Appendix K - Guidelines on measures to control the risk of *Vibrio parahaemolyticus* in live oysters

1. **Purpose**

The purpose of this document is to provide information on options for controlling the risk of *Vibrio parahaemolyticus* (Vp) in live oysters. This will help federally registered establishments and importers understand and control the risk of Vp in oysters they process or import for raw consumption. This document covers some generic best practices and example control measures. It is not intended as an exhaustive list of measures. Always ensure that the control(s) chosen are tailored to the uniqueness of your business and shown to be effective for your situation.

2. **Requirements for controlling the risk of Vp**

   If you are a federally registered establishment, you are required to do the following:
   - Do a hazard analysis on the processing of live oysters in your establishment.
   - Implement control measures to prevent or eliminate the significant hazards identified so that the oysters meet the Canadian guideline for Vp found in Appendix 2 - Bacteriological Guidelines for Fish and Fish Products (end product).

   If you are an importer, you are required to understand the risk(s) associated with the oysters you import. You must do the following:
   - Take appropriate actions to source product only from suppliers that can provide assurances that the oysters meet the Canadian guideline for Vp.
   - Ensure proper temperature control during the transportation and storage of your oysters.

3. **Understanding Vp**

   3.1 **Why Vp is a hazard in live oysters**

   Vp can cause food-borne illness in humans.
   - Vp is a food-borne pathogen that is commonly found in shellfish such as oysters.
   - Vp has been linked to gastroenteritis (“stomach flu”) outbreaks associated with people consuming shellfish that is raw or insufficiently cooked.\(^1\)

   3.2 **How oysters can become contaminated with Vp**

   Vp is a naturally occurring bacteria found in estuaries throughout the world.
   - It is known to occur in some Canadian coastal waters.
• It can be present in shellfish growing areas, regardless of their regulatory classification as suitable for the harvesting of shellfish according to accepted water quality standards and general sanitary conditions in the shellfish area.

### 3.3 When can Vp levels increase to an unacceptable level in the harvest sites?

The level of Vp in the harvest waters can change quickly. This is due to a variety of factors such as a rise in temperature, heavy rainfall, flood or plankton blooms.

- Vp levels in shellfish harvest sites are at their highest:
  - during summer months
  - at the end of the low tide cycle after the oysters are out of the water and have been exposed to the warm air and the sun.

- Vp can multiply rapidly in live oysters in their marine environment. It can increase in numbers to a level that cause gastroenteritis when the water temperature is at 15°C or higher.
  - Vp is at its highest level during the warmer months. It is present in Canadian Pacific and Atlantic waters, usually from June until September. But it has been detected in the Pacific Ocean in May and October.
  - Oysters completely submerged in deep water have also been found to have Vp levels that greatly exceed Canadian guidelines. This is likely due to the growth of Vp in the warmer marine environment.

- Vp has been found to attach itself to zooplankton. When zooplankton increases in the water as the temperature rises, Vp levels in the waters can also increase.

### 3.4 Factors favourable to the growth of Vp

- Vp can grow:
  - in the water and oysters at the harvest areas when:
    - the water temperature is 15°C and above
    - the water salinity is between 0.5% and 8%.
  - in harvested oysters that are maintained at a temperature of 5°C or higher. Vp can double in number in under 2 hours when the oysters are maintained at 25°C.
  - in final oyster products that have a pH of 4.8 or higher or a water activity of 0.93 or higher.

### 4. Controlling the risk of Vp in live oysters

#### 4.1 Control the risk of Vp at the harvest site

Vp is a significant hazard when detected in the oysters at a harvest site and:
- the levels are persistently near or exceed the limit set by the Canadian guideline for Vp in the oysters, or
- the water temperature is 15°C or higher
Measures are needed at harvest to ensure that the oysters that will be harvested meet the Canadian guideline for Vp.

The following are example measures that could contribute to acceptable levels of Vp in oysters at harvest time. You can use these alone or in combination.

