operator of the fish processing establishment. In addition to the requirements listed in Section 5 of the QMP Reference Standard, a HACCP plan for live molluscan shellfish shall comply with the following requirements.

### **Product Description**

In order to conduct a hazard analysis and a determination of critical control points, the product description must identify all product attributes that influence the safety and acceptability of live molluscan shellfish. Product descriptions shall indicate:

- ▶ the CSSP classification of all harvest waters where the shellfish are sourced from.
- ▶ if the harvesting is subject to a conditional management plan or a decontamination plan.
- ▶ all culturing, harvesting, holding and transportation practices that may influence safety and acceptability.

Note: More detailed guidelines and references for the development of an acceptable product description can be found in Appendix A of the QMP Reference Standard.

### **3.1 Conduct a hazard analysis (Principle 1)**

The hazard analysis shall identify the following as a significant hazards:

- a) the presence of microbiological pathogens in harvest waters. Shellfish can be contaminated with these pathogens from sources of human sewage or animal feces in harvest waters. These waters can be:
  - ▶ subject to decontamination fisheries
  - ▶ subject to conditional management plans
  - ▶ subject to natural events (e.g. herring spawning activities)
  - ▶ subject to a technology used to grow shellfish that could create or attract significant potential sources of contamination (e.g. floating bags where large numbers of birds could perch)
  - ▶ closed to harvesting (emergency closures or sanitary closures)

- b) the presence of naturally occurring pathogenic microorganisms hazard where applicable. *Vibrio parahaemolyticus* (Vp) is considered a significant hazard in shellfish harvested in Pacific Northwest waters during the warmer months. Specific HACCP controls for this hazard are detailed in the document "HACCP Controls to Prevent the Growth of *Vibrio parahaemolyticus* to Unacceptable Levels in Live Oysters Destined for Raw Consumption".\*
- c) the presence of marine biotoxins in all harvest waters.

### **3.2 Determine the critical control points (Principle 2)**

For each significant hazard, a critical control point must be identified where appropriate control measures are applied to prevent or eliminate or reduce the hazard to an acceptable level.

For situations where it is possible for shellfish to be received by the processor before an area was closed to harvesting, a critical control point must be identified for the application of control measures involving monitoring of the harvest area status. Such situations include:

- ▶ Shellfish sourced from harvest waters subject to a conditional management plan for waste water treatment plant operation and which are inside the response line as identified on the classification map for that area.

### **3.3 Establish critical limits (Principle 3)**

A critical limit is a maximum or minimum value to which a hazard must be controlled at a critical control point. Critical limits shall be designed to:

- a) confirm that the safe harvest conditions were in place at time of harvest in conditionally classified areas. The conditional management plan (CMP) will define the required conditions and can be a source of validation of this critical limit.
  - ▶ Critical limits for a CMP for waste water treatment plant (WWTP) operation shall be designed to confirm acceptable WWTP operation at the time of harvest.
- b) confirm that shellfish are harvested from classified areas (except prohibited) and are in the open status.
- c) confirm that the terms of the relay or depuration as described in the decontamination plan have been achieved. The decontamination plan will serve as validation of the critical limits.

- d) ensure shellfish are not exposed to sources of contamination or conditions allowing microbiological pathogens to grow to unacceptable levels during harvesting, holding, and transporting from the harvest area to the processing establishment.

### 3.4 Establish a system to monitor control of the CCP (Principle 4)

At each CCP, the processor shall establish monitoring procedures to determine that the system is operating within the critical limits identified.

- a) For CCPs identified for shellfish harvested under a CMP, monitoring procedures must be in place to check that the conditions described in the CMP were in place at time of harvest.
  - ▶ Where the CMP is for the operation of a WWTP, monitoring procedures must take into account the time required for processors to become aware that the WWTP is not operating normally as described in the CMP. Acceptable monitoring procedures, for every lot of shellfish received, may involve:
    - \* Checking the status of the harvest area only after the response time identified in the CMP has elapsed.
    - \* Establishing direct communication systems with the operator of the WWTP to check that the conditions of the CMP were in place at time of harvest or equivalent monitoring procedures.
- b) For CCPs identified to prevent the processing of illegally harvested shellfish from closed areas (emergency closures, sanitary closures and marine biotoxin closures), monitoring procedures must be able to demonstrate that all harvesters are licensed and that all lots of shellfish correctly identify the harvest location. Examples of acceptable monitoring procedures may include but are not limited to:
  - ▶ Maintaining lists of licensed commercial harvesters that the processor will only accept shellfish from
  - ▶ Checking tags or questioning harvesters at receipt to identify the harvest location
  - ▶ Buying at the harvest location
  - ▶ Having a representative of the processor at the harvest area to observe harvesting practices (master harvester)
  - ▶ Establishing harvest plans that identify, in advance, the harvesters and location of harvest
  - ▶ Establishing supplier quality assurance agreements (SQAs) with lease holders

