



**STATE OF DELAWARE**  
**DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL**  
**SHELLFISH AND RECREATIONAL WATER PROGRAM**

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**Vibrio parahaemolyticus (Vp) Control Plan**

for Eastern Oysters (*Crassostrea virginica*)  
Harvested from Rehoboth Bay (GA-2) and Indian River Bay (GA-3)

Effective June 1, 2024 through September 30, 2024  
Unless Revised and Reissued

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## **SECTION I. INTRODUCTION**

1. **PURPOSE:** The purpose of this *Vibrio parahaemolyticus* (Vp) Control Plan is to protect public health by reducing the risk of Vp illnesses from oysters harvested from Rehoboth Bay and Indian River Bay from June 1, 2024 through and including September 30, 2024. The plan seeks to reduce Vp illness risk by establishing temperature control requirements, such as shading and icing, and other requirements for oyster aquaculture growers, harvesters, and dealers as necessary to prevent proliferation of Vp in oyster tissue once oysters are removed from the water.
2. **BACKGROUND:** Oysters pose a significant and unique risk of foodborne illness because they are filter feeders that concentrate pathogens that may cause human illness from surrounding waters and because they are commonly eaten whole and raw or partially cooked. Many of the pathogens that may be concentrated inside oyster tissue can be controlled via shellfish growing area classification or other means; however, the bacterium *Vibrio parahaemolyticus* is naturally-occurring and present in all seawater and shellfish, and at far higher levels when waters are warm. Therefore, post-harvest temperature control and other Vp control measures are necessary to preclude an unacceptable risk of illness to consumers. Delaware and other states are federally required to comply with the National Shellfish Sanitation Program (NSSP), which includes requirements that states must conduct a risk evaluation that considers particular criteria in assessing whether Vp infection from consumption of bivalve shellfish from each growing area is likely to occur, and if so develop and implement a Vp Control Plan that establishes control measures to reduce Vp illness risk and procedures for plan evaluation and modification. DNREC has performed the Vp risk evaluation per NSSP criteria and determined that Vp illness is reasonably likely to occur in oysters harvested from Rehoboth Bay and Indian River Bay from June 1 through September 30, unless control measures are implemented. This Vp Control Plan seeks to reduce that risk by requiring growers, harvesters, and dealers to practice control measures such as shading, icing, resubmergence, and temperature control. The oyster industry is encouraged to strictly adhere to Plan requirements and also to further reduce Vp illness risk by practicing additional, optional measures for post-harvest temperature control. Education on these additional measures can be obtained by contacting the DNREC Shellfish and Recreational Water Program. Conscientious Vibrio control during warm months will protect not only public health, but also industry by preventing illness outbreaks which may result in harvest closures, product recalls, negative publicity, and diminished consumer confidence.
3. **AUTHORITY:** This Vp Control Plan is implemented under the authority of the National Shellfish Sanitation Program Section II. Model Ordinance and under the authority of the Delaware Administrative Code Title 7: 7402 Shellfish Sanitation Regulations, Section 4.3.4.3.
4. **SCOPE:** The requirements herein apply to oysters which appear, in the opinion of DNREC, to be intended for harvest\* and, after harvest, to be intended for human consumption. This Plan does not apply to oysters which appear, in the opinion of DNREC, to be appear intended for shellfish enhancement or for transfer between harvest sites prior to resubmergence and later harvest. These activities are subject to other requirements established by DNREC.
5. **EXCEPTION TO SCOPE – REMOVAL OF OYSTERS FROM LEASE FOR HUSBANDRY:**
  - A. Oysters brought on land for husbandry\* purposes such as sorting and tumbling, then placed back on the lease shall be resubmerged\* for at least 14 days before harvest, according to the stipulations of this Plan.
  - B. Oysters removed from the lease for husbandry\* purposes shall not be removed from the lease after a curfew time of 5 hours after the legal sunrise time\*, except for oysters with a maximum size of less than 2 inches. After the curfew time, no oysters greater than 2 inches shall be removed from the lease unless intended for final harvest\* and adequately iced\* according to the stipulations of this Plan.
  - C. Such oysters shall be returned to the lease on the same calendar day of removal and may be returned to the lease after the curfew time.
  - D. Oysters shall not be removed from or returned to the lease between the legal sunset time\* and the legal sunrise time\*.
  - E. Oysters brought on land for husbandry\* purposes shall be adequately shaded\* immediately after removal from the water, except for oysters with a maximum size of less than 2 inches. A gap of at least

3 feet shall be maintained between the top of oysters and the shade cover to allow adequate air flow. The shade cover shall extend at least one foot beyond the perimeter of the oyster containers. The shade cover shall be maintained in sanitary and operational condition. The shade cover shall be capable of withstanding normal operating and weather conditions.

6. **APPLICATION:** The terms and provisions of this Plan shall be liberally construed to allow DNREC to effectuate the purposes of this Plan, National Shellfish Sanitation Program requirements, and state law and regulations.
7. **SEVERABILITY:** Should any section, paragraph, sentence, clause, or phrase of this Plan be declared invalid for any reason, the remainder of the Plan shall not be affected thereby.