- Monitor the water temperature in the harvest sites, at the same area and level where the oysters are. This will help determine the site-specific season for Vp becoming a significant hazard in a given harvest area.

- When the water temperature rises to 15°C or above during Vp season, and when weather conditions are favorable to the growth of Vp, consider the following:
  
  o Test levels of Vp in oysters regularly at the harvest sites, at a frequency that provides reasonable assurance that oysters harvested would meet the Canadian guideline for Vp.
  
  - Base the frequency of Vp testing on an assessment of the combined factors that influence the level of Vp such as the water temperature, air temperature, water salinity, and water depth.
  
  - Sample several oysters. Because Vp levels can vary, broad sampling will give you test results that better reflect the levels that would be found in the oysters in the harvest site.
  
  - Do additional oyster testing when:
    i) there is a change in the conditions that affect the Vp level (such as storms, dredging, construction, accidents)
    ii) Vp illnesses have been reported.
    iii) Vp levels are persistently near or exceed the limit set by Canadian guideline for Vp.
  
  - Take samples that are representative of the lot, location and method of harvest. Take the samples consistently.

  Examples on how to achieve this include the following:
  
  - For deep water harvest sites (10 to 30 feet below surface), take samples of oysters closest to the surface so that the sample represents the worst case scenario.
  
  - When both deep water and beach/intertidal oysters are harvested from a site, take a sample that represents the “worst case scenario” from both areas of the site.
  
  - Take 10 to 12 oysters per sample.
  
  - Cool the samples rapidly, maintain them at a temperature below 4°C and send them to the laboratory for testing within 24 hours.

  o Harvest oysters from intertidal or beach harvest sites only:
    
    - When Vp test results meet the Canadian guideline for Vp and are low enough to account for the potential growth that can occur in the oysters after harvest.
• On a high tide, a receding tide or after the incoming tide has covered the oysters long enough so that the temperature of the oysters is at its lowest\(^5\).

When the level of Vp in the oysters is close to or exceeds the Canadian guideline for Vp you may apply measures to reduce the Vp level as long as they are validated to be effective in reducing Vp to an acceptable level. The following are examples of measures that may be considered:
• Re-submerging the oysters for the number of tidal cycles determined to be effective.
• Placing the oysters in cool water during wet storage or relay.

4.2 Control the risk of Vp after harvest

The presence of Vp in oysters is a significant hazard when the temperature of the oysters or surrounding air after harvest and during handling, storage and transportation become favorable to its growth. Measures are needed after harvest to prevent the growth of Vp. These focus on controlling temperatures.

The following are examples of measures that could prevent Vp from increasing to an unacceptable level in the oysters after harvest. You can use them alone or in combination,

• Cover the oysters onboard the harvest vessel with ice slurry immediately after harvest to reduce the internal temperature of the oysters to 4°C\(^{10}\). Place the oysters in a refrigerator at 4°C or lower within 5 hours of harvest\(^{11}\).

• The cooling measures need to take into consideration the temperature of more than one oyster at more than one area within the middle of the lot and the surrounding air.
  o When the water or oyster temperature is 15°C or higher, the cooling measures should reduce the internal temperature of the oysters to 10°C within 20 minutes.
  o When the water or oyster temperature is 15°C or lower, the cooling measures should reduce the internal temperature of the oysters to 10°C within 3 hours of harvest\(^9\).

• Maintain the internal temperature of oysters at 4°C or lower during transportation.\(^{10}\)

• Place the oysters uniformly in a refrigerated transport truck to allow air circulation for more effective cooling. If using an unrefrigerated transport truck, place the oysters in insulated containers with flake/slush ice for transport.

• Protect the oysters from exposure to the sun.\(^{10}\)

4.3 Control the risk of Vp during wet storage or relay

When Vp is present in the waters used for wet storage or relay, or present in the oysters placed there, it is a significant hazard if the conditions become favorable to its growth. To prevent the growth of Vp, use measures similar to those applied at harvest (see section 4.1).

