Appendix H
Guidelines for Effective HACCP Controls for Molluscan Shellfish Processing Establishments

1. Purpose

The purpose of this document is to advise registered shellfish processing establishments of the minimum expected HACCP controls for processing live molluscan shellfish. The criteria listed below are intended 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 and related QMP requirements.

2. HACCP Controls for the Processing of Live Molluscan Shellfish

The Canadian Shellfish Sanitation Program (CSSP) is administered by the Canadian Food Inspection Agency, Environment Canada and Fisheries and Oceans Canada and provides the basis for determining which areas are acceptable for shellfish harvesting in most circumstances. The CSSP provides information to interested stakeholders about which shellfish areas are open and closed to shellfish harvesting. The use of open and closed status as a critical limit when receiving shellfish may not be an adequate or appropriate control measure for some hazards or certain situations. Alternative or additional control measures are discussed in more detail within these guidelines.

It is the responsibility of each registered shellfish processing establishment to use the information provided by the CSSP and any other applicable information source to develop the required control measures which will ensure shellfish are safe for consumption.

Registered shellfish processing establishments that purchase shellfish from other registered shellfish processing establishments must ensure that appropriate HACCP controls are being applied. Shellfish processing establishments must consider any other activities that occur prior to receipt (e.g. relay by harvesters under a Management of Contaminated Fisheries Regulations (MCFR) licence, time-temperature controls for Vibrio parahaemolyticus, on board human waste containment, surface aquaculture bird contamination control measures, etc.) and incorporate appropriate control measures into their QMP plan. The development and routine verification of a Supplier Quality Assurance (SQA) agreement may be part of an appropriate control measure for these situations. Further guidance on the development of an SQA can be found in Appendix E of the QMP Reference Standard, Criteria for an Acceptable Supplier Quality Assurance Agreement.

Registered shellfish processing establishments that receive shellfish from integrated multi-trophic aquaculture sites may require special control measures as described in appendix XII of CSSP Manual of Operations - Procedure for Development, Approval and Review of an Integrated Multi-trophic Aquaculture Management Plan.

All control measures developed must be clearly documented in each establishment's QMP.

An acceptable HACCP plan requires the appropriate application of the seven principles of HACCP by the operator of the processing establishment. The first step in developing an effective HACCP plan is to accurately describe the product and processing through a product description and process flow chart.

A HACCP plan (and related documents) for live molluscan shellfish shall comply with the following requirements.
2.1 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:

- which harvest area(s) and/or registered establishments (if applicable) shellfish are sourced from;
- whether the harvesting is subject to a conditional management plan, or a decontamination plan;
- whether the shellfish are wet stored near shore or on shore (including the water source);
- all culturing, pre-harvest, harvesting, holding, wet storage and transportation practices that may influence safety;
- special labelling instructions; and
- intended use (i.e. consumed raw or cooked).

More detailed information on product descriptions can be found in Appendix A of the QMP Reference Standard, Guidelines for the Development of a Product Description.

2.2 Process Flow

The process flow diagram must outline all production steps under the control of the registered shellfish processing establishment (e.g. pre-harvest, harvest, buy stations, buy trucks, transportation, near shore or on shore wet storage, relay, receiving, heat shock, depuration). The process flow diagram must be complete and accurate.

Note: Registered shellfish establishments must also be aware of production steps that are under the control of a third party and occur prior to receipt at the establishment. A supplier quality assurance agreement may be required (see Section 2).

2.3 Conduct a hazard analysis (Principle 1)

The hazard analysis is conducted at each process step identified in the process flow diagram. This will assist the establishment in identifying the process step(s) where a significant hazard may be present, introduced or increase to unacceptable levels. For molluscan shellfish, hazards related to natural toxins and chemical contamination cannot be eliminated, reduced or controlled by cooking or heat processing, therefore these hazards must be considered as significant and controlled prior to or at receiving.

There may be hazards present at process steps that are not under direct control of the registered molluscan shellfish processing establishment. These hazards must be identified for consideration at the step where the shellfish comes under the processor’s control (e.g. at receiving).