## **SECTION II. DEFINITIONS**

*NOTES: All definitions herein apply only to the purposes of this Vp Control Plan. Definitions of the words and phrases defined herein may be different when used in other contexts. The definitions in this section also apply to reasonably similar forms of the words and phrases defined (e.g. the definition for “landing” also applies to “land” and “landed”). For clarity and convenience, throughout this Plan, some words and phrases defined in this section are indicated by an asterisk; however, as appropriate these definitions apply even if defined words and phrases are not asterisked.*

1. **Adequate Icing:**
  - a. means, prior to landing\*, placement by a harvester\* of oysters between layers of wet ice, so that oysters are resting on top a layer of ice and generally covered by a layer of ice, such that the amount and placement of ice is capable of beginning cooling of oysters and facilitating continued cooling of oysters; and
  - b. means, starting no more than 30 minutes after landing\*, placement by the original dealer\* of oysters into wet ice which completely surrounds the oysters on the bottom, sides, and top. The ice must be composed of particles not to exceed an average size of 2 inches in all dimensions.
2. **Sanctioned Source of Ice** means pre-bagged ice purchased from a reputable commercial source, such as a convenience store, that is approved by DNREC, or ice made from potable water\* in a commercial ice machine that has been inspected and approved by DNREC.
3. **Adequate Shading** means measures taken to shelter oysters from direct exposure to sunlight that may cause a significant increase in Vibrio growth due to an increase in temperature. Adequate shading may be accomplished by any means that effectively protects oysters from direct sunlight and prevents excessive heat build-up in the shaded area. A gap of at least 3 feet must be maintained between the top of the oysters and the shade cover to allow sufficient air flow.
4. **Dealer/Certified Shellfish Dealer** means a person or business, including any associated facility, buildings, and equipment, to whom current shellfish dealer certification is granted by DNREC to engage in one or more of the following activities: receipt of oysters from harvesters\*, wholesale\* of oysters to retailers, retail\* of oysters to consumers, storage of oysters, shipping of oysters, or shucking, packing, or other processing/handling of oysters. The dealer may also be the harvester\*, if the harvester is permitted by DNREC as a certified shellfish dealer.
5. **Dealer Sales Log** means a record maintained by a certified shellfish dealer\* which documents information pertinent to the sale of shellfish, including but not limited to the date and time of sale, the source of the shellfish, the shellfish species and type, the harvest date and harvest location\*, the quantity sold, and the person or business to whom the shellfish were sold.
6. **Original Dealer** means the dealer\* who initially received oysters from a harvester\*. The original dealer may also be the harvester\*, if the harvester\* is permitted by DNREC as a certified shellfish dealer.
7. **Receipt by Dealer** means the point of time, after or upon landing\*, when oysters are received from the harvester\* by the original dealer\*. Receipt by dealer is a Critical Control Point that must be listed in the dealer's HACCP plan.

- a. In cases where the original dealer\* is not also the harvester\*, receipt by dealer occurs when the oysters arrive at the facility of the original dealer\* and the original dealer\* takes possession of the oysters from the harvester\*.
  - b. In cases where the original dealer\* is also the harvester\* and is receiving in the capacity as a dealer the oysters he/she has harvested\*, receipt by dealer occurs at the time of landing\*, unless the harvester\*-dealer\* is transporting the oysters to mechanical refrigeration\* at their physical facility which is permitted as part of a certified shellfish dealer operation, in which case, the receipt by the dealer shall be considered to take place upon arrival at the physical facility.
8. **Dealer Tag** means a durable, waterproof tag affixed by a certified shellfish dealer\* to an individual container of oysters or, if a bulk tag is used, an individual lot\* of oysters, and meeting the specifications for dealer tags contained in the National Shellfish Sanitation Program Model Ordinance and the Delaware Administrative Code Title 7: 7402 Shellfish Sanitation Regulations, Appendix 10.
  9. **Grower** means a person to whom permission has been granted by DNREC to engage in oyster aquaculture.
  10. **Harvest** means the removal of an oyster from the water with the intention, in the opinion of DNREC, of not returning the oyster to the water after husbandry\* practices. Harvest commences when the first oyster not intended to be returned to the water is removed from the water, regardless of whether the oyster is temporarily placed back into the water after culling, sorting, or other activities.
  11. **Harvester** means a person, in the opinion of DNREC, engaged in the activity of commercial harvest\*.
  12. **Harvest Location** means “Rehoboth Bay, DE” or “Indian River Bay, DE”, as appropriate.
  13. **Harvester Tag** means a durable, waterproof tag affixed by a commercial shellfish harvester\* to an individual container of oysters or, if a bulk tag is used, an individual lot\* of oysters, and meeting the specifications for harvester tags contained in the National Shellfish Sanitation Program Model Ordinance and the Delaware Administrative Code Title 7: 7402 Shellfish Sanitation Regulations, Appendix 10.
  14. **Husbandry** means any activity related to the cultivation and management of shellstock before their harvest\*, including but not limited to grading, sorting, culling, tumbling, and cleaning.
  15. **Internal Temperature** means the internal temperature of the meat of an oyster as measured using a calibrated probe thermometer. The internal temperature of oysters is, under most circumstances, reflected by the external temperature of the space surrounding the oysters, or the external temperature of its shell. The internal temperature of oysters may be measured by inserting a thermometer probe into a container of oysters to an appropriate depth or by measuring the external shell temperature with an infrared thermometer. Should circumstances dictate, it may be necessary for DNREC or industry to open the oyster to measure its internal temperature with a thermometer probe, taking care to avoid transferring heat from hands or equipment to the oyster; oysters opened for temperature measurement must be discarded.
  16. **Landing** means the point of time at which oysters are put on land or a dock.
  17. **Legal Sunrise Time** means the sunrise time at Dover, Delaware, as established by DNREC and available for view at [www.eregulations.com/delaware/hunting/sunrise-sunset-table](http://www.eregulations.com/delaware/hunting/sunrise-sunset-table)
  18. **Legal Sunset Time** means the sunset time at Dover, Delaware, as established by DNREC and available for view at [www.eregulations.com/delaware/hunting/sunrise-sunset-table](http://www.eregulations.com/delaware/hunting/sunrise-sunset-table)
  19. **Lot** means all the oysters harvested\* by a single harvester\* during a single harvest operation from a single shellfish harvest location\*. A lot of oysters may be identified by a single bulk harvester tag\* or a single bulk dealer tag\*.
  20. **Mechanical Refrigeration** means a mechanically refrigerated cooler, not to include a truck or other conveyance, which is part of a certified shellfish dealer\* operation permitted by DNREC and which is pre-chilled to and maintained at an ambient air temperature of 45°F or below and capable of achieving the time-temperature requirements of this Plan.
  21. **On-Water Retail – On-Lease** means the retail\* sale of oysters to consumers without the oysters having left the lease, such as sales to boaters who pull up to the lease while a grower\* is harvesting\* or performing husbandry\*, but not a Lease Tour\*.