If you use wet storage or relay to reduce the level of Vp in oysters, you must do this in
accordance to the requirements outlined in chapter 5 and 10 of the Canadian Shellfish Sanitation Program and the methods must be validated as effective in reducing Vp to an acceptable level.

4.4 Control the risk of Vp at the receiving step

The presence of Vp in oysters should have been controlled by measures taken during and after harvest. If these measures are not implemented directly by you, Vp is a significant hazard in the oysters received. Measures are then needed at the receiving step to prevent oysters with an unacceptable Vp level from being received for processing as live oysters.

The following are examples of measures you could use to prevent receiving oysters that have an unacceptable Vp level. You can use them alone or in combination.

- Have in place a **Supplier Quality Assurance Agreement** with the independent harvesters or aquaculturists that outlines:
  - the control measures they implement at the harvest sites and after harvest to ensure that the oysters comply with the Canadian guidelines for Vp, and
  - the process to notify you when there is information that indicates the oysters you received may have an unacceptable Vp level.

- Measure and record the internal temperature of the oysters received.
  - Accept only oysters which have been rapidly cooled to an internal temperature of 10°C or lower.

- Get a copy of the records which demonstrate that the oysters comply with the requirements of the SQA. For example, records of temperature and Vp levels at the harvest sites and records of the time and temperature controls measured after harvest. Do this for each lot of oysters you receive.

- Store oysters received at 4°C or lower.

4.5 Control the risk of Vp during processing at the establishment

Vp is a significant hazard during processing when the oysters are exposed, for a prolonged period, to a temperature favorable to its growth.

Measures are needed during processing to prevent the growth of Vp.

The following are examples of measures that could prevent Vp from increasing to an unacceptable level in oysters during processing.

- Maintain the oysters at a temperature of 10°C or lower for the duration of the processing steps.
- Control the cumulative duration of exposure to temperatures above 10°C in the processing environment to no more than 3 hours\(^1\).  
  - Record the time and temperature at the start of each processing step.
5. Verifying your control measures

You must routinely verify that your control measures are being implemented as you intended and that they are effective. Verification activities are typically carried out by someone other than the person in charge of monitoring. You must document your verification activities.

Examples of verification activities include the following:

- Review records to make sure they are being completed and that the critical limits are being met consistently.

- Interview and observe staff (for example at the cooling shellfish step) to make sure they understand the procedures and that they are following them correctly.

- Take measurements to confirm that you are operating within your pre-defined time/temperature limits. These include time and temperatures checks, additional to those done during monitoring if applicable.

- Follow the verification procedures described in your Supplier Quality Assurance agreement (if you have one), for example:
  - Review aquaculturists or harvesters’ records.
  - Inspect products and materials (for example, how product is stored and maintained at cold temperatures).
  - Sample products at supplier and analyse for Vp.
  - Observe how procedures are followed and interview staff.

- Test the oysters at a set frequency and at specific steps of the process, to verify that they comply with the Canadian guidelines for Vp.
  - Note that the methods recognized by the Canadian Food Inspection Agency (CFIA) for decision making can be found in Health Canada's Compendium of Analytical Methods.
  - As per the Policy on the Use of Third Party Laboratories for Testing Fish and Fish Products Under the Fish Inspection Program, the CFIA recognizes the results of testing conducted by laboratories accredited under ISO/IEC 17025.

Depending on the risk, you may need to do different verification activities at different levels of frequency. You should increase the monitoring and verification frequency when operational conditions change (for example, change in production volume, fluctuating weather, rapidly increasing water and air temperatures), or when Vp illnesses are known to be occurring in your region. This will confirm that control measures are continuing to be practical and effective.

Changes to your control measures must be validated following one or a combination of approaches as illustrated in Codex guidance and Appendix L of the QMP reference standard on HACCP Validation of Controls for Vibrio parahaemolyticus.
References


10. Government of Canada. Fish Inspection Regulations (C.R.C., c. 802)
