Appendix L - HACCP Validation of Controls for *Vibrio parahaemolyticus*

**Purpose**

The main purpose of this document is to illustrate the application of the Codex Guideline for the Validation of Food Safety Control Measures (CAC/GL 69-2008) as it relates to *Vibrio parahaemolyticus* in bivalve shellfish. The Codex validation guidelines are comprehensive in nature and describe the interrelationships between validation, monitoring, and verification. Therefore, it is recommended to read and understand those concepts prior to reading this document.


The following provides an example only of how validation of a process designed to control Vp might be structured. The technical details in this document are not exhaustive. The use of scientifically valid experimental data or harvest to shipping validation studies under controlled conditions (collecting and analyzing one’s own scientific data) to demonstrate the adequacy of the control measures is required.

**I. Tasks Prior to Validation of Control Measures**

1. **Description of the food commodity:**
   a) **Product Name:** Live Oysters
   b) **Source of Raw Material:** Oysters harvested from shellfish areas classified as approved or conditionally approved in subarea XX-XX; landfile #1234, lease 9876, BC, NB, PE, NS
   c) **Important Product Characteristics**
      Needs refrigeration
   d) **Ingredients**
      No ingredients
   e) **Product Packaging**
      Mesh bags, waxed cardboard boxes
   f) **End Product Use**
      Consumed raw
   g) **Product Shelf Life**
      7-14 days, refrigerated
   h) **Where the Product will be sold**
      Retail stores and restaurants, in Canada
   i) **Labelling Instructions Related to Food Safety**
      Keep refrigerated: < 5°C
   j) **Special Distribution Controls**
      Keep refrigerated: < 5°C

2. **Hazard to be controlled:**

   *Vibrio parahaemolyticus*
3. Intended outcome:

To ensure that the controls to manage the risk of *Vibrio parahaemolyticus* in live oysters are effective and that products meet the CFIA bacteriological guideline for *Vibrio parahaemolyticus*.

4. Control measure(s) (process design) to be validated:

- Shellstock temperature at harvest is reduced in a time frame to effectively limit Vp growth.
- Relay of shellstock to ensure consistent Vp levels after relay are below X/g
- Onshore wet storage of shellstock to ensure Vp levels are below X/g.

II. Validation Process

1. Approach to Validate the Control Measure

- Validation study - Validation of Time-Temperature Controls for *Vibrio parahaemolyticus* conducted at the registered Shellfish Processing Establishment XYZ.
- Validation study - Validation of X days relay on Lease # XYZ prior to harvest for direct consumption.
- Validation study - Validation of X days in a controlled onshore wet storage environment at registered shellfish processing establishment XYZ.

2. Defining the Control Measure Parameters and Acceptance Criteria

a. Control Measure Parameters: According to the most recent scientific literature rapidly cooling shellfish to below 10°C limits Vp growth. The goal is to have the shellfish reach an internal temperature of X°C within Y hours of harvest. Assuming some growth may occur during the cooling phase, the Vp target at harvest will be set at a maximum of X/g.

b. Control Measure Parameters: When handling product where the harvest area is not directly monitored by the processor or the harvest area has historically high Vp levels, relay product for X days in water < X°C to ensure Vp levels at harvest are less than X/g as stipulated in (a).

c. Control Measure Parameters: When handling product from harvest areas with historically high Vp levels (list areas and time of year) product is wet stored in a controlled environment in a registered establishment for X days in water < X°C to ensure Vp levels are less than those referenced in section I.3.
Control Measure Acceptance Criteria: Final product meets the CFIA bacteriological guideline for *Vibrio parahaemolyticus*.

3. Assemble Relevant Validation Information and Conduct the Validation Studies

Obtain and review scientific literature/data on Vp growth and control.

b. Identify the level of the hazard(s) to be used in the validation study.
Example: Vp at <X/g at harvest, ≤ CFIA bacteriological guideline upon shipment.

c. Design and document the steps involved in conducting the validation study.

Time-Temperature Control Validation

- A lot of shellfish is harvested and placed uniformly in trays/sacks
- Temperature of shellstock and water is measured upon harvest
- Date and time of harvest is recorded.
- A sample is taken and sent for Vp analysis
- Shellstock containers are uniformly placed in a refrigerated truck to allow air circulation (document spacing and take photographs of loading arrangement) or shellfish is placed in insulated containers in truck with flake/slush ice. Note air temperature in truck.
- Measure internal temperature of shellstock (sample farthest from cooling unit) every hour during transit or continuously using time/temperature recording probes until receipt at processing establishment. Record data.
- Measure time and temperature every hour during processing/packing/storage at registered establishment, record data.
- Analyse this lot for Vp (n=5) just prior shipping.
- Repeat the above steps during high risk Vp season until confidence is established that controls are effective. Statistical analysis of the data may be necessary.
- Determine the outcome of the validation study

Relay validation

- A lot of shellfish (with high Vp levels) is placed on a designated sub-tidal relay lease.
- The lot is sampled for Vp immediately prior to being placed at the relay site. The location of this sample site(s) selection within the lease is noted and is to be used for all subsequent validation samples.
- Temperature of relay water and shellstock is recorded at the zero hour.
• Water/shell stock temperature at the sites within the relay lease is recorded daily throughout the proposed relay period.
• Relayed lot is sampled representatively at predetermined days from start of relay and until X/g target for harvest is achieved consistently throughout the lot.
• Repeat the above steps during high risk Vp season until confidence is established that controls are effective. Statistical analysis of the data may be necessary.
• Determine the outcome of the validation study.

Onshore Wet Storage Validation

A lot of shellfish (with high Vp levels) is placed in a wet storage system.

• The lot is sampled for Vp immediately prior to being placed at the wet storage site. The location of this sample site(s) selection within the wet storage system is noted and is to be used for all subsequent validation samples.
• Temperature of wet storage water and shellstock is recorded at the zero hour.
• Water and shellstock temperature is recorded daily throughout the proposed wet storage period.
• The lot is sampled representatively at predetermined days from start of wet storage process and or until X/g target for harvest is achieved consistently throughout the lot.
• Repeat the above steps during high risk Vp season until confidence is established that controls are effective. Statistical analysis of the data may be necessary.
• Determine the outcome of the validation study.

d. For time/temperature validation, confirm that the initial Vp level at harvest is low enough to be effective. If not, adjust control measures or reset Vp level at harvest to a lower level.

e. Conduct validation study described in part 3c. and verify during the study that the control measure parameters and acceptance criteria are met.

4. Analyze the Results and Confirm the Effectiveness of the Control Measure(s)

a. All data acquired during the validation study must be included in the validation report.
b. Statistical analysis (if required/if necessary).
c. State the Time-Temperature controls (<X°C in Y hours) that are effective at limiting Vp growth when Vp levels are <X/g at harvest.
d. Relay for X days at X°C is effective to reduce Vp levels to X/g prior to harvest when water temperatures below X°C.

e. Onshore wet storage for X days in a controlled environment at X°C is effective to reduce Vp levels to X/g.

5. Document and Review the Validation

The results and analysis for this validation study have been documented and can be found in file # 123.

It is important to note that in some cases Vp levels prior to harvest may be in excess of the bacteriological guideline and that other control measures (other than time/temperature controls) are warranted. These may include shucking and labeling products as "to be cooked" or applying a validated post-harvest treatment process that is designed to reduce Vp to acceptable levels (for example; high pressure processing).