Significant hazards to be considered for molluscan shellfish include, but are not limited to, the following:

a) The presence of microbiological pathogens in harvest, wet storage or relay areas. Sources of microbiological contamination can be from:

- human sources (e.g. wastewater treatment plants, direct discharges from boats or homes, malfunctioning septic systems);
- agricultural animals;
• natural sources (e.g. wildlife, marine mammals, birds, etc.);
• natural events such as herring spawning which can attract birds or mammals; and
• birds which are roosting on aquaculture equipment (e.g. floating Vexar® bags, buoys, etc.)

b) The presence and growth of naturally occurring pathogenic microorganisms such as *Vibrio parahaemolyticus* where applicable.

c) The presence of marine biotoxins in all harvest areas and in areas where shellfish are wet stored (either near shore or on shore).

d) The presence of chemical contamination (e.g. heavy metals, hydrocarbons, etc.).

### 2.4 Determine the critical control points (CCP) (Principle 2)

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

a) It is required that all shellfish processing establishments will have a critical control point at receiving.

i) The processor must be able to determine that shellfish are harvested from an approved or conditionally approved area in the open status, or are harvested under an appropriate MCFR licence and where the conditions of the licence have been met.

ii) The processor must be able to determine that the shellfish are from harvest vessels that have adequate control measures to prevent contamination of shellfish by human waste and that have sanitary practices on the use of human waste receptacles or washroom facilities.

b) Shellfish harvested under an MCFR licence must be subject to a decontamination process. A CCP must be established at the processing step where the decontamination occurs (e.g. relay, depuration, or shucking of scallops).

c) In some circumstances shellfish may be exposed to hazards before the harvest area is closed. Shellfish may be harvested in offshore areas which are not subject to routine CSSP monitoring. Additional or alternate CCPs must be identified to control potential hazards in such situations. Some examples include:

• shellfish sourced from harvest areas subject to a conditional management plan based on the operation of a waste water treatment plant (WWTP) and are harvested inside the response line as identified on the classification map for those areas;
• shellfish sourced from harvest areas where biotoxin levels are known to rapidly rise above action levels;
• harvesting and processing the shellfish species which are being used as the sentinel species for biotoxin monitoring and the harvest areas are subject to periodic closures; and
• monitoring marine biotoxin levels in shellfish from offshore harvest areas on a lot by lot basis

d) In certain situations, a critical control point(s) to limit time-temperature exposure may be required to control specific microbiological hazards (such as *Vibrio parahaemolyticus*) from harvesting to final product shipping.
e) Shellfish that are subject to near shore wet storage, on shore wet storage or depuration may need a CCP to control the introduction of microbiological, biotoxin or chemical hazards. For additional guidance on wet storage refer to chapter 5 of the CSSP manual of operations.

2.5 Establish critical limits (Principle 3)

One or more critical limits must be established for each CCP as determined by established control measures. As a minimum, critical limits in a shellfish processing establishment must address the following:

a) Shellfish are harvested from approved or conditionally approved areas and are in the open status.

b) Shellfish are sourced from harvest vessels that have adequate control measures to prevent contamination of shellfish by human wastes and that have sanitary practices on the use of human waste receptacles or washroom facilities.

c) Shellfish harvested under a MCFR licence are decontaminated (e.g. relayed, depurated, shucked) as per the conditions stipulated in the MCFR licence. For relay and depuration applicable requirements of Chapter 10 of the CSSP must be met.

d) Shellfish can be harvested and received by a processor before the harvest area is closed. This may include conditionally classified areas that are based on the operation of a WWTP or areas that are subject to a rapid rise in marine biotoxin levels. Shellfish can be harvested from offshore areas not subject to routine CSSP monitoring for marine biotoxins.

e) Levels of naturally-occurring microbiological pathogens (e.g. *Vibrio parahaemolyticus*) must meet identified standards in the final product. For example, critical limits are identified to address the level of microbiological pathogens at the time of harvest and limit time/temperature exposure from harvest to final product shipping. These critical limits must be established during warmer months if the shellfish are destined for raw consumption.

f) Near shore wet storage areas must be in the open status prior to removing shellfish from a wet storage site.