22. **On-Water Retail – On-Lease: Lease Tour** means an event in which an aquaculture grower\* arranges for people to visit the lease for educational, tourism, or similar purposes, and oysters are either consumed by tour participants while on the lease or provided to tour participants after landing\*.
23. **On-Water Retail – Off-Lease/After Landing\*** means the retail\* sale of oysters to consumers after the oysters have left the lease. This sale must occur after landing\* and in the capacity of the original dealer\*.
24. **Potable Water** means water from a water supply which meets the requirements of the Safe Drinking Act, as administered by the US Environmental Protection Agency, and all applicable state or local requirements.
25. **Retail** means sale of oysters to final consumers, not to entities who will then resell the oysters. Before removal from the lease, retail is conducted in the capacity of a grower\*, while after removal from the lease or after landing, retail must be conducted in the capacity of a certified shellfish dealer.
26. **Wholesale** means the sale of oysters to entities, such as restaurants or stores, that will resell the oysters. Wholesale must be conducted in the capacity of a certified shellfish dealer.
27. **Resubmergence** means the placement by an aquaculture grower\* of oysters below the mean low tide level of the waters of the lease where the oysters were originally planted.
28. **Temperature Control** means the use of adequate icing\* or mechanical refrigeration\*, not to include a truck or other conveyance, which is capable of lowering the internal temperature\* of oysters to 50°F then maintaining the internal temperature of oysters at 50°F or below, and of achieving the time-temperature requirements of this Plan.
29. **Time of Initial Harvest** means the time when the first oyster harvested\* in a lot\* is removed from the water. In cases where the grower\* removes oysters from the water for culling, sorting, or other activities then temporarily places the oysters back into the water, the time of initial harvest is when the oysters were initially removed from the water before temporary placement back into the water.
30. **Time of Final Harvest** means the time when the last oyster harvested\* in a lot\* is removed from the water.
31. **Time of Initial Icing** means the time when the first oyster in a lot\* is adequately iced\*.
32. **Time of Final Icing** means the time when the last oyster in a lot\* is adequately iced\*.
33. **Vibrio Harvester Record** means a document provided by DNREC on which, in some cases, harvesters\* must record the date, harvester name, harvest location\*, the time of initial harvest\*, the time of initial icing\*, the time of final harvest\*, and the time of final harvest\*, the quantity harvested, and the receiver of the oysters (which is the original dealer\*, unless the oysters were retailed\* on the lease to consumers prior to landing\*, subject to the requirements herein) and the time the receiver received the oysters.

### **SECTION III. CONTROL MEASURES**

#### **1. RESUBMERGENCE\* BY GROWERS\*:**

- A. **GENERAL:** Prior to harvest\*, growers\* shall ensure that all oysters are resubmerged\* for at least 14 days below the mean low tide level to allow natural depuration of Vibrio within the oyster tissue back to the level of the surrounding water.
- B. **APPLICABILITY:** This resubmergence\* requirement shall apply to oysters exposed to the air for time periods exceeding 2 hours, during grow-out operations or during husbandry\*, handling, or maintenance activities, and to oysters grown in gear held at the water surface or in other methods that otherwise increase the risk of Vibrio accumulation within oysters.
- C. **CLARIFICATION:** For clarification, oysters grown in methods that present a risk of contamination by bird waste must be resubmerged for at least 21 days at least 18 inches below the mean low tide level. This applies to oysters grown in methods where oysters float at the water's surface or where oysters are suspended in the water column at above 18 inches below the mean low tide level.
- D. **RECORDKEEPING:** Growers\* shall document such resubmergence\* of oysters prior to harvest, and make such records available for inspection by DNREC

