４．各州のビブリオ管理計画

VIBRIO PARAHAEMOLYTICUS CONTROL PLAN - CALIFORNIA

Harvest Time to temperature control in California.

Following the NSSP Model Ordinance, the maximum allowable time to temperature control is 5 hours for months in which *Vp* illness is reasonably likely to occur.

The two exceptions to this requirement are for the offshore lease in Santa Barbara Channel and the growing areas in Humboldt Bay, which have a 10-hour and 8-hour time to temperature control, respectively.

Required Maximum Time to Temperature Control (hours) by Growing Area and Month.

Month	Humboldt Bay	Outer Tomales Bay 1	Inner and Mid Tomales Bay 2	Morro Bay	Santa Barbara Channel	Agua Hedionda Lagoon
January	24	18	18	16	18	18
February	24	18	18	16	18	18
March	24	18	16	14	18	5
April	21	18	13	13	18	5
May	18	18	5	13	18	5
June	8	15	5	5	10	5
July	8	5	5	5	10	5
August	8	5	5	5	10	5
September	8	5	5	5	10	5
October	16	11	5	5	10	5
November	23	16	14	12	10	5
December	24	23	18	16	18	5

For the Santa Barbara growing area, a 10-hour time to temperature control has been implemented for months in which the monthly average water temperature is greater than 60 °F. The FDA risk assessment tool shows that with a maximum time to temperature control of 10 hours, less than 1 illness out of 1 million servings can be expected to occur. This growing area is approximately 1 mile offshore and the shellfish are cultured at a depth of 30 feet in an approximate depth of 90 feet of seawater. The position of this lease may shelter it from resuspended Vp in sediment. There has been

no history of Vp illness associated with product from this growing area.

For Humboldt Bay, an 8-hour time to temperature control has been implemented for months in which the monthly average water temperature is greater than 60°F. The FDA risk assessment tool shows that with a maximum time to temperature control of 8 hours, less than 1 illness out of 1 million servings can be expected to occur. There has been only one Vp illness associated with product from Humboldt Bay.

Time to Internal temperature control

During months that *Vp* illness is reasonably likely to occur the original dealer of oysters is required to cool the oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less after placement into refrigeration. The dealer's Hazard Analysis Critical Control

Points (HACCP) Plan shall include the controls necessary to ensure, document, and verify that this requirement is met.

Months in which a 10 Hour Time to Internal Temperature of 50°F is Required for Oysters. (Indicated by letter "Y")

Month	Humboldt Bay	Outer Tomales Bay[1]	Inner and Mid Tomales Bay[2]	Morro Bay	Santa Barbara Channel	Agua Hedionda Lagoon
January	-	-	-	-	-	-
February	-	-	-	-	-	-
March	-	-	-	-	-	Y
April	-	-	-	-	-	Y
May	-	-	Y	-	-	Y
June	Y	-	Y	Y	Y	Y
July	Y	Y	Y	Y	Y	Y
August	Y	Y	Y	Y	Y	Y
September	Y	Y	Y	Y	Y	Y
October	-	-	Y	Y	Y	Y
November	-	-	-	-	Y	Y
December	-	-	-	-	-	Y

Closure and Recall

- California Department of Public Health (CDPH) will immediately close a growing area to oyster harvest if the total *Vp* tlh1 of an oyster sample collected from the growing area2 is 10,000 MPN/g or greater3.
- CDPH will immediately initiate a voluntary industry recall if an oyster sample from a harvest lot contains total *Vp tlh* of 10,000 MPN/g or greater.
- When a post-harvest sample is greater than or equal to the closure limit of 10,000 MPN/g total *Vp tlh*, the harvester will immediately collect and submit an oyster sample from the source growing area for *Vp* analysis.

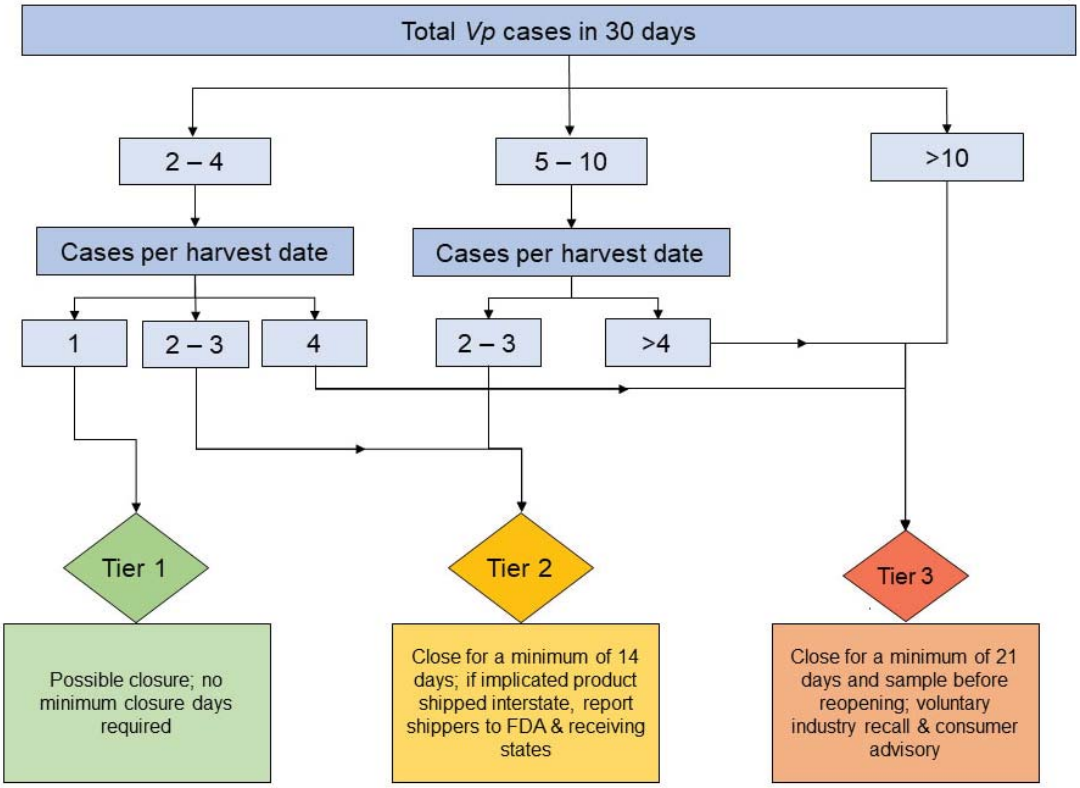
Table below lists the Vp thresholds and actions.

Threshold	**Total *Vp tlh* (MPN/g)**	***Vp tdh* or *Vp trh* (MPN/g)**	**Sample Location**	**Action**
NSSP/FDA	≥ 10,000	N/A	Growing area	Growing area closure
			Harvest lot	Voluntary recall of lot, if applicable. Collect and submit a growing area sample.
CDPH	≥ 100	N/A	Growing area	No action required. Recommend Optional *Vp* Control Measures
CDPH	N/A	≥ 10	Growing area	No action required. Recommend

				Optional *Vp* Control Measures

- When any commercial growing area is epidemiologically associated with a *Vp* illness outbreak, defined as two or more persons from different households with laboratory confirmed *Vp* illnesses within a 30-day period, and a single source of consumed shellfish product has been traced to the growing area, CDPH will follow the closure and recall procedures prescribed in the NSSP Model Ordinance.

The flow chart below shows the NSSP Model Ordinance (2017) 3-tier response to the outbreak of a Vibrio parahaemolyticus illness adopted by the State of California.



- If an investigation of Vp illnesses cannot be completed within 24 hours, CDPH may close the implicated growing area to harvest until enough information is provided to allow reopening of the growing area or place it in one of the closure tiers described above. During the investigation CDPH may require additional samples from the implicated growing area as needed.

RECONDITIONING

A. Temperature Control Not Met

If the required time to temperature control requirements are not met after harvest, the harvester shall dispose of the oysters using one of the methods below and record the disposition on the harvest record:

(i) destroy the oysters; or

(ii) place the oysters within the original growing area or another approved growing area and allow a minimum of 14 days before harvesting. This must be done with CDPH approval and product must be tracked, separated, and marked.

B. Recalled Product

Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *Vp* or exceeding the sample closure threshold may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing or placing product into a classified growing area for a minimum of 14 days. This must be done with CDPH approval and product must be tracked, separated, and marked.

GROWING AREA REOPENING

A. Reopening from Elevated Sample

- For growing area closures resulting from Vp growing area samples, the closed status shall remain in effect until a representative sample of oyster meat, contains less than 10,000 MPN/g total Vp tlh.
- It is the responsibility of the affected harvester(s) to sample for reopening. The affected area will remain closed until a representative sample meets the reopening criteria stated above.
- Samples for reopening must by analyzed by a conforming laboratory using the NSSP approved Vp methods for reopening. It is the individual harvester's responsibility to make all necessary arrangements with the laboratory for receipt and processing of the samples. CDPH can assist with identification of available laboratories. All costs related to sampling, transportation, and laboratory assay and reporting are the responsibility of the individual shellfish harvester. CDPH may direct the shellfish harvester to collect additional samples from other areas as needed.

B. Vp illness outbreak reopening.

When a growing/harvesting area is closed due to an outbreak of a Vp illness, reopening shall follow the criteria as indicated in the table below;

Illness Outbreak	Period for reopening
Tier 1	there are no minimum required closure days. Reopening can occur as determined by CDPH.
Tier 2	reopening can occur after at least 14 days of closure.
Tier 3	reopening can occur after at least 21 days of closure and after representative samples of oyster meats contain less than 10 MPN/g tdh and trh Vp.

Sample Protocol

a. Sample Collection

Each sample for Vp analysis will consist of at least 15 unshucked whole oysters or more if necessary to provide the laboratory with 250 grams of tissue. Care must be taken to avoid damaging the shell and cross-contaminating samples. Each unshucked shellfish sample will be placed in a clean plastic bag, labeled with the sampling location (e.g., lease number, specific location within the lease), the date and time of sample collection, the date and time of harvest if appropriate, and the ambient water temperature at the exact location where the oysters were collected. Each bag must be sealed to prevent commingling of samples. Samples must be immediately placed in a clean ice chest filled with enough blue ice to chill and hold the samples at 4°C to 10°C (39.2°F - 50°F). Samples should be delivered to the laboratory as soon as possible and must be delivered within 22 hours to allow the lab time to process the sample before the required 24-hour holding time is up.

b. Laboratory Methods

Commercial shellfish harvesters who have been directed to collect monitoring samples for Vp must submit samples to a laboratory identified by CDPH using an appropriate screening method for Vp genes tlh, tdh, and trh.

A regulatory reopening sample must be tested by a laboratory in conformance with the current NSSP approved method for enumeration of total Vp tlh and the pathogenic Vp genes thermostable direct hemolysin (tdh) and tdh-related hemolysin (trh). Currently no laboratories in California meet this criterion. CDPH can assist with identification of appropriate available laboratories for reopening samples.

Water salinity in the growing areas in California

All monthly average salinities are in the range of 24 parts per thousand (ppt) to 35 ppt.

CONNECTICUT DEPARTMENT OF AGRICULTURE

PO Box 97, 190 Rogers Avenue, Milford, CT 06460
Bureau of Aquaculture

CONNECTICUT 2020 *VIBRIO PARAHAEMOLYTICUS* CONTROL PLAN (VPCP) EFFECTIVE JUNE 1 THROUGH SEPTEMBER 30

June1, 2020

(NOTE: OYSTER HARVEST FROM DARIEN, NORWALK AND WESTPORT REQUIRES ADDITIONAL VPCP)

Harvester Company Name: _____ SS# _____

Method of Cooling (truck, cooler, ice, slurry): _____

☐ *Aquaculture producer request for exemption from shading requirement?*

☐ *Aquaculture producer practicing Re-submergence or Off-site Culling?*(see section A.2 for definitions)*

Signature: _____ Date: _____

Licensed Shellstock Shipper Responsible for Cooling Process (if different than above)

Company Name: _____ SS# _____

Facility Address: _____ Town: _____

Signature: _____ Date: _____

STATE OF CONNECTICUT DEPARTMENT OF AGRICULTURE COMMERCIAL HARVEST RESTRICTIONS FOR OYSTERS:

A.1. SSI (Harvester/Dealer):

1. This plan applies to all oysters harvested for human consumption. No provision of this plan shall apply to seed oysters.

2. The requirements of this plan shall apply to all oysters harvested in Connecticut's coastal waters from June 1 through September 30, 2020, both dates inclusive. *NOTE: For oyster harvest from Darien, Norwalk, and/or Westport growing areas, this Connecticut VPCP must be signed in addition to the 2020 VPCP for Darien, Norwalk, and Westport Growing Areas.*

3. All oysters harvested from June 1 through September 30, 2020 shall be adequately shaded* from direct sunlight while onboard the vessel and during transport from harvest area to original dealer. (*Aquaculture producers may request an exemption from the shading requirement from DA/BA when submitting their signed CT VP Control Plan prior to the start of Vibrio season. Unless an exemption is granted by DA/BA, adequate shading remains a requirement of all producers.*) *See Definitions Section

4. All oysters shall be adequately iced* or placed under temperature control* **within five (5) hours from the beginning of harvest during June, July, August and September.** Upon landing, all oysters shall be adequately iced or placed under temperature control immediately or transported directly to the wholesale dealer's physical facility to be placed under temperature control within these time frames.