- ▶ Checking the area status for emergency closures, sanitary closures and biotoxin closures on Fisheries and Oceans Canada websites or by other means of communication with DFO
- c) For CCPs identified for shellfish harvested under a MCFR licence, monitoring procedures must be able to demonstrate that the terms of the relay or depuration, as described in the decontamination plan, have been achieved. Examples of acceptable monitoring procedures may include but are not limited to:
- ▶ Monitoring shellfish tracking records to ensure all lots of shellfish are relayed or for the appropriate amount of time (i.e., 14 days).
  - ▶ Monitoring shellfish tracking records to ensure all lots of shellfish are depurated for the appropriate amount of time (i.e., 48 or 72 hours) and other key depuration parameters such as:
    - \* tank flow rates
    - \* loading capacity of tanks and trays
    - \* faecal coliform levels
    - \* spacing of trays within tanks
    - \* water quality parameters such as temperature, salinity, dissolved oxygen, turbidity, ammonia, etc.
  - ▶ Establishing supplier quality assurance agreements (SQAs) with holders of the MCFR licence
- d) For CCPs identified for the conditions during the holding and transport of shellfish from the harvest site to the processor, monitoring procedures must be able to demonstrate that shellfish are not exposed to sources of contamination or conditions allowing microbiological pathogens to grow to unacceptable levels. Examples of acceptable monitoring procedures may include but are not limited to:
- ▶ Establishing supplier quality assurance agreements (SQAs) with suppliers.
  - ▶ Requiring suppliers to document harvest and transport conditions.
- 3.5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control (Principle 5)**
- a) Corrective action procedures must address the segregation of affected product and the culling, reworking and/or disposition of affected product.
- ▶ Unless otherwise specified in the CMP, shellfish

received by the processor that was harvested when the conditions (such as the normal operation of the WWTP) described in the CMP were not in place, must be returned to the original harvest area or disposed

- ▶ Corrective action procedures must identify that when the safety of shellfish is in question, it will be returned to the harvest area or disposed.
- b) Corrective action procedures must prevent or reduce the likelihood of reoccurrence of the problem
- ▶ by investigating how the problem developed
  - ▶ by reviewing the QMP Plan to determine where changes are required to prevent re-occurrence of the problem
  - ▶ by implementing the changes
- c) Unacceptable shellfish sample results can be an indication that existing CCPs are not effective in ensuring that shellfish received for processing originated from the identified harvest waters. In response to unacceptable lab results, the processor is required to re-evaluate their HACCP plan and make modifications as required.
- ▶ Where the investigation determines that problem is related to the misrepresentation of the harvesting area then the processor shall modify the controls for assuring that shellfish labels accurately identify the harvest location
  - ▶ Where the investigation determines that the problem is linked to the harvest area then the processor shall consider modifying controls to ensure that harvest practices are adjusted to take into account any potential sources of contamination
- d) In response to any other information questioning the effectiveness of HACCP controls, the processor shall re-evaluate their HACCP plan and make modifications as required.

Additional guidance for implementing acceptable corrective actions, applicable to the processing of all fish and seafood products, is contained in Appendix I of the Reference Standard (to be issued at a later date).

### **3.6 Establish procedures for verification to confirm that the HACCP system is working effectively (Principle 6)**

The HACCP plan must identify the verification activities designed to demonstrate that the HACCP controls are implemented effectively. Processors are required to have two types of ongoing verification procedures:

- a) Records of the monitoring actions for CCP critical limits and corrective actions taken must be verified at an established frequency to confirm that they are occurring as described in the QMP plan.
- b) Independent checks must be completed to verify that the control measures implemented at each CCP are adequate and effective.
  - ▶ For shellfish harvested under a CMP, the processor shall review the results of the verification activities described in the CMP annual report.
  - ▶ For shellfish that is delivered to registered establishments by harvesters, procedures must be in place to verify that harvest area information on tags and/or harvester verbal or paper declarations are accurate.
  - ▶ microbiological analysis, at specified frequencies, is required for incoming shellfish, shellfish before and after depuration, and for shellfish after relay if the relay period is less than 21 days.

Additional guidance for the development of acceptable QMP Verification and Maintenance activities applicable to the processing of all fish and seafood products is contained in Appendix G of the Reference Standard.

**3.7 Establish documentation concerning all procedures and records appropriate to these principles and their application (Principle 7)**

- a) For shellfish harvested under a Conditional Management Plan, a copy of the plan must be included in the QMP plan documentation.
- b) For shellfish harvested under a MCFR licence, a copy of the decontamination plan must be included in the QMP plan documentation.
- c) EC classification maps showing where shellfish can be harvested from must be readily accessible.
- d) Current DFO shellfish prohibition orders which delineate what areas are closed to shellfish harvesting must be readily accessible.
- e) Supplier Quality Assurance (SQA) agreements that are used as a control measure as well as a record of verification of the SQA.
- f) Records shall be kept for all testing, measurements, and monitoring at CCPs.

- g) Records shall be kept for corrective actions when the critical limits are exceeded.
- h) Records shall be kept of all verification activities.
- i) Records shall be kept of any changes made to the QMP plan.