## 2. HARVESTER TAGS:

- A. **SPECIFICATIONS:** Harvesters\* shall record, at the time of initial harvest\* and in legible writing with indelible ink, on the harvester tag\* the harvester name or identification number, harvest date, harvest location\*, type of shellfish (“Oysters”), and time of initial harvest\*.
- i. The quantity of oysters harvested is also required to be listed on the harvester tag\* but may be filled in at a later time, as it is recognized that the harvested quantity may not yet be known at the time of initial harvest\*.
  - ii. Failure to record the time of initial harvest\* on the harvester tag\* at the time of initial harvest\* is a violation of this Plan; however, if no time of initial harvest\* is recorded on the harvester tag\*, the time of initial harvest\* may, at the discretion of DNREC, be assumed by DNREC to be the legal sunrise time\*.

## 3. HARVEST OPTION #1 – HARVEST CURFEW:

- A. **LANDING TIME:** Oysters shall be landed\* (and received by dealer\*) within 5 hours of the legal sunrise time\*, and harvesters\* shall not land\* oysters after 5 hours after the legal sunrise time\*.
- i. For clarification, this option allows harvesters\* to land\* oysters without use of ice if the landing occurs within 5 hours of the legal sunrise time\*. This option may be used by harvesters starting from the legal sunrise time\* until 5 hours after the legal sunrise time\*. This option shall not be used after 5 hours after the legal sunrise time\*; starting at 5 hours after the legal sunrise time\*, harvesters\* shall use Harvesting Option 2 – On-Board Icing.
    1. If initial harvest\* occurs within 5 hours of the legal sunrise time\* and final harvest\* occurs after the legal sunrise time, the requirements of Harvest Option 2 – On-Board Icing shall go into effect at the time of 5 hours after the legal sunrise time. That is, starting at 5 hours after the legal sunrise time, oysters shall be adequately iced\* within 1 hour of harvest\*. For oysters harvested prior to 5 hours after the legal sunrise time, if these oysters were harvested over 1 ago, the oysters shall immediately be adequately iced upon 5 hours after the legal sunrise time.
  - ii. For clarification, as pursuant to requirements detailed later in this Plan, oysters shall be not only landed\* but also received by the dealer\* within 5 hours of the legal sunrise time\* and shall be placed under temperature control\* within 30 minutes of receipt by the dealer\*.
- B. **SHADING:** Harvesters shall provide adequate shading\* sufficient to protect oysters from exposure to hot sun, as well as potential contamination by birds. Oysters shall be adequately shaded\* immediately after harvest\* until landing\*.
- i. **AIR GAP:** A gap of at least 3 feet shall be maintained between the top of oysters and the shade to allow adequate air flow.
  - ii. **SPECIFICATIONS:** The shade cover shall extend at least one foot beyond the perimeter of the oyster containers. The shade cover shall be maintained in sanitary and operational condition. The shade cover shall be capable of withstanding normal operating and weather conditions.
    1. **RECOMMENDATION** to harvesters: It is recommended that the shade cover be light-colored to maximize its capacity for shading.
  - iii. **EXCEPTION:** It is not required (but remains recommended) that oysters are shaded if they are adequately iced\* within a container with a cover directly on top the container. If adequate icing\* is practiced without shading, the harvester\* shall adequately ice\* each oyster within 1 hour of the oyster’s harvest\*. That is, within 1 hour of removing an oyster from the water, the oyster shall be adequately iced\*. Oysters shall not be removed from the lease unless adequately iced\*. From 1 hour after harvest\* until receipt by the original dealer\*, all oysters shall remain adequately iced\*.
- C. **RECOMMENDATION:** Though not required when oysters are harvested within 5 hours of the legal sunrise time\*, it is recommended that harvesters adequately ice oysters within 1 hour of harvest, or that

harvesters periodically spray oysters with water from a shellfish growing area classified as Approved in the open status so that the oysters are cooled as water evaporates.

**4. HARVEST OPTION #2 – ON-BOARD ICING:**

- A. **GENERAL:** Starting at 5 hours after the legal sunrise time\*, the harvester\* shall adequately ice\* each oyster within 1 hour of the oyster's harvest\*. That is, within 1 hour of removing an oyster from the water, the oyster shall be adequately iced\*. Oysters shall not be removed from the lease unless adequately iced\*. From 1 hour after harvest\* until receipt by the original dealer\*, all oysters shall remain adequately iced\*.
- B. **LANDING\* TIME:** Oysters shall be landed\* (and received by dealer\*) within 5 hours of the time of initial harvest\*, as recorded on the harvester tag\*.
  - i. Failure to record the time of initial harvest\* on the harvester tag\* at the time of initial harvest\* is a violation of this Plan; however, if no time of initial harvest\* is recorded on the harvester tag\*, the time of initial harvest\* may, at the discretion of DNREC, be assumed by DNREC to be the legal sunrise time\*.
  - ii. For clarification, as pursuant to requirements detailed later in this Plan, oysters must be not only landed\* but also received by the dealer\* within 5 hours of the legal sunrise time\* and must be placed under temperature control\* within 30 minutes of receipt by the dealer\*.
- C. **RECORDKEEPING:** At the times when these activities occur, the harvester\* shall record, on a Vibrio Harvester Record\* provided by DNREC and in indelible ink, the date, harvester name, harvest location\*, the times of initial harvest\*, initial icing\*, final harvest\*, final icing\*, and landing\*; the quantity harvested; and the receiver of the oysters (which is the original dealer\*, unless the oysters were retailed\* on the lease to consumers prior to landing\*, subject to the requirements herein) and the time the receiver received the oysters.
  - i. This Vibrio Harvester Record\* shall be provided to the original dealer\* at the time of receipt by the dealer\*.
- D. **RECOMMENDATION:** It is recommended that even when oysters are adequately iced\* within 1 hour of initial harvest\*, as required under Harvest Option #2, harvesters provide adequate shading\* sufficient to protect oysters from exposure to hot sun, in order to prevent oyster temperatures from increasing and to delay melting of ice.