5. Each harvester shall maintain a harvest log book that

records the date, start time of harvest, time to dock, amount harvested (count, bags, etc) and time sold or time refrigerated recorded in indelible ink. Harvest start time shall be recorded in log before the vessel leaves the harvest area.

6. Shellstock invoices/documentation shall include the time of harvest* in addition to harvest date, harvest area (lot and Town), type of shellstock and quantity, as well as Shipping Document* including *VPCP Time to Temperature Control Statement**.

7. Pursuant to *CGS Sec. 26-192c. Inspection and regulations concerning shellfish* any license may be suspended pending revocation proceedings, or amended, if shellfishing operations or harvesting areas are a public health hazard or if the licensee has violated any provision of this section, section 26-192e, 26-192f, or 26-192h or any applicable department regulation or any section of the public health code.

A.2. Re-submergence* and Off-site Culling*

- Oyster Handling, Off-site Culling, and Re-submergence:
  - Market-sized oysters removed from the waters of a growing area for any oyster culture activities (e.g. culling, sorting, anti-fouling, etc.) for a period of more than five (5) hours will be considered **offsite culled*** and must be returned to the same license site and re- submerged for a minimum of ten (10) days prior to harvest.
  - Oyster culture activities of market-sized oysters conducted on barges, boats, or other floating structures within the same designated shellfish growing area that do not exceed the

five (5) hour requirement for adequate icing or temperature control will not be considered off-site culled. These oysters may be harvested in accordance with this Plan or returned to the original license site and harvested the following calendar day.

- Oyster culture activities of market-sized oysters conducted on barges, boats, or other floating structures that exceed five (5) hours from the time of harvest or exposure shall be considered off-site culled and are subject to ten (10) day re-submergence.
- All containers of re-submerged oysters or areas used for broadcast re-submergence must be segregated on the original license site. If containerized, tags must identify the oysters as "re- submerged" and must include the date the oysters were re-submerged.
    - Tags must be waterproof, legible and completed with indelible ink.
    - After ten (10) days the tags may be removed and discarded.
    - Producers who engage in broadcast re-submergence or batch tagging for re-submerged oysters must submit a re-submergence plan to DMF for approval 30 days prior to the start of the activity. Re-submergence plans must, at a minimum, include:
        - A description of the re-submergence method (broadcast on bottom, cages, etc.);
        - A description of segregation method; and
        - A description of tagging method.
- All producers engaging in re-submergence must record all re-submergence activities in their Relay or HACCP logbook, which must include at a minimum the information outlined below:

- The producer shall record:
  - the date shellfish are returned to the growing area for re-submergence,
  - the earliest date oysters may be removed from re-submergence,
  - the harvest area,
  - quantity of oysters resubmerged,
  - the type and number of containers, and
  - the category of re-submergence (antifouling, off-site culling, recall, etc.).

B. Original Receiving Dealer (SSI/Harvester or SSIII):

1. **All oysters received by the original dealer* between June 1 and September 30, 2020 shall be cooled to 50° F internal temperature within 5 hours of being placed under temperature control.** It is strongly recommended that cooling be achieved as quickly as possible; based on cooler validation studies conducted in Connecticut, cooling to 50° F internal temperature can be readily achieved within 5 hours by dealers.

   *For the purposes of this plan, the "original dealer" is the first to receive shellstock from the harvester and initiate the cooling process; the original dealer may be an CT SSI or an CT SSIII. If an SSI has access to mechanical refrigeration, they are required to act as the original dealer and must ensure that oysters reach an internal temperature of **50°F within 5 hours of being placed under temperature control and prior to being sold.** This original dealer must have access to mechanical refrigeration or a conveyance which has been inspected and Approved by the DA/BA for the storage of shellstock. This conveyance must be pre-chilled prior to loading oysters and must be maintained at 45°F or below when shellstock is stored. This conveyance must be capable of reducing the internal temperature of product to 50°F within 5 hours.

   If the SSI/harvester does not have access to mechanical refrigeration, they shall not be considered the "original dealer";

the original dealer is the first to receive shellstock from the SSI/harvester and initiate the cooling process. This original dealer must receive shellstock within harvest time limits and shall meet and document the internal temperature requirements for oysters under this plan.

The “original dealer” responsible for initiating the cooling process and documenting internal temperatures critical limits must be recorded on this form and Approved by DA/BA prior to the start of the VPCP season.

2. All dealers who receive oysters harvested from Connecticut coastal waters between June 1 and September 30 inclusive shall implement a HACCP plan that indicates pathogen growth of naturally occurring Vp as a significant hazard that is reasonably likely to occur and includes the following:

   a. Critical Control Point Receiving: All oysters received by the original shipper shall be accompanied by invoice and shipping document in accordance with section A.6 of this Plan;

   b. Critical Control Point Receiving: All oysters shall be harvested in accordance with the time temperature requirements of Chapter VIII @.02 A.(2); according to the requirements of this Plan oysters must be received within 5 hours from the start of harvest during June, July, August, and September. In order for the original dealer to receive shellstock, the original dealer must know what time the shellstock was first harvested and receive that shellstock within the required time frame.

      When receiving oysters from a Connecticut Licensed Harvester/Shipper I, shellstock acceptability (receiving Critical Control Points) can be determined as follows:

      1. The shipment of shellfish is accompanied by

documentation that indicates time of harvest; and

2. The time between shellstock harvest and shellstock icing or refrigeration does not exceed 5 hours during June, July, August and September.

c. Critical Control Point Storage: A Critical Limit indicating that the internal temperature*of oysters has reached 50° F (10° C) or below within 5 hours and prior to sale. During Vibrio control plan months, the original dealer may not ship oysters until the internal temperature has reached 50° F (10° C) or below; the oysters must reach 50° F (10° C) or below within 5 hours (1 hour from time of harvest for Darien, Norwalk or Westport). Time into refrigeration and time that internal temperature reaches 50° F must be documented on a HACCP record. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50° F (10° C) or below within 5 hours or less.

Please note that each observation of internal temperature must include:

- Actual temperature observation (i.e. 47° F NOT <50° F)
- Actual time that the temperature was recorded (i.e. 2:15 pm NOT <5 hours);
- Initial of person performing the observation.

d. Critical Control Point Storage: A Corrective Action to ensure that oysters that are not cooled to an internal temperature of 50° F (10° C) within 5 hours are not sold for human consumption.

3. A dealer shall ensure that mechanical refrigeration used for the cooling and storing of oysters meets model ordinance requirements and the requirements of

this plan:

a. Mechanical refrigeration or other conveyance must be pre-chilled and maintained at 45° F or below; and

b. Mechanical refrigeration or conveyance must be capable of reducing the internal temperature of product to 50° F within 5 hours.

c. The use of temporary or inadequate cooling is not acceptable.

Note: Dealers should be advised that cooling rates for oysters will depend on size and capacity of refrigerated storage areas. Oysters should be stored in a manner that allows for the free circulation of refrigerated air in order to achieve even and rapid cooling throughout each containerized lot of shellstock.

4. Pursuant to *CGS Sec. 26-192c. Inspection and regulations concerning shellfish* any license may be suspended pending revocation proceedings, or amended, if shellfishing operations or harvesting areas are a public health hazard or if the licensee has violated any provision of this section, section 26-192e, 26-192f, or 26-192h or any applicable department regulation or any section of the public health code.

C. Corrective Action:

1. Dealers shall reject any lots of oysters that are not properly tagged and invoiced as required by this Plan.

2. Dealer shall reject any lots of oysters that have not been received within the harvest time frames required by the Plan.
3. Dealers who receive shipments of oysters that are not

compliant with the requirements of Section A or B of this Plan shall place the shellstock on internal hold and immediately notify the Department of Agriculture Bureau of Aquaculture (DABA). Dealers shall then document the deviation as a Corrective Action and await instruction from the DABA for final disposition of time/temperature abused oysters.

D. Enforcement:

1. Representatives of regulatory agencies (DA/BA, Food and Drug Administration (FDA), Department of Environmental Protection (CT DEEP), etc.) shall conduct periodic unannounced inspections at harvest sites, common landings and wholesale dealer facilities to determine compliance with the requirements of this Plan.

2. Any new cooling process or any process that has changed since the previous season (such as a new cooler, different equipment, change in volume of shellfish harvested, etc.) must be evaluated by DA/BA prior to the start of the VPCP season.

3. Cooling processes that have been previously evaluated and validated by DA/BA will be re-evaluated during the VPCP season.

4. Cooling processes may be evaluated by DA/BA under worst case conditions during the course of the VPCP season.

5. All shellfish harvested under this plan shall be subject to embargo, disposal, or return to growing area under supervision if found to be significantly time/temperature abused or non-compliant with requirements of this Plan. Refusal of harvesters and/or dealers to allow inspection or inability to maintain compliance with the requirements of this

plan may result in enforcement up to and including suspension and revocation of harvester and/or dealer license in accordance with *CGS Sec. 26-192c.*

*Definitions:

Adequately Iced means the containers holding the shellfish have enough ice on the shellfish that is sufficient to ensure that immediate cooling begins and continues to provide cooling until required internal temperatures are achieved within 5 hours of being placed under temperature control.

Adequately Shaded means that measures shall be taken to prevent oysters from direct exposure to sunlight that might cause a significant increase in pathogenic growth due to an increase in temperature.

Internal Temperature means the internal temperature of the meat of the animal as measured using a calibrated probe thermometer; under most circumstances when measuring the temperature of previously cooled product, the internal temperature of shellstock is reflected by the external temperature of the space surrounding the shellfish, or the external temperature of the shell at the center of a packaged mass of shellstock (box, bag, etc) and may be measured by inserting a thermometer probe into the package to an appropriate depth.

NOTE: When verifying a rapid cooling procedure, the shellstock must be opened and the actual internal temperature of the meat measured using a calibrated probe thermometer, as there may be a significant difference between the amount of time it takes to cool the shell of the animal compared to the meat. An approved rapid cooling procedure must be verified using the internal temperature of the meat as measured.

Shipping Documentation *is defined as the documentation required by the NSSP Model Ordinance to accompany all shipments of shellstock that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice*

of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature recording device indicating that continuing cooling has occurred. In order to comply with the requirements of this VPCP, the ***VPCP Time to Temperature Control Statement*** must also be included with the shipping documentation.

Temperature Control is defined as mechanical refrigeration or other conveyance pre-chilled and maintained at 45°F or below and capable of reducing the internal temperature of product to 50°F within 5 hours.

Time of Harvest means the time when the first shellstock is removed from the water or, in the case of intertidal harvest, the time of first exposure.

VPCP Time to Temperature Control Statement is a statement that accompanies a shellstock shipment that indicates the time interval at which shellstock was placed under temperature control and cooled to an internal temperature meeting applicable VPCP control plan requirements.

The CT Department of Agriculture Bureau of Aquaculture will review this Plan on an annual basis and revise it as needed to maintain compliance with the National Shellfish Sanitation Program's Model Ordinance.

VIBRIO PARAHAEMOLYTICUS CONTROL PLAN – FLORIDA

Requirements for Harvest Areas

Approved Harvest areas shall meet the following requirements:

(a) The area is not so contaminated with fecal material or poisonous or deleterious substances that consumption of the shellfish might be hazardous; and,

(b) The bacteriological quality of every sampling station in those portions of the area most probably exposed to fecal contamination shall meet one of the following standards during the most unfavorable meteorological, hydrographic, seasonal, and point source pollution conditions:

i) The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 14 per 100 ml., and not more than 10% percent of the samples shall exceed a fecal coliform MPN of 43 per 100 ml. (per 5-tube, 3-dilution test) or

ii) The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 14 per 100 ml., and not more than 10% percent of the samples shall exceed a fecal coliform MPN of 33 per 100 ml. (per 12-tube, single-dilution test) or

iii) The median or geometric mean fecal coliform Membrane Filter (MF) colony forming units of water shall not exceed 14 per 100 ml., and not more than 10% percent of the samples shall exceed a fecal coliform MF colony forming unit of 31 per 100 ml.

Harvest from temporarily closed approved areas shall be unlawful.

Restricted harvest areas

– An area shall be classified as restricted when a sanitary survey, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that fecal material, pathogenic microorganisms, radionuclides, harmful chemicals, and marine biotoxins are not present in dangerous concentrations after shellfish from such an area are subjected to a suitable and effective purification process. The bacteriological quality of every sampling station in those portions of the area most probably exposed to fecal contamination shall meet the following standard: The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 88 per 100 ml. and not more than 10 percent of the samples shall exceed a fecal coliform MPN of 260 per 100 ml. (per 5-tube, 3-dilution test) or the median or geometric mean fecal coliform Membrane Filter (MF) colony forming units of water shall not exceed 88 per 100 ml., and not more than 10 percent of the samples shall exceed a fecal coliform MF colony forming unit of 163 per 100 ml. in those portions of the area most probably exposed to fecal contamination during the most unfavorable meteorological, hydrographic, seasonal, and point source pollution conditions.

Conditionally approved harvest areas –

An area shall be classified as conditionally approved when a sanitary survey, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that the area is subjected to intermittent microbiological pollution. The suitability of such

an area for harvesting shellfish for direct marketing may be dependent upon attainment of established performance standards by wastewater treatment facilities discharging effluent directly or indirectly into the area.