) Source water for on shore wet storage or depuration systems must originate from shellfish harvest areas that are approved or conditionally approved in the open status or be treated by a validated water treatment system and approved by the CFIA.

Each water treatment system must be validated to ensure it can eliminate or reduce the potential microbiological or biotoxin hazards to acceptable levels.

- Ultraviolet (UV) water treatment systems used to eliminate microbiological hazards in source water must ensure that:
  - the turbidity does not exceed the manufacturer’s specifications, or in the absence of the manufacturer’s specifications, must be less than 20 Nephelometric turbidity units;
  - the UV intensity meets the manufacturer’s specifications for adequate disinfection; and
  - the water flow rate does not exceed the manufacturer’s specifications.

- Water filtration systems designed to filter toxic phytoplankton from source water must ensure that the toxic phytoplankton of concern are eliminated or reduced to an acceptable level (as measured in post filtered water samples).
2.6 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 identified critical limits.

a) For CCPs identified to prevent the processing of shellfish from restricted, prohibited, unclassified areas or from areas in the closed status, monitoring procedures must be able to demonstrate that the area is classified as approved or conditionally approved and in the open status for every lot of shellfish received. Examples of acceptable monitoring procedures may include but are not limited to:

- checking the harvest area status for sanitary closures, biotoxin closures, emergency closures posted by Fisheries and Oceans Canada on websites or by other means of communication with DFO;
- maintaining lists of licensed commercial harvesters that the processor will only accept shellfish from;
- checking tags or questioning harvesters at receiving to identify the harvest location;
- buying at the harvest location;
- having a representative of the processor at the harvest area to observe harvesting practices (e.g. master harvester for wild harvest); and
- establishing harvest plans that identify, in advance, the harvesters and location of harvest;

Use of multiple monitoring procedures will increase confidence that a critical limit has been met.

b) For CCPs identified to prevent the sourcing of shellfish from harvest vessels that do not have adequate controls to prevent contamination of shellfish by human waste or sanitary practices on the use of human waste receptacles or washroom facilities:

- monitoring procedures must demonstrate that the shellfish are sourced from harvesting vessels that have adequate controls to prevent the contamination of shellfish by human waste (list of acceptable harvesters).
- monitoring procedures must demonstrate that the shellfish are sourced from harvesting vessels that have sanitary controls to ensure that all persons sanitize their hands after using or cleaning an on board waste receptacle or using a washroom facility.

c) For CCPs identified for shellfish harvested under a MCFR licence, monitoring procedures must be able to demonstrate that the terms of the decontamination plan have been achieved. Minimum decontamination plan requirements for depuration and relay can be found in Chapter 10 of the CSSP manual of operations. Each depuration facility will have specific requirements that are based on species specific validated depuration processes. Examples of acceptable monitoring procedures may include but are not limited to:

- monitoring shellfish relay times to ensure all lots of shellfish are relayed for the required amount of time (e.g.14 days);
- monitoring shellfish depuration times to ensure all lots of shellfish are depurated for the required amount of time (e.g. 44, 48 or 72 hours);
- monitoring key depuration parameters that affect depuration performance; and
- monitoring the shucking of scallops to ensure the adductor muscle is free of viscera.

d) For CCPs identified where shellfish are received and can be potentially affected by a hazard before an area is closed or from offshore areas that are not routinely tested, monitoring procedures must be able to demonstrate that the shellfish are safe at time of harvest.
• For harvest areas 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.
  
  o 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 inside the response line only after the detection, notification and response (DNR) time identified in the CMP has elapsed.

• For open harvest areas known to have biotoxin events that can rapidly rise above the action level or shellfish species that are used as the sentinel species in biotoxin monitoring, monitoring procedures must be in place to confirm the action levels have not been exceeded. Examples of additional acceptable monitoring procedures may include but are not limited to:
  
  o hold product until a biotoxin monitoring result from the same harvest date or subsequent harvest date is available; and/or
  o analyze product using a rapid test kit or by other means.