5. **HARVEST AFTER HUSBANDRY – RECOMMENDATION** to harvesters: It is recommended that if harvesters perform on-lease husbandry\* or maintenance activities in addition to harvesting\*, they conduct the harvesting last, so that oysters remain in the water until it is necessary that they be removed from the water.

**6. RECEIPT BY DEALER\*:**

- A. **GENERAL:** No matter which of the two Harvest Options is used, oysters shall be landed\* and received by the original dealer\* within 5 hours of the time of initial harvest\*, as recorded on the harvester tag\*. Once oysters are harvested and removed from the lease, harvesters\* shall sell oysters only to a certified shellfish dealer\*. Immediately after landing\*, harvesters\* shall transport oysters to the point of receipt by dealer\* (in some cases, receipt by dealer\* is at landing\*).
  - i. Failure to record the time of initial harvest\* on the harvester tag\* at the time of initial harvest\* is a violation of this Plan; however, if no time of initial harvest\* is recorded on the harvester tag\*, the time of initial harvest\* may be assumed by DNREC and by the original dealer\* to be the legal sunrise time\*.
- B. **TIMING OF RECEIPT BY DEALER\*:**
  - i. Oysters shall not be considered to be received by a dealer\* until after landing\*. Until landing, oysters shall be considered to be in the possession of the harvester\*.
  - ii. In cases where the harvester\* is certified as a shellfish dealer\* and is receiving in the capacity as a dealer the oysters he/she has harvested\*, receipt by the dealer\* shall be considered to take place at the time of landing\*, unless the harvester\*-dealer\* is transporting the oysters to mechanical refrigeration\* at their physical facility which is permitted as a certified shellfish dealer\* operation, in which case receipt by the dealer\* shall be considered to take place upon



arrival at the physical facility. Pursuant to these definitions of the time of receipt, receipt by a dealer\* must occur within 5 hours of the time of initial harvest\*.

- C. **RECORDKEEPING:** The original dealer\* shall include in their HACCP plan as a critical limit under the Receiving Critical Control Point that oysters harvested\* under this Vp Control Plan are received within 5 hours of the time of initial harvest\*. This critical limit shall be monitored and documented at the time of receipt by dealer\*.
- i. If Harvester Option 2 – On-Board Icing was used, such that oysters were landed\* after 5 hours after the legal sunrise time\*, the original dealer\* shall also include as a critical limit under the Receiving Critical Control Point that oysters are adequately iced\* upon receipt\*, and are accompanied by a Vibrio Harvester Record\* containing all required information and showing that Plan requirements were met. This critical limit shall be monitored and documented at the time of receipt by dealer\*.
  - ii. If these critical limits are not met, the original dealer\* shall immediately perform and document the corrective action of deeming the oysters unfit for consumption and either destroying them or, with the prior approval of DNREC, returning them to the grower\*/harvester\* for resubmergence\* for at least 14 days.
    1. The original dealer\* shall immediately report this incident, including the name of the harvester\*, to the DNREC Shellfish and Recreational Water Program.
    2. The original dealer\* shall address the root cause of this critical limit deviation by discontinuing receipt of oysters from the harvester\* until compliance with the Plan requirements is improved.
    3. If oysters are to be resubmerged\*, the grower\*/harvester\* shall submit a written resubmergence\* strategy for pre-approval by DNREC, and oysters shall not be transferred back to the grower\*/harvester\* and resubmerged\* until the strategy is approved. The resubmerged\* oysters shall not be harvested\* until approved for harvest\* by DNREC. The resubmergence\* of the oysters shall be documented by the grower\*/harvester\* to ensure its duration is at least 14 days, and resubmerged\* oysters shall be segregated from other oysters and held below the mean low tide level.
- D. **VIOLATION:** No oysters which do not meet the requirements of this section shall be sold or shipped.