Conditionally restricted harvest areas – An area shall be classified as conditionally restricted when a sanitary survey or other monitoring program data, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that the area is subjected to intermittent microbiological pollution. The suitability of such an area for harvest of shellfish for relaying or depuration activities is dependent upon the attainment of established performance standards by wastewater treatment facilities discharging effluent, directly or indirectly, into the area. In other instances, the sanitary quality of such an area may be affected by seasonal population, non-point sources of pollution, or sporadic use of a dock, marina, or harbor facility, and these intermittent pollution events are predictable.

Prohibited harvest areas

– An area shall be classified as prohibited if a sanitary survey indicates that the area does not meet the approved, conditionally approved, restricted, or conditionally restricted classifications. Harvest of shellfish from prohibited areas shall be unlawful. The waters of all man-made canals and marinas are classified prohibited regardless of their location.

Requirement for handling shellfish

Wet storage

Harvesters and dealers using wet storage facilities shall ensure that the shellstock are free any source of contamination within the facility. The shellfish processors shall be require to submit to the authorities among others the particulars, description, location of the wet storage facility. They shall also indicated the species to be stored in the facilities.

Records and logs

Shellfish processors must maintain an oyster replant log of all replant/resubmerged activities including:

i) Date of initial removal from water at lease site;

ii) Lease number;

iii) Date of replant;

iv) Replant lease number;

v) Replant location on lease; and,

vi) Replant Quantity.

Shellfish processor must provide access to records upon request by the Department

Replanting/resubmergence

All replanted/resumberged shellfish must be segregated from other shellfish and clearly identified on

the lease.

Replanted/resumberged aquaculture oysters larger than 25 millimeters (3/4 inch) that are removed from the water during the course of routine oyster husbandry practices for more than 4 hours during April through October must be returned to the lease and submerged on an aquaculture lease for a minimum of 14 days before they can be harvested and sold to a certified shellfish processing facility. Routine oyster husbandry practices include the use of suspended grow out containers that maybe unsubmerged during natural tidal cycles.

Harvesting time to temperature control requirements

Throughout the year, shellfish shall be harvested between sunrise and sunset as established by the U.S. Weather Service. All shellfish shall be delivered, same day of harvest, by the harvester directly to a certified shellfish processing facility.

(a) Clams:

i) During the months of November, December, January, February, and March, all clams harvested shall be delivered to a certified shellfish processing facility and placed under temperature control by 10:00 p.m. of the same day as harvest.

ii) During the months of April, May, and October, all clams harvested shall be delivered to a certified shellfish processing facility and placed under temperature control within twelve (12) hours of the time of harvest, or within the same day as harvest, whichever is earlier.

iii) During the months of June, July, August, and September, all clams harvested shall be delivered to a certified shellfish processing facility and placed under temperature control within ten (10) hours of the time of harvest, or within the same day as harvest, whichever is earlier.

Tempering, as an alternative process, shall consist of those methods which have demonstrated through verification studies that the process renders hard clams which are as safe as hard clams. Prior to initiating tempering a certified shellfish facility shall have written approval from the Department.

The certified shellfish facility must provide the following:

i) A description of all facilities, equipment and methods to be used in the alternative process. This process must be included in the facility's HACCP plan.

ii) The source of hard clams and the maximum capacity of hard clams to undergo the process at any one time.

iii) The process to be followed shall not exceed 16 hours total time between hard clam harvest and refrigeration at 45º F or less. Product harvest, processing, tempering and food storage at 45º F or less must be scheduled to occur as a continuous procedure.

iv) Upon initiation, the tempering process must have temperature control of 68^{o}F or less and be maintained until hard clams are placed into refrigeration of 45º F or less.

b) Oysters

- Non-Vibrio Control months include November, December, January, February and March.
- Vibrio Control months include April, May, June, July, August, September and October.
- During the months of November, December, January, February, and March, all oysters harvested shall be delivered to a certified shellfish processing facility and placed under mechanical refrigeration by 5:00 p.m. of the same day as harvest.
- During the month of April, all oysters harvested shall be delivered to a certified shellfish processing facility and placed under mechanical refrigeration by 11:00 a.m. of the same day of harvest unless the harvester is identified in the certified shellfish processing facility's HACCP plan for the onboard cooling option or the certified shellfish processing facility is authorized for the rapid cooling option.
- During the months of May, June, July, August, and September, all oysters harvested shall be tagged as "FOR SHUCKING ONLY BY A CERTIFIED FACILITY" or "FOR POST HARVEST PROCESSING ONLY" and delivered to a certified shellfish processing facility and placed under mechanical refrigeration by 4:00 p.m. of the same day of harvest unless the harvester is identified in the certified shellfish processing facility's HACCP plan for the onboard cooling option, or the certified shellfish processing facility is authorized for the rapid cooling option.
- During the month of October, all oysters harvested shall be delivered to a certified shellfish processing facility and placed under mechanical refrigeration by 11:00 a.m. unless the harvester is identified in the certified shellfish processing facility's HACCP plan for the onboard cooling option, or the certified shellfish processing facility is authorized for the rapid cooling option.
- Once received by a certified shellfish processing facility, the shellstock lot shall be immediately processed and placed under temperature control and until sale to final consumer, the shellstock shall be maintained at an environmental temperature of 45º F or less and not be permitted to remain outside of temperature control for more than 2 hours cumulative at points of transfer within the processing facility such as loading docks or in the facility during processing. All certified shellfish processing facilities handling oysters must have a cooling system capable of reducing the internal temperature of shellstock oysters to 55º F or less within eight (8) hours.

Onboard Cooling Option

Onboard cooling equipment includes systems using ice, mechanical refrigeration, or vacuum cooling. If a commercial oyster harvester is using onboard cooling with ice slurry, the maximum time oysters can remain outside the cooling system is one hour from time of harvest and the onboard cooling system shall be capable of reducing the internal temperature of oysters to 55º F or less and maintaining at 55º F or less until delivery to the certified shellfish processing facility. Commercial

Harvesters must maintain an onboard time and temperature record documenting time of harvest, time oysters placed under refrigeration, and time that oysters reach 55º F or less.

Commercial harvesters using onboard cooling systems must deliver the oysters to a certified shellfish processing facility and oysters must be placed under mechanical refrigeration by the shellfish processor no later than 3:00 p.m. of the harvest day. Oysters must be at 55°F or less at time of delivery.

Rapid cooling option requirements:

Rapid cooling equipment includes systems using ice, mechanical refrigeration, or vacuum cooling. If a shellfish processor elects to rapidly cool oysters:

(a) During the month of April shellfish processors must place all harvested oysters under mechanical refrigeration no later than 1:00 p.m. and cooled down to 55º F or less no later than 3:00 p.m. of the harvest day.

(b) During the months of May, June, July, August, and September shellfish processors must place all harvested oysters under mechanical refrigeration no later than 11:00 a.m. and cooled down to 55º F or less no later than 1:00 p.m. of the harvest day.

(c) During the month of October shellfish processors must place all harvested oysters under mechanical refrigeration no later than 1:00 p.m. and cooled down to 55º F or less no later than 3:00 p.m. of the harvest day.

Below is the summary of the Handling time/temperature controls for oysters and clams

	Oysters (Times are when oysters must be placed in cooler at a certified shellfish processing facility)				Clams
	Traditional Cooling	Rapid Cooling	Onboard Cooling with Ice Slurry	Restricted Use Only (Green Tag)	Delivery to processor (same day of harvest)
November	5:00 p.m.	Non-Vibrio Control Month	Non-Vibrio Control Month	Non-Vibrio Control Month	10:00 p.m.
December	5:00 p.m.	Non-Vibrio Control Month	Non-Vibrio Control Month	Non-Vibrio Control Month	10:00 p.m.
January	5:00 p.m.	Non-Vibrio Control Month	Non-Vibrio Control Month	Non-Vibrio Control Month	10:00 p.m.
February	5:00 p.m.	Non-Vibrio Control Month	Non-Vibrio Control Month	Non-Vibrio Control Month	10:00 p.m.
March	5:00 p.m.	Non-Vibrio Control Month	Non-Vibrio Control Month	Non-Vibrio Control Month	10:00 p.m.
April	11:00 a.m.	1:00 p.m.	3:00 p.m.	4:00 p.m.	12 Hours

May	Not permitted	11:00 a.m.	3:00 p.m.	4:00 p.m.	12 Hours
June	Not permitted	11:00 a.m.	3:00 p.m.	4:00 p.m.	10 Hours
July	Not permitted	11:00 a.m.	3:00 p.m.	4:00 p.m.	10 Hours
August	Not permitted	11:00 a.m.	3:00 p.m.	4:00 p.m.	10 Hours
September	Not permitted	11:00 a.m.	3:00 p.m.	4:00 p.m.	10 Hours
October	11:00 a.m.	1:00 p.m.	3:00 p.m.	4:00 p.m.	12 Hours

Water treatment standards

The table below show the summary of the water treatments standards required for depuration:

DEPURATION TREATMENT PROCESS WATER STANDARDS		
Parameter	**Minimum**	**Maximum**
Bacteriological	0	Less than 1
Dissolved Oxygen (Milligrams/liter)	5.0	Saturation
Temperature	Suitable	Suitable
Turbidity (Nephelos Turbidity Units)	0	20 units
Salinity	Suitable	Suitable
Parameter	Minimum	Maximum
pH	7.0	8.4
Metallic Ions and Compounds	Not exceeding levels found in approved shellfish harvesting areas.	
Pesticides, Detergents and Radionuclides	Not exceeding levels found in approved shellfish harvesting areas.	

Vibrio parahaemolyticus Control.

A. A dealer and a shellfish aquaculture harvester permittee shall implement control measures as set forth in §B of this regulation to reduce the occurrence of Vibrio parahaemolyticus illness.

B. Control Measures.

(1) From June 1 through September 30, a shellfish aquaculture harvester permittee shall:

(a) Protect harvested oysters from direct sun by providing shade over the area where the harvested oysters are stored;

(b) Maintain air flow to the area where the harvested oysters are stored;

(c) Designate a single site for landing the harvested oysters;

(d) Document the harvest start time, which is the time the first oysters are removed from the water, on a harvest trip record or harvest tag; and

(e) Provide the harvest time record as set forth in §B(1)(d) of this regulation to a dealer on delivery.

(2) From June 1 through June 30, a shellfish aquaculture harvester permittee shall deliver harvested oysters to a dealer by 11:30 a.m. on the day of harvest.

(3) From July 1 through August 31, a shellfish aquaculture harvester permittee shall deliver harvested oysters to a dealer by 10:30 a.m. on the day of harvest.

(4) From September 1 through September 30, a shellfish aquaculture harvester permittee shall deliver harvested oysters to a dealer by 12:30 p.m. on the day of harvest.

(5) From June 1 through September 30, a dealer may not:

(a) Receive oysters harvested from Maryland waters:

(i) After the harvest delivery times set forth in §B(2)-(4) of this regulation; and

(ii) Without a harvest time record as set forth in §B(1)(d) of this regulation; or

(b) Sell or ship oysters that have not reached an internal temperature of 50° F (10° C) or below.

(6) From June 1 through September 30, a dealer shall:

(a) Place oysters under temperature control immediately upon delivery from the shellfish aquaculture harvester permittee:

and

(b) Implement a HACCP plan as defined in COMAR 10.15.04 that recognizes pathogen growth of naturally occurring Vibrio bacteria present from June through September 30 as a significant hazard and includes:

(i) Control measures necessary to ensure, document, and verify that the internal temperature of oysters has reached 50° F (10° C) or below within 10 hours or less after being placed under temperature control; and

(ii) Corrective action to ensure that oysters that are not cooled to an internal temperature of 50° F (10° C) within 10 hours are not directed to the raw shellfish market.

(7) To comply with §B(6) of this regulation, a dealer shall ensure that a temperature control mechanism for cooling and storing of oysters:

(a) Maintains a temperature of 45° F; and

(b) Cools oysters to an internal temperature of 50° F (10° C) in 10 hours or less.

(8) A shellfish aquaculture harvester permittee who is a dealer shall comply with the requirements set forth in §B(1)-(7) of this regulation.

(9) The Department may except a shellfish aquaculture harvester permittee who is a dealer from the harvest delivery times set forth in §B(2)-(4) and the receiving time set forth in §B(5)(a)(i) of this regulation if the permittee/dealer:

(a) Places harvested oysters under temperature control within 5 hours of harvest start time, which is the time the first oysters are removed from the water; and

(b) Implements an HACCP plan as defined in COMAR 10.15.04 that includes the control measures necessary to ensure, document, and verify that the harvested oysters are placed under temperature control within 5 hours of harvest start time.

Massachusetts 2020 *Vibrio parahaemolyticus* (*Vp*) Control Plan

Commercial Harvest Restrictions for Oysters May 19, 2020 - October 19, 2020

A. Definitions:

Adequately iced means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all oysters as described in Section B.5 of this Plan.

Adequately shaded means measures have been taken to prevent **market bound** oysters from direct exposure to sunlight. Materials in direct contact with oysters must be smooth, easily cleanable and impervious to water.

Approved means a classification used to identify a growing area where harvest for direct marketing is allowed.

Aquaculturist means any person authorized by the Director of the Division of Marine Fisheries (DMF) to propagate or rear shellfish for commercial purposes under the authority of a shellfish propagation permit issued pursuant to 322 CMR 7.01(4).