• For offshore harvest areas monitoring procedures must be in place to confirm biotoxin levels are acceptable.

e) 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 (i.e. *Vibrio parahaemolyticus*). One example of an acceptable control measure may be to monitor time and temperatures (e.g. reviewing records, measuring temperatures, etc.).

f) For near shore wet storage, monitoring procedures must ensure that the wet storage site is in the open status when shellfish are removed.

g) When source water for on shore wet storage or depuration systems originates from shellfish harvest areas, monitoring procedures must ensure that harvest area is in the open status or the water treatment system is functioning as designed.

• Monitoring of ultraviolet (UV) water treatment systems used to eliminate microbiological hazards in source water must ensure that:
  
  o the turbidity does not exceed the manufacturer’s specifications, or in the absence of the manufacturer’s specifications, must be less than 20 Nephelometric turbidity units;
  o the UV intensity meets the manufacturer’s specifications for adequate disinfection; and
  o the water flow rate does not exceed the manufacturer’s specifications.

• Monitoring of water filtration systems designed to filter toxic phytoplankton from source water must ensure that the toxic phytoplankton of concern are eliminated or reduced to an acceptable level (as measured in post filtered water samples).
2.7 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control (Principle 5)

When monitoring indicates that a critical limit has not been met, corrective action procedures must be initiated. The written corrective action procedures must address:

- how the deficiency that gave rise to the problem will be corrected;
- how affected product will be identified and segregated;
- how affected product will be disposed of in an appropriate manner. When the safety of shellfish is in question, it must be returned to the harvest area or destroyed.
- how reoccurrence of the problem will be prevented. This will likely include:
  - a review of the QMP Plan and identification of necessary changes (e.g. changes of procedures, control measures, standards, etc.);
  - the implementation of necessary changes;
  - identification of changes in the QMP amendment log.
- a record keeping system to document the details of the problem, including the date the problem was identified, the corrective action taken, the person(s) responsible for the action, the date the action was taken and the changes needed to eliminate or prevent re-occurrence of the problem.

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 areas. In response to unacceptable laboratory results, the processor is required to re-evaluate their HACCP plan and make modifications as required.

- Where the investigation determines that the problem is related to inadequate controls under the QMP, the processor shall take appropriate steps to review, modify and implement effective controls to bring the QMP into compliance.
- Where the investigation determines that the problem is linked to the harvest area then the processor shall modify controls to ensure that harvest practices are adjusted to take into account any potential sources of contamination.

2.8 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) For each monitoring procedure there must be verification procedures in place to ensure that the control measures implemented at each CCP are adequate and effective.

- 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 information provided by the harvester is accurate.
- Microbiological analysis, at specified frequencies, is required for shellfish before and after depuration, and for shellfish after relay if the relay period is less than 21 days.
- For depuration systems or on shore wet storage systems where water treatment is required, microbiological analysis of water is required to verify the ongoing effectiveness of the treatment system.
For filtration systems that are used to remove toxic phytoplankton, biotoxin analysis of shellfish is required.

**Note:** Re-validation is required after any alteration to the treatment system or a change in source water is made.

More detailed information on verification can be found in [Appendix G of the QMP Reference Standard, Guidelines for the Verification and Maintenance of the QMP](#).

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

Some examples of documentation and records that may be part of a shellfish QMP or be readily available (internet access) include:

- for shellfish harvested from a WWTP conditional area, a copy of the conditional management plan;
- for shellfish harvested under a MCFR licence, a copy of the decontamination plan;
- supplier Quality Assurance (SQA) agreements;
- records of all testing, measurements, and monitoring at CCPs;
- records of all corrective actions when the critical limits are exceeded;
- records of all verification activities; and
- records of wet storage history.

- growing area documents showing where shellfish are harvested; and
- current DFO shellfish prohibition orders which delineate what areas are closed to shellfish harvesting.