7. **TEMPERATURE CONTROL\* BY DEALER\*:**

- A. **TEMPERATURE CONTROL\*:** Within 30 minutes of receipt by the original dealer\*, the original dealer shall adequately ice\* the oysters, such that oysters are surrounded by ice on the bottom, sides, and top, OR place them in mechanical refrigeration\*, which is part of the dealer's facility as permitted by DNREC, pre-chilled and set to 45°F or below (not to include a refrigerated truck unless oysters are surrounded by ice). That is, for a harvester\*-dealer\*, unless transporting oysters to mechanical refrigeration\* at their physical facility, within 30 minutes of landing\* the requirement for adequate icing\* changes from the requirement that the oysters be resting on a layer of ice and generally covered in ice to the requirement that oysters be completely surrounded on all sides with ice.
- i. Oysters shall be temperature controlled\* by the original dealer\* to an internal temperature\* of 50°F or below within 8 hours of the time of initial harvest\*, as recorded on the harvester tag\*, and before sale or shipment.
  - ii. Unless the oysters are placed into the original dealer's\* mechanical refrigeration\*, the oysters must be completely surrounded by ice before and until sale by the original dealer\*.
- B. **STORAGE:** During storage by the dealer\*, oysters shall be adequately iced\* or be placed in mechanical refrigeration\* pre-chilled to and maintained at an ambient air temperature of 45°F or below, subject to the specifications of this Plan, except for allowable periods of 30 minutes at points of processing or transfer.
- C. **TRANSPORT:** During transport by the dealer\*, oysters shall be adequately iced\* or be placed in a mechanically refrigerated conveyance pre-chilled to and maintained at an ambient air temperature of

45°F or below, subject to the specifications of this Plan, except for allowable periods of 30 minutes at points of processing or transfer.

D. **RECORDKEEPING:** The original dealer\* shall measure the internal temperature\* of the oysters and document that they were temperature controlled\* to at or below 50°F within 8 hours of the time of initial harvest\*. The original dealer\* shall include in their HACCP plan as a critical limit under the Storage Critical Control Point that oysters harvested\* under this Vp Control Plan are temperature controlled\* to an internal temperature\* of at or below 50°F within 8 hours of the time of initial harvest\*. The original dealer\* shall ensure that all oysters are temperature controlled\* to an internal temperature\* of 50°F or below within 8 hours of the time of initial harvest\* and before sale or shipment.

i. If this critical limit is not met, the original dealer\* shall immediately perform and document the corrective action of deeming the oysters unfit for consumption and either destroying them or, with the prior approval of DNREC, returning them to the grower\*/harvester\* for resubmergence\* for at least 14 days.

1. The original dealer\* shall immediately report this incident to the DNREC Shellfish and Recreational Water Program.

2. The original dealer\* shall address the root cause of this critical limit deviation by taking and documenting preventative measures to ensure that the dealer's temperature control\* system is capable of cooling oysters in accordance with the requirements of this Plan.

3. If oysters are to be resubmerged, the grower\*/harvester\* shall submit a written resubmergence\* strategy for pre-approval by DNREC, and oysters shall not be transferred back to the grower\*/harvester\* and resubmerged\* until the strategy is approved. The resubmerged\* oysters shall not be harvested\* until approved for harvest\* by DNREC. The resubmergence\* of the oysters shall be documented by the grower\*/harvester\* to ensure its duration is at least 14 days, and resubmerged\* oysters shall be segregated from other oysters and held below the mean low tide level.

E. **VIOLATION:** No oysters which do not meet the requirements of this section shall be sold or shipped.

8. **TEMPERATURE CONTROL\* – GENERAL:** Once placed under temperature control\* and until sale to the consumer, oysters shall be adequately iced\* or be placed in mechanical refrigeration\* or conveyance pre-chilled to and maintained at an ambient air temperature of 45°F or below, subject to the specifications of this Plan.

#### 9. **ICING OF OYSTERS**

A. **GENERAL:** Ice used by harvesters\* and dealers\* shall be obtained from a sanctioned source\* and shall be protected from contamination before and during use.

B. **ICING CONTAINER:** When icing is used by harvesters\* or dealers\*, the icing container shall be clean, smooth, and impervious. The container shall meet the regulatory requirements for shellfish food contact surfaces and shall not be constructed of wood or another pervious material. The container shall provide adequate drainage of ice-melt such that oysters are not sitting in liquid.

i. **RECOMMENDATIONS** to harvesters: It is recommended that the container be light-colored to delay melting of ice. It is recommended that oysters be adequately iced in a container with a tight-fitting lid, such as a cooler intended for beverages.

C. **ICE SIZE:** Ice used for adequate icing\* to meet the requirements of this Plan shall be composed of particles not to exceed an average size of 2 inches in all dimensions.

D. **RECOMMENDATION** to harvesters: It is recommended that, to facilitate rapid oyster cooling, harvesters initially cool oysters in an ice-water mixture, then to store oysters in solid ice. Oysters should be submerged for about 10-15 minutes in an ice-water mixture at no colder than 40°F to avoid shocking oysters. This method is recognized as the gold standard for oyster cooling. The method may or may not minimize the amount of ice needed (because hot oysters are not causing the ice to melt quickly).

E. **WATER FOR ICE-WATER MIXTURES:** If an ice-water mixture is used before adequate icing\*, the water constituting the ice-water mixture shall be potable water\* or water from a shellfish growing area classified as Approved in the open status. If using an ice-water mixture, harvesters\* shall monitor

water clarity to ensure against excessive turbidity from mud and other material, and when necessary the harvester\* shall change the ice-water mixture.