Batch tagging for re-submergence means the use of a single tag to identify multiple containers of **market-sized oysters** returned to the original oyster license site ("grant") following **oyster culture activities** requiring **re-submergence**.

Broadcast re-submergence means the return of loose, **market-sized oysters** back to the waters of the original license site ("grant") following **oyster culture activities** requiring **re- submergence** as approved by DMF.

Conditionally Approved means a classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.

Harvester means a person who takes shellstock by any means from a growing area

for commercial purposes.

Harvester icing tag means a harvester tag indicating the time of icing for a single harvester lot attached to a shellfish icing container.

Harvester lot means containers of oysters identified by the shellfish tag as having the same **time of harvest** and consisting of oysters from a single defined growing area gathered by a single licensed **harvester**.

Internal temperature means the external temperature of the shell of the animal, at the center of a packaged mass of oysters (a box, sack, bag, etc.) measured by the **original dealer**.

Market-bound Oysters means all oysters removed from a shellfish growing area by a commercial fisherman or aquaculturist intended for commercial purposes on that calendar day.

Market-sized oysters means those oysters measuring at least 3" in shell length or 2 ½" in shell length for those **aquaculturists** authorized by DMF to possess and sell undersized ("petite") oysters.

Off-site Culling means an aquaculture practice of temporarily removing shellfish from the licensed site (grant) to an aquaculturist's permitted off-site culling location for the purposes of sorting, grading and cleaning the individual shellfish.

Original dealer means a wholesale dealer authorized by the Division of Marine Fisheries as a primary buyer in order to purchase shellfish in Massachusetts directly from permitted commercial **harvesters**.

Oyster culture activities means activities conducted by some **aquaculturists** that require the removal of oysters from the waters of the license site (grant) for the purposes of sorting, culling, grading, pitting, over-wintering and/or the removal of fouling organisms to enhance oyster marketability.

Re-submergence means the return of **market-sized oysters** to the waters of the original license site ("grant") after they have been removed for off-site culling and/or oyster culture activities, pursuant to 322 CMR 16.07(4), or after being returned by a primary buyer, as a result of recall specified at 322 CMR 16.07(5).

Shellfish Growing Area means any geographic area within waters under the jurisdiction of the Commonwealth that have been listed and mapped by the Division as a Designated Shellfish Growing Area (DSGA) and made available to the public on the Division's website under

information on the Shellfish Sanitation and Management Program.

Shellfish icing container means a container that is smooth, in good condition, is easily cleaned, impervious to water, insulated, self-draining, has a tight-fitting lid, and has a light-colored exterior (e.g. Bonar box, etc.).

Time of icing means the time when the last oyster or bag of oysters in a **harvester lot** is placed in a **shellfish icing container** and is **adequately iced**.

Time of harvest for sub-tidal areas means the time when the first oyster in a **harvester lot** is taken from the water on a calendar day. Time of harvest for intertidal areas means the time when the first oyster in a **harvester lot** is exposed during a single low tide cycle or when the first oyster in a **harvester lot** is taken from the water, whichever occurs first.

B. Harvesters:

1. This plan shall only apply to **market-sized oysters**.

2. The requirements of this plan shall apply to the commercial harvest of both privately cultured oysters as well as wild oysters from the public fishery.

3. The requirements of this plan shall apply to all **market-sized oysters** in Massachusetts coastal waters from May 19, 2020 through October 19, 2020. For the purposes of this Plan, coastal waters are the inter-tidal and sub-tidal zones where oysters are cultured or grow naturally.

4. All **market-bound** oysters harvested from May 19, 2020 through October 19, 2020 shall be **adequately shaded** immediately after harvest and remain **adequately shaded** until placed in a **shellfish icing container** and **adequately iced.**

5. All **market-bound oysters,** with the exception of those described in Section B.6 of this Plan, shall be **adequately iced** within 2 hours of time of harvest or exposure, or prior to leaving the point of landing, whichever occurs first.

6. All **market-bound oysters** harvested from **shellfish growing areas** CCB-42, CCB-43, CCB-45, CCB-46, CCB-47 and V-20, between July 1 -

September 15, shall be **adequately iced** within one (1) hour of time of harvest or exposure, or prior to leaving the point of landing, whichever occurs first.

7. All **market-bound oysters** must remain **adequately iced** until received by the **original dealer**. To accomplish this, **harvesters** must place oysters into a **shellfish icing container** and:

    a. Mesh bags containing oysters must be completely surrounded by ice, with at least two (2) inches of ice between the bags and the bottom and sides of the container, and at least three (3) inches of ice on top;

    b. Loose oysters placed into a **shellfish container** must be completely surrounded by ice, with at least two (2) inches of ice at the bottom and sides of the container, and at least three (3) inches of ice on top; or

    c. Oysters held in an ice and water mixture (e.g. ice slurry, cold water dip) must be fully submerged and the ice and water mixture must be at or below 45° F to inhibit growth and proliferation of bacteria. Fresh potable water or ocean water from an area classified as **Approved** or **Conditionally Approved** by the Division of Marine Fisheries and in the "open status" may be used to constitute the mixture.

8. All ice used to cool shellfish must originate from approved sources of potable water or ocean water from an area classified by DMF as "**Approved**" or "**Conditionally Approved**," and in the "open status," as established under the National Shellfish Sanitation Program.

9. All containers of **market bound oysters** shall be tagged with the following information: **time of harvest, time of icing,** harvest date, harvest area, identification of **harvester**, type of shellstock and quantity (pieces). The tags shall be legibly written in indelible ink and attached to the shellfish container at the **time of harvest**. The **time of icing** shall be written on the **harvester** tags when the last oyster or bag of oysters is placed in a **shellfish icing container** and is **adequately iced**.

10. **Harvesters** may elect to record the **time of icing** on a single shellfish tag attached to the **shellfish icing container** provided that all oysters in the **shellfish icing container** are from a single **harvester** and a single **harvester lot**. The tag must be attached at the **time of icing** and remain attached until received by the **original dealer**.

    a. The **harvester icing tag** must at a minimum include the **time of harvest, time of icing**, the harvest date, harvest area, identification of **harvester**, type of shellstock, and quantity. The **harvester icing tag** must be attached prior to receipt by the **original dealer**.

    b. **Harvesters** who elect to use a **harvester icing tag** are still required to attach harvester tags to all individual containers of shellfish inside the **shellfish icing container** with the **time of harvest**, harvest date, harvest area, identification of **harvester**, type of shellstock, and quantity.

11. Harvest Logbooks:

    a. The Division of Marine Fisheries will issue each **harvester** a *Vibrio parahaemolyticus* (*Vp*) harvest logbook to record the following information detailing oyster harvest and **re-submergence** activities:

        i. For each **harvester lot** the **harvester** shall record the date, harvest area, quantity harvested, **time of harvest**, **time of icing**, and the **original dealer** who received the oysters.

        ii. For all **re-submergence** activities the **aquaculturist** shall record the date shellfish are returned to the license site for **re-submergence,** the date **re-submergence** tags are removed, the harvest area, quantity returned, type and number of containers, and the category of **re-submergence** (anti- fouling, **off-site culling**, recall, etc.).

iii. **Re-submergence** information shall be recorded on the date of **re- submergence** prior to the return of the first shellfish container or oyster to the license site.

b. Harvest information shall be completed before leaving the landing site and before harvested oysters are placed in transit to the **original dealer.**

c. All information shall be recorded legibly and with indelible ink.

d. All **harvesters** are required to return their completed *Vibrio parahaemolyticus* (*Vp*) harvest logbook to the Division of Marine Fisheries by December 31, 2020.

12. Oyster Handling and Re-submergence by **Aquaculturists**:

a. **Market-sized oysters** removed from an aquaculture license site for any **oyster culture activities** (e.g. culling, sorting, anti-fouling, etc.) will be considered **off- site culled** and must be returned to the same license site and **re-submerged** for a minimum of 10 days prior to harvest.

b. **Oyster culture activities** of **market-sized oysters** conducted on barges, boats, or other floating structures within the same designated shellfish growing area that do not exceed the two (2) hour requirement for adequate icing at Section B.5 of this Plan will not be considered **off-site culled**. These oysters may be harvested in accordance with this Plan or returned to the original license site and harvested the following calendar day with the exception of those described in section B.12(c).

c. **Oyster culture activities** of **market-sized oysters** conducted on barges, boats, or other floating structures within **shellfish growing areas** CCB-42, CCB-43, CCB- 45, CCB-46, CCB-47 and V-20, between July 1 - September 15, that exceed the (1) hour requirement for icing at section B.6 of this Plan, but do not exceed (2) two hours from time of exposure, shall be returned to the original license site and harvested no sooner than the following calendar day.

d. **Oyster culture activities** of **market-sized oysters** conducted on barges, boats, or other floating structures that exceed (2) two hours from the time of harvest or exposure shall be considered **off-site culled** and are subject to 10 day **re-submergence**.

   i. **Off-site culling** activities are subject to the tagging and record keeping conditions of the **aquaculturist's** Division of Marine Fisheries Aquaculture Permit.

   ii. Prior to removal of any shellstock from a license site, **aquaculturists** are required to notify the local shellfish authority.

e. All containers of **re-submerged** oysters or areas used for **broadcast re- submergence** must be segregated on the original license site and tagged. The tags must identify the oysters as **"re-submerged"** and must include the date the oysters were **re-submerged**.

   i. Tags must be waterproof, legible and completed with indelible ink.

   ii. After 10 days the tags may be removed and discarded.

   iii. **Aquaculturists** who engage in **broadcast re-submergence** or **batch tagging for re-submerged** oysters must submit a **re-submergence** plan to the Division of Marine Fisheries for approval 30 days prior to the start of the activity. **Re-submergence** plans must, at a minimum, include:

      1. A description of the **re-submergence** method (broadcast, holding cars, cages, etc.);

      2. A description of segregation method; and

      3. A description of tagging method.

f. All **aquaculturists** must record all **re-submergence** activities in their *Vibrio parahaemolyticus (Vp)* logbook with the information outlined in Section B.11(a)(ii).

13. Transportation of Oysters to Original Dealers:

a. All market bound oysters shall be transported by the **harvester** directly from the landing site to the **original dealer's** physical facility or received by the **original dealer** at the landing site as required by 105 CMR 500.021(B)(6)(a) and (b) (or any successor regulation).

b. **Harvesters** are prohibited from storing or handling market bound oysters at a private residence or unlicensed facility prior to delivery to the **original dealer**.

c. All oyster transactions must be completed by the **harvester** and an employee of the **original dealer**.

C. Original Dealers:

1. All oysters received by the **original dealer** between May 19, 2020 and October 19, 2020 shall be cooled in the **original dealer's** facility to 45° F within 10 hours of the **time of harvest** or tidal exposure before shipment.

2. Once received by the **original dealer**, oysters shall remain under refrigeration at or below 45° F for the duration of storage at the **original dealer's** facility until transfer to refrigerated vehicles for shipment. If an **original dealer** receives oysters from the **harvester** at the landing site, the dealer shall ensure that oysters remain iced throughout transportation to the **original dealer's** physical facility in their insulated, mechanically refrigerated vehicle. The vehicle must be pre-chilled to an ambient temperature at or below 45°F prior to loading.

3. Individual containers of oysters held in the vehicle must have at least three (3) inches of ice on top of each container. Transport

by this method does not require two (2) inches of ice on the sides and bottom of the container. Additionally, the **original dealer** must record the ambient temperature of the vehicle's refrigerated storage area (including the time the temperature was taken) in their **original dealer's** receiving records upon receipt at his or her facility.

4. Hazard Analysis Critical Control Point (HACCP)

All **original dealers** who receive oysters harvested from Massachusetts coastal waters between May 19, 2020 and October 19, 2020 shall implement a HACCP Plan indicating pathogen growth of naturally occurring *Vp* as a significant hazard reasonably likely to occur and include the following:

a. Critical Control Point Receiving: All oysters received by the **original dealer** shall be properly tagged in accordance with Section B.9 of this Plan and **adequately iced** in a manner sufficient to ensure that immediate cooling begins and continues for all oysters. Original dealers shall retain harvester tags for a minimum of 90 days. For oysters that are not properly tagged or **adequately iced** the following Corrective Actions shall be taken:

   i. **Original dealers** shall reject any **harvester lot** of oysters not **adequately iced** and/or not properly tagged per Sections B.5-9 of this Plan. When a shipment of oysters is rejected the dealer shall document the date and time of the incident, the name of the **harvester** and, if possible, the harvest date, harvest area, the time of delivery of the oysters, quantity of oysters, and the **harvester's** Division of Marine Fisheries Commercial Shellfishing Permit number. This information shall be recorded as a Corrective Action and immediately reported to the Division of Marine Fisheries; and

   ii. **Original dealers** who receive shipments of oysters not **adequately iced** and/or not properly tagged as harvested by a licensed **harvester** shall place the oysters on internal hold and immediately notify the Department of

Public Health's Food Protection Program, document the deviation in a Corrective Action Report, and await instruction from the Food Protection Program for final disposition of potentially time/temperature abused oysters; and

iii. **Original dealers** shall address the root cause of the deviation by discontinuing receipt of oysters from the **harvester** until compliance with the **harvester** requirements identified in Section B of this Plan have improved to ensure the Critical Limit at receiving is not exceeded.

b. Critical Control Point Cooling: The HACCP Plan shall include a Critical Limit indicating the **internal temperature** of oysters will be cooled to 45° F or below within 10 hours after the **time of harvest**. The **original dealer** shall verify and record in a monitoring record that all oysters have achieved an **internal temperature** at or below 45°F within 10 hours prior to release for shipment. **Original dealers** who fail to achieve the Critical Limit shall take the following Corrective Actions:

i. Ensure oysters that are not cooled to an **internal temperature** of 45° F within 10 hours are not directed to market and;

ii. Document the deviation in a Corrective Action Report; and

iii. Place any remaining oysters held at the facility on internal hold; and

iv. Recall any noncompliant oysters and dispose of all recalled oysters; and

v. Notify the Food Protection Program of the action taken; and

vi. Determine the root cause of the Critical Limit deviation and take preventative measures to ensure that the **original dealer's** refrigerated cold storage is capable

of cooling oysters in compliance with Section C.1 of this Plan.

c. Critical Control Point Storage: The **original dealer** shall ensure that oysters are held in refrigerated storage at an ambient air temperature at or below 45°F for the duration of refrigerated storage at the **original dealer's** facility per Section C.2 of this Plan. When the Critical Limit is exceeded the **original dealer** shall take the following Corrective Actions:

i. Document any deviations to the Critical Limit in a Corrective Action Report; and

ii. Dispose of oysters placed in refrigerated storage not capable of maintaining an ambient air temperature at or below 45°F; and

iii. Notify the Food Protection Program of the action taken; and

iv. Determine and address the root cause of the deviation by making necessary repairs to malfunctioning refrigeration equipment or adjusting oyster handling practices to decrease the likelihood of future deviations to the Critical Control Point at storage.

5. To comply with dealer requirements of the Plan, each **original dealer's** facility shall maintain insulated mechanical refrigeration for cooling and storage of oysters that:

a. Cools oysters to an **internal temperature** of 45° F in 10 hours or less after **time of harvest**; and

b. Maintains an ambient air temperature of 45° F or less.

6. Each **original dealer's** receiving records shall include the following minimum information:

a. **Harvester's** Division of Marine Fisheries Commercial Shellfishing Permit number;

b. Harvest date and area;

c. Time of harvest;

d. Time and confirmation that oysters are **adequately iced** (including ambient temperature of vehicle and time temperature was taken if a **harvester/original dealer** uses a pre-chilled vehicle for transport);

e. Transaction slip number;

f. The actual time oysters were cooled to less than or equal to 45° F with actual internal temperature; and

g. Quantity of oysters (pieces).

7. When an original dealer receives shipments of oysters in which the time of icing is recorded with a **harvester icing tag** in accordance with Section B.10(a) of this Plan, the original dealer shall retain the tag for a minimum of 90 days. Retention of this tag satisfies the requirement of 105 CMR 500.021(B)(8) and section C.4(a) of this Plan for the corresponding **harvester lot**.

8. Sales of shellfish by a **harvester** to an **original dealer** shall only be conducted by:

   a. The **harvester** transporting his or her product directly from the landing site to the **original dealer's** physical facility for sale, or

   b. The **harvester** selling the product to an employee of an **original dealer** at the landing site, provided that the employee transports the product to the **original dealer's** facility. Shellfish purchased at the landing site must be transported by the **original dealer** per the requirements of 105 CMR 500.000: *Good Manufacturing Practices for Food,* including but not limited to 500.021 (or any successor regulation).

9. Persons who are permitted both as a **harvester** and an **original dealer** are required to meet the conditions in both Sections B and C. If a **harvester/original dealer** is unable to meet both sets of conditions, the **harvester/original dealer** may operate as a **harvester** in accordance with Section B of this Plan.

10. Re-submergence of Recalled Oysters:

    a. In the case of a recall as the result of a harvest area closure due to increased risk, including confirmed illnesses, only oysters received from aquaculturists and stored at the **original dealer's** facility may be allowed to be **re-submerged**. Recalled oysters distributed into commerce by the **original dealer** may not be returned to the license site and will be subject to disposal.

    b. **Re-submergence** of recalled oysters may only be conducted after approval is granted by Division of Marine Fisheries and the Department of Public Health and under the supervision of the local Shellfish Constable.

    c. All **re-submergence** activities must be conducted in compliance with section B.11(a)(ii) and (iii) of this Plan.

D. Enforcement:

1. Representatives of state and local regulatory agencies (e.g. Division of Marine Fisheries, Department of Public Health, Office of Law Enforcement) shall conduct periodic unannounced inspections at harvest sites, common landings, and wholesale dealer facilities to determine compliance with the requirements of this Plan.

2. All oysters harvested under this Plan shall be subject to embargo and/or disposal if the oysters are found to be time/temperature abused or non-compliant with the requirements of this Plan.

3. Local Shellfish Constables and their deputies will conduct spot checks at harvest sites to verify harvest times on **harvester** tags and other controls such as shading and icing.

4. Inability or refusal of **harvesters** and/or **original dealers** to maintain compliance with the requirements of this plan may result in enforcement up to and including suspension and revocation of **harvester** and/or **original dealer** permits in accordance with Massachusetts General Laws Chapter 130, Section 2.

5. In the course of implementation of the Massachusetts *Vp* Control Plan, and in the event that an illness outbreak(s) occurs, the State Shellfish Control Authority, which consists of the Division of Marines Fisheries and the Department of Public Health, reserves the option of requiring more stringent *Vp* controls in specific affected area(s) in order to prevent additional illnesses and protect public health. In the event of sporadic illnesses, the State Shellfish Control Authorities will follow requirements established in the National Shellfish Sanitation Program's *Model Ordinance*, 2017 Revision, Section II, Chapter II Risk Assessment & Risk Management, to determine extent and duration of closure of areas due to illness(es).

The Massachusetts Department of Public Health, Food Protection Program and the Massachusetts Department of Fish and Game, Division of Marine Fisheries will review this Plan on an annual basis and revise as needed to maintain compliance with the National Shellfish Sanitation Program.

Vibrio Control Plan

June 1 – August 31, 2020

New Jersey Department of Environmental Protection
Division of Water Monitoring and Standards / Division of

Fish and Wildlife and

New Jersey Department of
Health Public Health and Food
Protection Program

A. Introduction

New Jersey's *Vibrio* Control Plan (*V*CP) addresses program coordination; response to potential outbreak; post-harvest time and temperature controls; hours of harvest for tidal, intertidal, and tide dependent harvest; and Hazard Analysis and Critical Control Points (HACCP) plan requirements. In addition, the *V*CP recommends additional best management practices to be implemented to further minimize risk from *Vibrio parahaemolyticus (Vp) and Vibrio vulnificus (Vv)*.

The nationally reported illnesses attributed to *Vp* have been on the increase (Marder, MPH EP, Griffin PM, Cieslak PR, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10
U.S. Sites, 2006–2017. MMWR Morb Mortal Wkly Rep 2018;67:324–328. DOI: http://dx.doi.org/10.15585/mmwr.mm6711a3external icon). *Vp* has become a significant problem for both regulators and the shellfish industry. Despite the implementation of Control Plans by States and industries and diligent efforts to implement such plans, shellfish related illnesses continue to occur and are on the increase, specifically in the northeast and northwest States.

Vp is an organism that occurs naturally in coastal waters. It is not related to pollution, which means that traditional controls for shellfish sanitation related to growing water classification are not effective. Instead, the occurrence of this pathogen in elevated levels generally appears to be related to water temperature and post-harvest handling. *Vp* levels increase rapidly.
Scientific studies have determined that when shellfish are exposed to temperatures greater than 60 degrees Fahrenheit the doubling of *Vp* occurs within 7.24 hours.

Vp is a curved, rod-shaped, Gram-negative bacterium found in the marine and estuarine environment. When shellfish, usually oysters, are eaten raw or undercooked with high levels of *Vp* it may result in gastrointestinal illness in humans. Symptoms typically resolve within 72 hours, but can persist for up to 10 days in immunocompromised individuals.

Vibrio vulnificus (Vv) bacterium are also naturally occurring and found in marine and estuarine environments. When shellfish are eaten raw or undercooked with high levels of *Vv* bacteria, illnesses may occur, but these illnesses are not common in the northeastern States like New Jersey. The mortality rate from *Vv* is approximately 50 percent in healthy people and 70 percent in people with liver disease. If *Vv* infections are not treated within 72 hours and septicemia occurs, death is likely.

Procedures for dealing with *Vp* and *Vv* have been developed over the past several years through the Interstate Shellfish Sanitation Conference (ISSC, http://www.issc.org/) and are part of the National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish (NSSP Guide).

B. Overview - 2019 *Vibrio* Season

New Jersey shellfish were implicated in twelve (12) potential *Vp* illness cases in 2019; 7

cases were confirmed by culture testing, 5 cases were not confirmed by culture testing. One of the 7 cases was a New Jersey only source and 6 cases were from multiple source cases. A multiple source case is when the consumer eats a mixed plate of oysters from variety of States and includes an oyster that may have been harvested from NJ waters. In these multiple source cases it is impossible to accurately determine which oyster is responsible for the illness unless directly linked to an outbreak. Four (4) multiple source cases involved oysters harvested from the New Jersey portion of the Delaware Bay, including both dredge harvest and aquaculture harvest. Two (2) multiple source cases were attributed to oysters harvested from the Barnegat Bay.

New Jersey was not implicated is any cases of *Vv* in 2019.

Oyster tissue, sediment, and water samples were analyzed for total *Vp*, the virulent genes of *Vp* (trh and tdh), and *Vv,* using Polymerase Chain Reaction. Strain identification was also performed using Pulsed-Field Gel Electrophoresis (PFGE). The data suggests that *vibrio* levels in oyster tissue are not always the highest during months with the warmest water and air temperatures, but high levels may occur when there is a quick rise in water temperature. In New Jersey, a quick rise in water temperature is commonly observed during the month of June. Highest levels of the virulent trh and tdh genes occurred during late June and early July, consistent with previous sampling.

C. Coordination of New Jersey Agencies Responsible for Shellfish Sanitation

The requirements for the Authority set forth in the NSSP Guide are accomplished through a coordinated effort of four agencies in New Jersey. These agencies, their physical locations, their role in shellfish sanitation, and their relationship to one another are shown below.

Implementation of the *V*CP requires cooperation and communication among these agencies. Department of Environmental Protection (DEP)

Bureau of Marine Water Monitoring (BMWM)
Division of Water Monitoring and Standards

P.O. Box 405
929
Stoney
Hill
Road
Leeds
Point,
NJ

08220
609-748
-2000
(Water monitoring, tissue monitoring, growing water classification, shellfish classification charts, and permits issued under N.J.A.C. 7:9)

Bureau of Shellfisheries
Division of Fish and
Wildlife
P.O. Box 418
360 North Route 9
Port
Republic,
NJ 08241
609-748-2
020
(Licensing, shellfish leases, and resource management)

Bureau of Law Enforcement – Marine Region
Division of Fish and Wildlife
P.O. Box 418
360 North Route 9
Port
Republic,
NJ 08241
609-748-2
050
(Patrol, enforcement, and inspections)

Department of Health (DOH)
Public Health and Food Protection Program Division of Consumer
Environmental and Occupational Health
P.O. 369
Trenton, NJ 08625-0369
609-826-4935
(Inspections, certified dealers, depuration, illness reporting and investigation)

The following agencies have primary responsibility for decision making and implementation of the following aspects of the *V*CP:

DEP Bureau of Marine Water Monitoring

- Develop and coordinate the *V*CP.
- Monitor and analyze water and air temperature data and conduct a risk assessment as the basis for developing a *V*CP to control naturally occurring pathogens.
- Develop control strategies to minimize potential *vibrio* illnesses.
- Close affected growing areas if outbreaks are epidemiologically associated.

DEP Bureau of Law Enforcement – Marine Region

- Prevent illegal harvest by enforcing closure of implicated growing areas.
- Ensure compliance with Harvest, Transport, and Temperature Control Measures in Section F below, including harvest hours and maximum hours to refrigeration.
- Enforce vessel requirements including, but not limited to, shading and icing of harvested oysters.

DOH – Public Health and Food Protection Program

- Ensure compliance with time and temperature restrictions including, but not limited to, harvester landings, certified dealer handling, processing and transport.
- Inspect and enforce certified dealers' operations and ensure required cooling times and temperatures are met and all HACCP plans are updates and implemented.
- Epidemiologically confirm, document, and conduct trace back for each *vibrio* species illness consumption case as reported in the State or from other authorities. Initiate, communicate, and monitor shellfish recall(s) if a growing area is implicated as a result of an illness or due to post harvest mishandling, initiating a firm specific related recall.
- Notification to DEP and USFDA any confirmed *vibrio* illness.
- Notify the shellfish industry and local health jurisdictions in the State of the potential for illnesses due to *vibrio* prior to historical times of onset or at a minimum of once a year.
- Issue a health advisory to the public about the potential problem

and advise the industry to educate wholesalers, retailers, and consumers about the potential problem.

D. Outbreak Response (*Vibrio parahaemolyticus and Vibrio vulnificus*)

In the event of confirmed cases of shellfish related food borne illnesses caused by the naturally occurring marine bacterium *Vp* and/or *Vv,* the DEP and the DOH shall comply with N.J.A.C. 7:12,
N.J.A.C. 8:13, the latest edition of the National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish and the *V*CP.