#### **10. RESUBMERGENCE\* OF RECALLED OYSTERS**

- A. In the case of a product recall resulting from a Vp illness outbreak, only oysters still on-hand at the original dealer\* may be returned to the aquaculture lease for resubmergence\*. Recalled oysters already distributed by the original dealer\* shall not be returned to the aquaculture lease for resubmergence\*, and shall be discarded, after return to the original dealer if possible.
- B. The grower\*/harvester\* shall submit a written resubmergence\* strategy for pre-approval by DNREC, and oysters shall not be transferred back to the grower\*/harvester\* and resubmerged\* until the strategy is approved.
- C. The resubmerged\* oysters shall not be harvested\* until approved for harvest\* by DNREC.
- D. The resubmerged\* oysters shall be segregated from other oysters and held below the mean low tide level.
- E. The resubmergence\* of the oysters shall be documented by the grower\*/harvester\* to ensure its duration is at least 14 days.

### **SECTION IV. ENFORCEMENT**

1. **INSPECTIONS:** DNREC may conduct reasonable unannounced inspections to determine compliance with the requirements of this Plan at aquaculture leases, grower\*/harvester\* boats, landing\* sites, and shellfish dealer\* facilities.
2. **RECORDS:** All records required herein shall be maintained by the grower\*, harvester\*, or dealer\* for a period of 1 year or 2 years, as required for the specific record. Records shall be provided by growers\*, harvesters\*, and dealers\* for inspection by DNREC to ensure compliance with the recordkeeping requirements of this Plan.
3. **NON-COMPLIANCE:** Any oysters determined by DNREC to be out of compliance with the requirements of this Vp Control Plan shall be considered unfit for consumption and subject to embargo, seizure, destruction, and/or other action at the discretion of DNREC, in accordance with Section 3.1.3 of the State of Delaware 7402 Shellfish Sanitation Regulations.
  - A. Significant non-compliance with the requirements of this Plan constituting a public health hazard may result in suspension or revocation by DNREC of harvester licensure and/or shellfish dealer certification or in other penalties.

### **SECTION V. PLAN EVALUATION AND MODIFICATION**

- **PLAN EVALUATION:** This Plan will be evaluated over the course of its implementation by the DNREC Natural Resources Police and the DNREC Shellfish and Recreational Water Program, which will communicate and coordinate to ensure that the Plan is adequate to meet the desired objectives of protecting public health and ensuring NSSP compliance, and that industry compliance with the Plan is generally good. The Plan will also be evaluated for adequacy in the event of a Vp illness outbreak associated with oysters that were harvested under this Plan.
- **PLAN MODIFICATION:** If the evaluation of this Plan shows that it is ineffective in controlling Vp risk, the Plan will be modified and reissued by DNREC as soon as possible. The Plan will also be modified if new information or technology becomes available and makes modification prudent as determined by DNREC. It may be necessary that modification include more stringent Vp controls to protect public health. It is recognized that many requirements of this Plan are being newly implemented this year and so it may be necessary to modify them as shown prudent by ongoing experience.

## **APPENDIX A. SPECIAL CIRCUMSTANCES – ON-WATER RETAIL:**

*NOTE: This appendix describes extra requirements for special circumstances where oysters are retailed on the water. These special circumstances are not necessarily exempt from the other requirements of this Plan, which apply to these special circumstances as appropriate. The special circumstances in this appendix are intrastate retail sales and as such are not under the jurisdiction of US Food and Drug Administration evaluation.*