E. DEP – Bureau of Marine Water Monitoring *Vibrio* Sampling

In 2020, BMWM will continue to sample and run analysis on oyster tissue from the Delaware Bay harvest areas during the *vibrio* season to evaluate the levels of *vibrio* (*Vp* and *Vv*) in oyster tissue. PFGE analysis will be performed to evaluate the different genetic strains present in the Delaware Bay. There will also be periodic oyster samples collected from the Barnegat Bay. This data will provide information on whether specific *Vp* genetic strains identified in isolates from illness investigations were also found in oysters harvested from implicated harvest areas.

F. Harvest, Transport, and Temperature Control Measures

N.J.A.C. 7:12-8.6 *Vibrio parahaemolyticus* Control Plan time to temperature control requirements for harvesting oysters.

1. SUBTIDAL HARVEST

If a shellfish license holder is conducting subtidal harvesting of oysters, the shellfish license holder shall comply with the following hours from harvest to refrigeration:

Dates of harvest	Maximum hours to refrigeration[1]	Start of harvest[2]
June 1 - June 14	7	Sunrise
June 15 - July 14	6	Sunrise
July 15 - August 31	7	Sunrise

[1] Hours to refrigeration means the total number of hours (inclusive of any transport time) from the start of harvest until the oysters are placed in refrigeration. "Refrigeration" means a mechanical unit that is chilled to a temperature of 45 degrees Fahrenheit (7.2 degrees Celsius) or colder at the time shellfish are placed in the unit and maintained at that temperature thereafter.

[2] For purposes of the start of harvest under this subsection, sunrise shall mean the time of sunrise in

Trenton, New Jersey. The sunrise time shall apply regardless of where a harvester intends to harvest or is harvesting shellfish. The Trenton sunrise timetable is included in the NJ Hunting and Trapping Digest available from the DEP's Division of Fish and Wildlife and on-line at https://www.nj.gov/dep/fgw.

a) A shellfish license holder conducting subtidal harvesting who places harvested oysters directly in refrigeration on the vessel is not subject to the maximum hours to refrigeration in the table (at 1) above. However, the shellfish license holder shall:
   i. Maintain a DOH approved refrigeration unit;
   ii. Notify the DEP's Division of Fish and Wildlife, Bureau of Law Enforcement - Marine Region, at njdfwcommercialnotify@dep.nj.gov or 609-748-2050 prior to June 1 that the harvester will be using, on the vessel, refrigeration that is approved by the DOH; and
   iii. Fly a flag that is a minimum size of 18 inches by 18 inches, orange, and bearing a black diagonal stripe.

2. INTERTIDAL HARVEST

If a shellfish license holder is conducting intertidal harvesting of oysters from June 1 through August 31, the maximum hours to refrigeration (inclusive of any transport time) is four hours, starting when the first oysters to be harvested are exposed to the air by the receding tide.

3. TIDE DEPENDENT HARVEST

If a shellfish license holder is conducting tide-dependent harvesting of oysters from June 1 through August 31, the maximum hours to refrigeration (inclusive of any transport time) is four hours, starting when harvest begins. On each harvest day prior to any harvest activity, the shellfish license holder shall notify the DEP's Division of Fish and Wildlife, Bureau of Law Enforcement - Marine Region, at njdfwcommercialnotify@dep.nj.gov or 609-748-2050 to provide the name of the shellfish license holder, location of harvest, and harvest start time.

4. ALL HARVEST

Each shellfish license holder harvesting oysters shall record on each harvest day, in a journal with permanently bound pages, the harvest start time, the time the last-harvested shellfish was

placed in refrigeration, and the shell temperature of the shellfish in one container from the day's harvest at offloading, including the time the temperature was measured.

a) To measure the shell temperature, the shellfish license holder shall use a handheld laser thermometer that is accurate and properly calibrated per the manufacturer's specifications. The shellfish license holder shall provide each harvest day's information to the certified dealer on the transaction record.

b) The shellfish license holder shall submit to the BMWM at the address in N.J.A.C. 7:12- 1.1(l) a copy of the journal by September 15 of each year.

G. Additional Required Control Measures

1. No product may be shipped the same day as harvest without prior approval from DOH.
2. Oyster vessels actively harvesting oysters during the *vibrio* season with adequate and approved refrigeration may, within a one hour interval, utilize and fill up to 24 individual bushel baskets on the shaded deck of the harvest vessel prior to placing the oysters into a refrigeration unit in an appropriately tagged oyster cage as required by N.J.A.C. 7:25A-2.3, for the purpose of limiting the number of times the unit doors are opened and closed to maximize cooling.
3. Proper shading of the shellfish product must be in place on the boat (N.J.A.C. 8:13).
4. For subtidal aquaculture activities, notification of landing location must be supplied to DOH Public Health and Food Protection Program, Virginia Wheatley at 609-826-4935 or virginia.wheatley@doh.nj.gov.

H. Additional Recommended Best Management Practices

The following Best Management Practices are recommended, but not required by the 2020 *V*CP.

*Method, if used, is required to be validated, inspected and approved by the DOH.

1. Evaporative Cooling* - Wet or mist oysters with water (from Approved classification), stored under required shading to reduce temperatures through evaporative cooling.
2. Rapid Chilling* - In between dredges, cool oysters in a container of

ice from a potable water source and sea water (from Approved classification). Proper drainage should be provided. Monitor water quality to prevent sediment buildup. The slurry is the most effective way of rapidly cooling shellfish. When the next dredge is brought in, transfer oysters in the slurry to a shaded area or into a refrigerated unit.

3. Icing* - Layer bushel baskets, bushel bags, or oysters in cages with ice to reduce shell temperatures during transport to landing.
4. Reduce time to refrigeration to 5 hours - Keeping the time to refrigeration to a maximum of 5 hours, especially when air temperatures exceed 70 degrees Fahrenheit, is the most effective way to maintain *vibrio* levels low without direct refrigeration.
5. If using onboard refrigeration, limit the number of times the refrigeration unit doors are opened and closed to maximize cooling.
6. Offload boats quickly, get product on a pre-chilled refrigerated vehicle efficiently, and get the product to the certified dealer as soon as possible.

I. Prohibitions for all Harvesters and Certified Dealers

1. Off-loading of oysters from boats directly onto interstate trucks intended for same day interstate shipment is prohibited.
2. No product shall be shipped the same day it was harvested without prior approval from the DOH.

J. Certified Dealers - Annual Evaluation of the Forced-Air Unit

1. Certified dealers shall annually conduct an evaluation of their forced-air unit operation.
2. The annual evaluation shall ensure the following:
   a) Unit is operating and in good repair;
   b) Unit is capable to hold a maximum day's harvest amount while providing adequate circulation of cold air;
   c) Unit is capable to hold day's harvest while holding other products;
   d) Compressor is sized adequately and can cool product down to fifty (50) degrees F or less (40 degrees F is optimum) in 8 hours in June, and 6 hours in July and August;

e) Time to temperature requirements are met. The DOH wholesale temperature requirement is 45 degrees F in 10 hours (overnight), to ship from a certified dealer. Due to 2018 *Vv* cases, oysters shipped form a certified dealer will be required to be cooled down to fifty (50) degrees F or less (40 degrees F is optimum) in 8 hours in June, and 6 hours in July and August. To meet this requirement cooldown should start at the dock. No product may be shipped the same day as harvest without prior approval from the DOH;

f) The DOH verification of adequate refrigeration and cooling prior to certification for *vibrio* season is required; and

g) The continuous temperature recording unit at the initial certified dealer is able to continuously record the ambient temperature of the product with back-up alarm.

3. The DOH has resource information in order to assist the purchase and installation of a recording thermometer on your forced air unit. The cost is inexpensive to install this device.
   a) The DOH will not certify the Certified Dealer operation unless a continuous recording thermometer is installed on your forced air unit. This will allow DOH to inspect and ensure that your forced air unit is operational and maintaining appropriate temperatures.

K. Hazard Analysis and Critical Control Points (HACCP) Plans

1. Certified Dealers shall record the time and the temperature of the shellfish when it is offloaded and received by the Certified Dealer. This can be done by utilizing a laser (infrared) thermometer (gun type) and "shooting" the temperature of the shell or by placing a probe thermometer between the shells and checking the meat. Thermometers must be calibrated and manufacturer's directions must be followed.
2. After being held overnight and before releasing the product for interstate shipment, the time released and the temperature of the product must be recorded. Product shall not be released for intrastate and/or interstate shipment until 5am after overnight holding. No product may be shipped the same day as harvest without prior approval from the DOH.
3. The implementation of the HACCP Plans includes monitoring records to indicate the time and temperature as indicated above, the

establishment of Critical Limits, and corrective actions when Critical Limits are not met.

a) HACCP plans state that this will be performed.

VIBRIO PARAHAEMOLYTICUS CONTROL PLAN – NEW YORK.

The following areas in New York are subject to Vibrio parahaemolyticus control plan: Oyster Bay Harbor, Cold Spring Harbor, Northport, Huntington Bay and their tributaries; and adjacent areas of Long Island Sound)

Requirements for Shellfish Harvesters (Diggers)

1. Shading of Shellfish

All shellfish must be shaded during the period May 1 - October 31; this applies to shellfish onboard the harvest vessel and during transport in any boat, vehicle or other means of conveyance, from the harvest area to the original dealer.

2. Tagging of Shellfish and Time of harvest

- Shellfish Harvester tags must include the time of harvest for all shellfish taken (time of harvest begins when the first shellstock are taken from the water); Time of harvest must be written in indelible ink on each tag and the tag must be affixed to the container prior to the placement of any shellfish into the container.
- Once a container has been completely filled as intended, a new time of harvest begins when the next lot of shellfish is removed from the water. All shellfish tags must be fully completed prior to leaving the area of harvest. All shellfish harvested from LS1 east of Eatons Neck Point must be tagged or labeled LS1 East.

3. Self-draining containers and ice slurry

Shellfish may not be placed or held in containers that aren't self-draining; they cannot sit in standing or stagnant water; except for placement in an ice slurry for rapid cooling when the temperature of ice slurry is less than or equal to 45ºF (7.2ºC). Water used for the ice slurry must come from the certified area where shellfish were taken. Any ice used must be drinking water quality or from an approved source.

4. Logbook

Shellfish harvesters must maintain a daily harvest log which includes: common name of shellfish harvested, quantities (net weights, numerical counts or standard measures) of shellfish harvested, the harvest date, an identification of the areas from which shellfish were harvested, time of harvest, and the names and permit numbers of all purchasers of shellfish (identify disposition of shellfish sold). The log must be completed prior to landing on a daily basis and made available to the Department or an environmental officer upon request.

5. Oyster Harvesting

- All oysters harvested from any certified shellfish lands for food consumption between the dates of May

1 through September 30, both dates inclusive, must be immediately culled and placed under temperature control through icing, mechanical refrigeration maintained at 33ºF (0.6ºC) to 45ºF (7.2ºC) or other cooling method approved by the Department upon commencement of time of harvest.
- Time of harvest begins when each lot of oysters is taken from the water and no longer submerged. Time of harvest must be written in indelible ink on each tag and the tag must be affixed to the container prior to the placement of any oysters into the container.

- All oysters shall be immediately culled and maintained under temperature control (cooling) throughout the harvest day once the time of harvest (start of harvest) begins. Once a container has been completely filled as intended, a new time of harvest begins when the next lot of shellfish is removed from the water.

Requirement for Diggers working in NS1, NS2, NS3 and LS1 West during the period May 1 - September 30:

Time of harvest, tagging, and time to temperature control

- Hard clams and oysters harvested for food consumption must be immediately culled and placed under temperature control (icing, mechanical refrigeration maintained at 33ºF (0.6ºC) to 45ºF (7.2ºC) or other cooling method approved by the Department) upon commencement of time of harvest.
- Time of harvest begins when hard clams or oysters are taken from the water and no longer submerged. Time of harvest must be written in indelible ink on each tag and the tag must be affixed to the container prior to the placement of any hard clams and/or oysters into the container.
- All oysters and/or hard clams must be immediately culled and maintained under temperature control (cooling) throughout the harvest day once the time of harvest (start of harvest) begins. Once a container has been completely filled as intended, a new time of harvest begins when the next lot of shellfish is removed from the water.

Tagging for LS1 (East and West)

- Shellfish harvested in that portion of LS1, west of Eatons Neck Point must be designated as LS1 west and those shellfish taken from that portion of LS1, east of

Eatons Neck Point must be labeled LS1 east; no commingling of LS1 east and LS1 west product is allowed.

Internal Temperature at Sale to Original Dealer

Oysters and hard clams must be cooled to an internal temperature of 60ºF or less prior to sale to the original dealer.

Requirements for Shellfish Shippers

These requirements apply to all dealers:

All shellstock must be cooled to an internal temperature of 50°F (10°C) prior to distribution and must be accompanied by a shipping document indicating one of the following:

- Shipped adequately iced, the date and time shipped and the initials of the shipper (shipping time must not exceed four hours for this option).
- Shipped in a conveyance pre-chilled and maintained at or below 45°F (7.2°C), the date and time shipped and the initials of the shipper.

- For shellstock picked up by the receiver at the dealer's facility: shipped adequately iced or the temperature of the storage area from where the shellfish were removed, the date and time removed and the initials of the shipper.

All shellstock received must be received with a document from the shipper indicating one of the following:

- Shipped adequately iced and the time shipped.
- Shipped in a conveyance pre-chilled and maintained at or below 45°F (7.2°C) and the time shipped.
- For shellstock received from a shellfish dealer located outside of New York prior to being cooled to an internal temperature of 50°F (10°C) - A time/temperature recording device shall accompany the shellstock indicating continuous cooling; the document must indicate that the product was shipped prior to achieving an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.

Shellfish received without a proper shipping document must be rejected.

Shellfish receiving records (a HACCP record) must include date, time and shellstock temperature (center of a lot/container of the shellstock) when received.

These requirements apply to all dealers who receive shellstock from diggers:

All shellfish received from harvesters must include the time of harvest on harvester tags and must be kept as part of your shellfish receiving records.

- All oysters received from harvesters between the dates of May 1 through September 30, both dates inclusive, must be cooled immediately following harvest. A record of the internal temperature (center of a lot/container of the oysters) at time of receipt and time received is also required.
- From May 1 through October 31, both dates inclusive, shellfish received from harvesters that are transported to the original dealer by the harvester must be received shaded at the time of delivery. The temperature within the conveyance used to transport the shellfish must not be higher than the ambient air temperature during transportation time.

Shellstock shall not be shipped or shrink wrapped prior to it reaching the temperature of 50°F (10°C) or below.

These requirements apply to all dealers who receive shellstock from diggers under a Vp Control Plan only:

These requirements shall apply from May 1 through September 30, both dates inclusive. Areas currently under Vp Control Plan include NS1, NS2, NS3 or that portion of LS1 west of Eatons Neck Point.

- All hard clams and oysters received from harvesters from in the affected areas will be rejected if the shellstock temperature at receiving is greater than 60°F (15.6°C) or if the shellfish harvester tag does not include the time of harvest. A record of the internal temperature (center of a lot/container of the shellstock) at time of receipt and time received is also required; and
- must be cooled to a temperature of 50°F (10°C) or less within 10 hours of time of receipt and prior to being shipped; and
- shall not be comingled with hard clams oysters harvested from LS1 East.

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

BUREAU OF NATURAL RESOURCES

DIVISION OF FISH AND WILDLIFE
DIVISION OF LAW ENFORCEMENT

Aquaculture of Marine Species in Rhode Island Waters

October 29, 2015

AUTHORITY: Chapter 42-17.1 and Sections 20-1-2, 20-1-4, 20-1-5, 20-10-5c, and 20-10-12, and in accordance with Chapter 42-35, of the Rhode Island General Laws of 1956, as amended.

TABLE OF CONTENTS

1. PURPOSE

The purpose of these regulations is to describe the permits, licensing, and conditions under which aquaculture shall be conducted in Rhode Island.

2. AUTHORITY

Chapter 42-17.1, and §§; 20-1-2; 20-1-4; 20-1-5; 20-10-5c; and 20-10-12, in accordance with Chapter 42-35 of the RIGL 1956, as amended.

3. ADMINISTRATIVE FINDINGS

These regulations acknowledge that aquaculture is a form of agriculture (RIGL 2-23-4) and that cultured crops are the property of the aquaculturist and are distinct from wild stocks.

Cultured crops are therefore not subject to the statutory and regulatory restrictions governing the protection of wild stocks, except that the minimum size limit established for quahaugs, *Mercenaria mercenaria,* applies to all wild and cultured quahaugs (RIGL 20-10-13.1).

4. APPLICATION

The terms and provisions of these rules and regulations shall be liberally construed to permit the Department to effectuate the purposes of state law, goals, and policies.

5. SEVERABILITY

If any provision of these Rules and Regulations, or the application thereof to any person or circumstances, is held invalid by a court of competent jurisdiction, the validity of the remainder of the Rules and Regulations shall not be affected thereby.

6. SUPERSEDED RULES AND REGULATIONS

On the effective date of these rules and regulations, all previous rules and regulations, and any policies regarding the administration and enforcement of aquaculture shall be superseded.

7. DEFINITIONS

As used in these rules and regulations, the following words and phrases have the following meanings:

Adequately Iced means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all shellfish. If ice slurry is used and the shellfish are submerged the presence of ice in the slurry indicates adequate icing. The water source for, the production of, and the handling of the ice must be approved by DOH for the intended use of cooling shellfish.

Approved waters or **Approved shellfish growing areas** mean waters of the state which have been classified by the RI Department of Environmental Management (DEM) Office of Water Resources as Approved Areas, fit for the taking of shellfish for human consumption on a regular basis, according to criteria established by the National Shellfish Sanitation Program (NSSP) Manual of Operations. These

classifications may be subject to change as water quality conditions dictate.

Aquaculture means the cultivation, rearing, or propagation of aquatic plants or animals, hereinafter referred to as cultured crops, under natural or artificial conditions.

Aquaculture facility means any properly permitted aquaculture operation, either in upland areas or in the State's waters or submerged lands.

Aquaculture lease means the permitted area for which the Coastal Resources Management

Council (CRMC) issues a lease in which aquaculture can be conducted. Leases are discretionary and granted for the express purpose of allowing aquaculture activities on the State's submerged lands or in the water column. Certain types of permitted activities, such as experimental aquaculture operations, may not require a lease.

Aquaculturist means the individual, firm, partnership, association, academic institution, municipality, or corporation conducting commercial, experimental or restoration aquaculture in Rhode Island.

Biosecurity Board means the board, within the Coastal Resources Management Council (CRMC), established pursuant to RIGL Section 20-10-1.1 and charged with assisting and advising the CRMC in carrying out its role under the provisions of RIGL Chapter 20-10.

Conditionally Approved Areas mean any shellfish grounds underlying waters examined and found fit for the taking of shellfish for human consumption on an intermittent basis, declared by the director as conditionally approved waters pursuant to RIGL Sections 20-8.1-3 and 20-8.1-4. Such classification may be subject to change as water quality conditions dictate.

Container means any bag, sack, tote, conveyance, or other receptacle used for containing shellfish for holding or transporting.

CRMC means the RI Coastal Resources Management Council.

Cultured crops mean aquatic or marine animals or plants: (i) that are in the location, water column or artificial conditions specified in a valid aquaculture permit issued pursuant to RIGL section 20-10-3 or that have been taken by the holder of such permit from the location, water column or artificial conditions specified in such permit, or (ii) that have been produced by aquaculture methods outside the state and have not been commingled with wild stocks that are in or have been removed from the waters of the state. Appropriate bills of sale, bills of lading and proper tags used in accordance with Rule 6.6 herein and all other applicable state and federal laws and regulations shall be prima facie evidence of the origin of cultured crops inside or outside the state.

DEM means the RI Department of Environmental Management.

Designated Temperature Control or Thermally Impacted Area means an area designated by the Department in which aquaculturists must comply with more stringent temperature controls for harvested shellfish. These areas have been determined to be Winnapaug Pond, Quonochontaug Pond, Ninigret Pond, Potter Pond, Point Judith Pond, Island Park Cove (Spectacle Cove), Hog Island Cove and Great Salt Pond.

Director means the Director of the RI Department of Environmental Management or his or her duly appointed agents.

DOH means the RI Department of Health.

Harvest means the act of removing shellstock with the intention of not returning to the water after husbandry practices. Harvest commences when the first shellfish not returned to the water is removed from the water on any given day, or is exposed by the receding tide.

Husbandry means any activity related to the cultivation and management of shellfish crops, including but not limited to grading, sorting, cleaning, or planting.

Mechanical Refrigeration means storage in a container or conveyance that is approved by the Rhode Island Department of Health and capable of cooling to, and maintaining, an ambient temperature of 45°F or less.

Operational plan means a written plan filed with CRMC and, approved by DEM prior to its implementation, that includes, at a minimum: description of the design and activities of the aquaculture facility, specific location and boundaries of the aquaculture lease and facility, types and locations of structures (rafts, pens, tanks, etc.), species to be cultured, source of these organisms (i.e., wild or cultured), procedures to prevent contamination, program of sanitation and maintenance, description of the water source including details of water treatment, program to maintain water quality, maintenance of records, and how shell stock will be harvested.

Person means an individual, firm, corporation, society, association, partnership, or private or public body.

Possession of aquaculture crops means the exercise of dominion or control over cultured crops commencing at the time at which a decision is made not to return the crops to the aquaculture lease or facility from which they were taken. This decision must be made at the first practical opportunity, taking into consideration the management practices set forth in the approved operational plan.

Possession of wild stocks means the exercise of dominion or control over wild stocks commencing at the time at which a decision is made not to return the resource to the immediate vicinity from which it was taken. This decision must be made at the first practical opportunity.

Resubmerge means, and is strictly limited to, reintroduction of shell stock into approved waters following the removal of such stock from approved waters for husbandry purposes.

Shading means to shelter by intercepting the direct rays of the sun to protect the shellfish from heat. Shading may be accomplished by any means that effectively protects the harvested shellfish from direct sunlight and prevents excessive heat build- up in the shaded area.

Shellfish means all species of: (a) Oysters, clams or mussels, whether: (i) Shucked or in the shell; (ii) Raw, including post harvest processed; (iii) Frozen or unfrozen; (iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only.

Shellfish seed means, for bay quahaug, a shell size less than 20 mm (0.78" (longest axis length); for oysters, a shell size less than 32 mm (1.25") longest axis length, and for blue mussels (*Mytilus edulis*) any mussel that settled during the current calendar year.

Spat means newly settled post-metamorphic bivalve.

Spat collection means the use of artificial apparatus (spat collectors) to induce settlement of larval shellfish.

Temperature control means the use of ice or mechanical refrigeration, which is capable of lowering the temperature of the shellstock and maintaining it at 50°F or less.

Wild stock means natural resources, including aquatic or marine animals or plants, which grow within the waters of the state, and are not cultured in any way. Any shellfish that have settled naturally within an aquaculture facility are considered wild stock.

8. Permitting and Licensing Requirements:

8.1 Aquaculture shall only be conducted within the waters of the state in a manner consistent with the best public interest, with particular consideration given to the effect of aquaculture on other uses of the free and common fishery and navigation, and the compatibility of aquaculture with the environment of the waters of the state. Applications shall be reviewed for consistency with RIGL Title 20 and no license shall be issued or renewed to any person where the application is found to be in conflict with any requirement found in these statutes.

8.2 Aquaculture License: An Aquaculture license from the Director is required for an individual to sell to licensed fish and shellfish dealers cultured crops ~~utilized in~~ from an aquaculture lease or facility permitted by CRMC and operated in accordance with the aquaculturist's approved operational plan.

8.2.1 Application shall be made on forms as prescribed by the Director and may be submitted at any time during the year. The license shall be issued on a calendar year basis (expiring December 31) with an

annual fee of two hundred dollars ($200).

8.2.2 Under no circumstances shall a license be granted for species that are not endemic to Rhode Island, without prior approval from the Director with the advice of the Biosecurity Board. Determination of what species are endemic to Rhode Island shall be determined by the Director.

8.2.3 No license shall be renewed unless the applicant's aquaculture activities are conducted in accordance with the approved operational plan. The operational plan must be updated, resubmitted to CRMC, and approved by DEM prior to any operational changes.

8.3 Coastal Resources Management Council (CRMC) Assent or Permit: An aquaculturist must apply for and receive a Coastal Resources Management Council (CRMC) Assent or permit to conduct aquaculture in accordance with RIGL Chapter 20-10. No application shall be approved by CRMC prior to the consideration of recommendations by the Department of Environmental Management (DEM) Director, who shall consult with and obtain input from appropriate divisions and offices within the department, the Rhode Island Marine Fisheries Council and the Department of Health.

8.3.1 The Director may review the application to determine whether the aquaculture activities proposed in the application are not likely to cause and adverse effect on the marine life adjacent to the area to be subject to the permit and the waters of the state, and not likely to have an adverse effect on the continued vitality of indigenous fisheries of the state, and for consistency with other state statutes as applicable.

8.3.2 The RI Marine Fisheries Council (RIMFC) may review the CRMC application to determine whether the aquaculture activities proposed in the application are consistent with competing uses engaged in the exploitation of the marine fisheries. The RIMFC shall provide a recommendation to the CRMC consistent with RIGL 20-10-5.

8.4 As applicable or required, a R.I. Pollutant Discharge Elimination System (RIPDES) permit shall be obtained from DEM Office of Water Resources.

8.5 Water quality at any site used for open water aquaculture or land-based aquaculture must meet the water quality criteria appropriate to the aquaculture activity as determined by the DEM Office of Water Resources. As applicable or required, a Water Quality Certification shall be obtained from DEM Office of Water Resources.

9. Shellfish Culture Requirements

9.1 Cultured crops exempt from wild stock regulations: Aquaculturists harvesting their cultured crops, in accordance with their CRMC Assent, DEM Aquaculture license, and operational plan are exempt from the statutory and regulatory harvest restrictions governing wild stocks, including: seasons, catch or bag limits, minimum sizes, quotas, and methods of harvest. In no case may aquaculturists possess, import, transport or offer for sale for human consumption to any person bay quahaugs with a hinge width of less than one inch, unless specifically authorized to possess, import, transport, or sell legal quahaug seed.

9.2 Shipment and importation of shellfish seed: All shipments of shellfish brought into Rhode Island for aquaculture operations must be approved by the Director or his/her designee and must be labeled or tagged indicating the origin (operator/company name, license number and body of water), date of importation and destination and must be accompanied by a certificate of disease inspection.

9.2.1 All persons wishing to import shellfish seed must submit a written request or email to the Aquaculture Coordinator of CRMC at least five working days prior to entry into the state. Such request to be mailed to Coastal Resources Management Council, Stedman Government Center, Suite 3, 4808 Tower Hill Road, Wakefield, RI 02879.

9.2.2 Prior to shipment, the Aquaculture Coordinator will make a recommendation to the Director whether to approve or deny any request to import shellfish seed and notify DEM Division of Law Enforcement and Agriculture. The Aquaculture Coordinator may seek the advice and consent of the Aquaculture Biosecurity Board in regard to such request to import shellfish seed.

9.3 Only shellfish cultured in approved waters or within an approved land-based system meeting the water quality criteria for harvesting, may be sold for human consumption, and such sales may only be made to licensed RI dealers. All requirements for handling, tagging, use of shellfish containers, and temperature control, as set forth herein, as well as all other applicable DOH standards, must be adhered to.

9.4 Taking or possession of wild stock shellfish:

9.4.1 Aquaculturists who also hold a commercial shellfishing or multipurpose license may not take or possess wild stock shellfish while they are in possession of cultured shellfish crops.

9.4.2 An aquaculturist may not be in possession of wild stock shellfish while visiting their lease or tending their shellfish crops, unless they are a properly licensed shellfish dealer and the wild stock shellfish is properly tagged and being held in or at their dealer facility, buy boat, or wet storage operation.

9.4.3 The taking or possession of undersized wild stock shellfish is prohibited, except for spat collection within lease boundaries approved by the Director or his/her designee. If authorized, the site, species and amount must be specified by the Director or his/her designee in writing.

9.5 Water quality changes: Water quality and water quality classification of waters within the state as determined by the Office of Water Resources are subject to change due to various environmental conditions. In some cases the aquaculturist shall be required to respond to these changes. DEM shall not assume any liability for any changes in classification and shall assume no liability to the aquaculturist for damages incurred due to such actions.

9.6 Shellfish aquaculture in conditionally approved growing areas: When a shellfish aquaculture lease is located in a conditionally approved area, the aquaculturist is prohibited from visiting the lease to tend the shellfish crops when the area is in a closed status, unless the aquaculturist has received permission from the Director. The harvest of cultured stock from the lease when the growing area is in the closed status is prohibited.

9.7 Transfer of seed from other than approved waters: Shellfish seed cultured in other than approved waters in accordance with a CRMC permit must be transferred by the aquaculturist to an approved aquaculture lease in approved waters in accordance with the approved assent, license, and operational plan prior to the shellfish exceeding the seed size limit. If more than 10 percent of the cultured shellfish within a lot or batch exceed the seed size limit, they shall not be moved from other than approved waters to an approved growing area without prior permission of the DEM Director and the DOH.

9.8 Harvest of shellfish transferred from other than approved waters as seed: An aquaculturist wishing to use seed that have been produced in other than approved waters must describe in the operational plan how he/she intends to track and document the growth and harvest of these shellfish. Aquaculturists must maintain accurate and complete records of all shellfish seed culture in other than approved waters and removal of such shellfish seed to approved waters including, but not limited to, source, numbers transferred, size composition, time/dates of transfer, harvest and sale of the shellfish. These records must be maintained for a minimum of two years and must be available for inspection by agents of the DOH, DEM, or CRMC upon request. If record keeping and tracking protocols are inadequate, then the aquaculturist must only use seed from approved waters. No shellfish may be harvested until they have spent at least six (6) months in approved waters.

10. Handling of Shellfish

10.1 General requirements: Shellfish aquaculturists shall conduct all activities and operations involving or relating to the possession and handling of shell stock so as to prevent contamination, deterioration and decomposition of such shell stock.

10.2 Containers: Containers used for storing shell stock must be clean.

10.3 Vessels: Vessel decks and storage bins used in the harvest or transport of shell stock shall be kept clean with potable water or water from the growing area in approved classification or the open status of conditional areas. Aquaculturists using a vessel to harvest and transport

shell stock shall assure that said vessel is properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of shell stock. Aquaculturists using a vessel to harvest and transport shell stock shall prevent bilge water from coming into contact with shell stock.

10.4 Bilge water: Aquaculturists using a vessel to harvest and transport shell stock shall provide such vessel with effective drainage to avoid contact between bilge water and shell stock. Aquaculturists using a vessel to harvest and transport shell stock shall locate bilge pumps so that discharge shall not contaminate shell stock.

10.5 Waste discharge prohibited: It is unlawful to discharge any sewage from a vessel into the waters of the state.

10.6 Washing: Shell stock shall be washed reasonably free of bottom sediments as soon after harvesting as possible. The harvester shall be primarily responsible for washing shell stock. If shell stock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for washing shall be from a potable water source, or growing area in the approved classification or open status of the conditionally approved classification.

11. Tagging of Shellfish

11.1 Required Use of Tagged Containers: Aquaculturists must place any and all shellfish taken by them (except those shellfish returned to the waters of the aquaculture lease or facility) into containers, and must tag each and every container with a completed harvester tag, prior to harvested shellfish being placed in the container. The approximate quantity of shellfish may be completed at the conclusion of harvest.

11.2 Tags: The harvester tag shall be durable, waterproof and sanctioned by the DOH. The tag shall contain the following indelible, legible information in the order specified below:

11.2.1 Aquaculturist’s license number as assigned by DEM;

11.2.2 Harvest commencement time and date;

11.2.3 The harvest location as identified by the CRMC Assent number;

11.2.4 Type (species) of shellfish;

11.2.5 Approximate quantity of shellfish; and

11.2.6 The following statement in bold capitalized type: **"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS"**

11.3 Commingling Prohibition and Tagging by Aquaculturists/Dealers: Aquaculturists shall not place shell stock harvested from more than one growing area into the same container. When the aquaculturist is also a dealer, the aquaculturist has the option to tag the shell stock with a harvester tag or a dealer's tag meeting the requirements of the DOH regulations.

11.4 Bulk Tagging: Bulk tagging of shell stock will be permitted under the following criteria:

11.4.1 When shell stock are harvested from one aquaculture lease site or facility on a single day, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, in a single boat, in a vehicle or other container, and the unit tagged with a single tag, provided that the tag specifies the number of individual containers in the unit or an estimate of the total weight, volume, or count; and

11.4.2 A written statement is provided that "All shell stock containers in the lot have the same harvest data and area of harvest."

12. Temperature Control of Shellfish

12.1 General requirements: Aquaculturists shall not allow shell stock to deteriorate or decompose from exposure to excessive temperature and shall deliver shell stock to a licensed dealer before such deterioration or decomposition occurs.

12.2 Harvest of oysters and quahaugs annually from September 15 through June 30 inclusive: The maximum allowable time between the harvest of shell

stock and delivery to a dealer shall be twelve hours. Possession of shell stock by anyone other than a licensed dealer in excess of twelve (12) hours is prohibited. This maximum allowable time may be reduced by DEM, via emergency regulation, in certain harvest areas if environmental changes necessitate such adjustment.

12.3 Harvest of oysters and quahaugs annually from July 1 through September 14 inclusive:

12.3.1 All oysters and quahaugs harvested shall be transferred to a licensed dealer within five (5) hours of the commencement of harvest

12.3.2 All harvested oysters and quahaugs shall be subject to shading immediately upon harvest.

12.3.3 All oysters and quahaugs that are removed from the water for less than twelve (12) hours for husbandry purposes must be re-submerged for no less than forty-eight (48) hours before harvest.

12.3.4 All oysters and quahaugs that are removed from the water for twelve (12) hours or greater for husbandry purposes must be re-submerged for no less than seven days (168 hours) before harvest.

12.3.5 All oysters and quahaugs that are exposed to air drying must be re- submerged for no less than seven days (168 hours) before harvest.

12.3.6 All oysters and quahaugs harvested from a Designated Temperature Control or Thermally Impacted area shall also be harvested in compliance with one of the following requirements:

(A) Harvesters shall terminate all harvest activities and all harvested oysters and quahaugs must be transferred to a dealer or placed in mechanical refrigeration or adequately iced by 11:00 a.m. between the dates of July 1st and August 31st, inclusive; and by noon between September 1 and September 14th, inclusive. Upon being placed in mechanical refrigeration or adequately iced, oysters must remain under temperature control until transferred to a licensed dealer.

(B) Oysters and quahaugs that are harvested after the times

specified in this section must be delivered to a licensed dealer within two (2) hours of the commencement of harvest; or placed in mechanical refrigeration or adequately iced within two (2) hours of the commencement of harvest until the oysters and quahaugs are transferred to a licensed dealer.

13. Enforcement

13.1 Authority to Enter and Inspect: The Director shall have the authority to enter and inspect any and all aquaculture facilities for the purposes of determining compliance with the terms and provisions of the CRMC assent or permit, DEM license, and approved operational plan (RIGL 20-10-15).

13.2 Violations: Unless otherwise provided, violations of and/or noncompliance with the regulations set forth herein shall be prosecuted under the applicable sections of RIGL Chapter 20-10. In addition to other penalties provided by law or other rule or regulation, any licensed aquaculturist who violates the provisions of these rules or any order issued by the director shall be subject to suspension, revocation or denial of his/her license and/or permit in accordance with RIGL Sections 20-2-13, 20-10-16.1, and 42-17.1-2(19).

14. Effective Date

The foregoing rules and regulations, "*Aquaculture of Marine Species in Rhode Island Waters*", after due notice, are hereby adopted and filed with Secretary of State in accordance with Chapter 42-17.1, and §§; 20-1-2; 20-1-4; 20-1-5; 20-10- 5c; and 20-10-12, in accordance with Chapter 42-35 of the RIGL 1956, as amended.

Janet L. Coit, Director
Department of Environmental Management

Notice Given:	08/21/2015
Public Hearing:	09/21/2015
Filing date:	10/29/2015
Effective date:	11/18/2015

ERLID# 8177

VIBRIO PARAHAEMOLYTICUS CONTROL PLAN – WASHINGTON.

The designated vibrio season in Washington is between May 1 – September 30. During this period, strict oyster harvesting requirements are imposed on the shellfish companies.

The temperature requirements are as follows:

The Washington's Harvest time to cooling requirements and controls are based on a risk categorization of each growing area.

The growing areas are categorized as 1, 2, or 3; where Category 1 represents the least stringent and Category 3 correspond to the most stringent controls.

The categorization is based on the number of cases that occurred during the previous consecutive five-year period within the control months and were attributed to that growing area as shown below:

Category	**Indicator**
Category 1	An average of 0.2 or fewer cases attributed to the growing area over a five-year period.
Category 2	An average of more than 0.2, but less than 1.0 cases attributed to the growing area over a five-year period.
Category 3	An average of 1.0 or more cases attributed to the growing area over a five-year period.

The table below indicates the harvest time to temperature control requirements for each category of growing areas:

a. Category 1

Requirements	**Time to cooling**

Except as noted below, the time of harvest to cooling requirement from June 1st through September 30th is:	9 hours
When ambient air temperature at harvest is greater than 90°F, the time of harvest to cooling requirement is:	7 hours
When harvest temperature is between 68°F and 70°F from July 1st through August 31st, the time of harvest to cooling requirement is:	5 hours
Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 70°F.	

b. Category 2

Requirements	**Time to cooling**
Except as noted below, the time of harvest to cooling requirement from May 1st through September 30th is:	7 hours
When ambient air temperature at harvest is greater than 85°F, the time of harvest to cooling requirement is:	5 hours
When harvest temperature is between 66°F and 68°F from July 1st through August 31st, the time of harvest to cooling requirement is:	3 hours
Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 68°F.	

c. Category 3

Requirements	**Time to cooling**
Except as noted below, time of harvest to cooling requirement from	5 hours

May 1st through September 30th is:	
When ambient air temperature at harvest is greater than 80°F, the time of harvest to cooling requirement is:	3 hours
When harvest temperature is between 64°F and 66°F from July 1st through August 31st, the time of harvest to cooling requirement is:	1 hour
Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours when harvest temperature is above 66°F.	

-When a harvester or shellfish dealer places oysters in a container or conveyance, but does not remove them from the tide flat as part of their harvest and the harvest exceeds the time to cooling requirements as above, then the oysters in the container or conveyance must be covered by the tide for a minimum of four (4) hours before harvest can be completed.

The harvesters shall take the measurements of the air temperature, and water temperatures at the depth of oysters at the time and location of harvest and record this information for all harvest occurring with the control months.

- If the required time of harvest to cooling requirements are not met after removal from the tide flat, the harvester or shellfish dealer shall dispose of the oysters using one of the methods below and record the disposition on the harvest record:

(a) Destroy the oysters;

(b) Place the oysters within the original growing area or another approved growing area and allow a minimum of fourteen days before re-harvesting; or

(c) Deliver the oysters to a certified shucker packer for shucking or PHP and attach a harvest tag meeting the prescribed requirements.

- The Washington Vibrio control plan requires all persons handling the shellfish to keep the oysters in a controlled environment with a temperature of 45^0 F (7.2^0 C) and Reach and maintain an internal oyster tissue temperature of 50°F (10°C) or less.