1. **GENERAL:** The provisions in this section apply to retail\* of oysters by growers\* and dealers\* while on the water, both on the lease\* and off the lease\*. While on the water, oysters shall never be wholesaled\* to retailers such as restaurants or seafood markets, but may be retailed\* only to final consumers. Oysters harvested\* under this Plan and retailed\* to final consumers while on the water may not be made available for subsequent sale or trade.
2. **ON-WATER RETAIL – ON-LEASE\*:**
  - A. **APPLICABILITY:** This section applies to oysters retailed\* by the harvester\* to consumers before the oysters have been removed from the lease, such as sales to boaters who pull up to the lease, but not on a lease tour\*. This type of sale shall be conducted in the capacity of a harvester\*.
  - B. **ICING:** Before sale, oysters shall before sale be adequately iced\* and at an internal temperature\* of 50°F or below. Along with the oysters in their container, the grower\* shall provide the customer with an amount of ice sufficient to prevent the temperature of the oysters from immediately beginning to increase.
  - C. **HARVESTER TAG\*:** If oysters are harvested\* for sale in this way, the harvester\* shall complete the harvester tag\* at the time of initial harvest\*, according to the requirements of this Plan. The harvester\* shall retain the harvester tag\* in his or her possession even after the retail sale.
  - D. **RECORDKEEPING:** Oysters retailed\* in this way are exempted from requirements that they must be received by a certified shellfish dealer\*. However, harvesters\* must document at the time of sale the date, harvester name, harvest location\*, the quantity sold, that oysters were adequately iced\* before sale, and the oyster internal temperature\* before sale, and make these records available to inspection by DNREC.
  - E. **BILL OF SALE:** Upon sale of oysters, the harvester\* shall provide the consumer with a bill of sale listing the harvester name, the harvest date, the harvest location\*, the shellfish type (“Oysters”), the shellfish quantity, the date of sale, the name of the consumer, and the statement “Perishable – Keep Iced or Refrigerated at 50°F or below”.
3. **ON-WATER RETAIL – ON-LEASE: LEASE TOUR\*:**
  - A. **GENERAL:** This type of sale shall be conducted in the capacity of a harvester\*, except for oysters provided to tour participants who accessed the lease on the grower’s boat, in which case the sale shall be conducted in the capacity of a certified shellfish dealer\* after landing\*.
  - B. **HARVESTER TAG\*:** If oysters are harvested\* as part of a lease tour\*, the harvester\* shall complete the harvester tag\* at the time of initial harvest\*, according to the requirements of this Plan.
  - C. **SHADING:** Oysters shall be adequately shaded\* immediately after harvest, in accordance with the specifications of this Plan and subject to its exemption for oysters adequately iced\* within 1 hour of removal from the water\*.
  - D. **ICING:** Oysters consumed while on the lease by tour participants are not required to be iced within 5 hours after the legal sunrise time\*. Starting at 5 hours after the legal sunrise time\*, oysters consumed while on the lease by tour participants are not required to be iced provided that such oysters are consumed within 1 hour of harvest; any oysters not consumed within 1 hour of harvesting\* shall be adequately iced\*, as required for all oysters.
  - E. **LANDING\* TIME:** Oysters shall not be consumed by tour participants while on the lease after 5 hours of the time of initial harvest\*. Oysters shall be landed\* within 5 hours of the time of initial harvest\*.
  - F. **RECORDKEEPING:** Oysters consumed by tour participants are exempted from requirements that they must be received by a certified shellfish dealer\*; however, harvesters\* must document the date, harvester name, harvest location\*, and quantity consumed and make these records available to

inspection by DNREC. Starting at 5 hours after the legal sunrise time\*, and if oysters are not consumed by tour participants within 1 hour of harvest, the harvester\* shall record, on a Vibrio Harvester Record\* provided by DNREC and in indelible ink at the times when these activities occur, the date; harvester name; harvest location\*; the times of initial harvest\*, initial icing\*, final harvest\*, final icing\*, landing\*; the quantity harvested; and the receiver of the oysters and the time they received the oysters.

G. **OYSTERS TAKEN HOME:** If oysters are provided to tour participants but not consumed by tour participants on the lease, the applicable requirements depend on whether the tour participants have accessed the lease on the grower's boat or on their own boats.

- i. If the tour participants accessed the lease on the grower's boat, any oysters provided to tour participants but not consumed on the lease are subject to all regular requirements of this plan. Before receipt by the tour participant, such oysters shall be landed\* by the harvester\*, received by the original dealer\*, adequately iced\*, and documented by the original dealer\* as received within 5 hours of the time of initial harvest\* and temperature controlled\* to an internal temperature\* of 50°F or below within 8 hours of the time of initial harvest\*.)
- ii. If the tour participants accessed the lease on their own boats, any oysters provided to tour participants but not consumed by tour participants on the lease shall be subject to the requirements in Section III. 10. A. On-Water Retail – On Lease.

4. **ON-WATER RETAIL – OFF LEASE/AFTER LANDING\*:**

A. **GENERAL:** Retail\* sales of oysters to consumers while on the water but off the lease or after landing\* (such as sales to boaters at sand bars) are subject to all requirements herein. Before these retail sales can occur, such oysters shall be landed\*, received by the original dealer\*, adequately iced\*, and documented by the original dealer\* as received within 5 hours of the time of initial harvest\* and temperature controlled\* to an internal temperature\* of 50°F or below within 8 hours of the time of initial harvest\* before being brought back out on the water for retail sale. This type of sale shall be conducted in the capacity of a certified shellfish dealer acting as a retailer\*.

B. **ICING:** In all cases, oysters shall be completely surrounded by ice from the time they are brought back out on the water until the time of retail\* sale.

- i. In cases where the harvester\* is certified as a shellfish dealer\*, is receiving in the capacity as a dealer the oysters he/she has harvested\*, and is not transporting the oysters to mechanical refrigeration\* at their physical facility which is permitted as a certified shellfish dealer operation, receipt by the dealer\* shall be considered to take place at the time of landing\*. In accordance with requirements for all oysters, within 30 minutes of the time of landing\*/receipt by dealer\*, the oysters shall be completely surrounded by ice before being brought back out on the water for retail sale. That is, from 30 minutes after landing\* and until retail sale, all oysters shall be completely surrounded by ice.

- ii. Along with the oysters in their container, the grower\* shall provide the customer with an amount of ice sufficient to prevent the temperature of the oysters from immediately beginning to increase.

C. **DEALER POSSESSION:** Oysters shall be in the possession of the original dealer\* when retailed\* on the water off the lease or when brought after landing\* back out on the water for retail sale. On-water retail off-lease\* shall be conducted in the capacity of the original dealer\* acting as a retailer (not in the capacity of a harvester\*). Dealers other than the original dealer shall not sell or possess oysters on the water.

D. **DEALER TAGS\*:** Before being brought back on the water for retail\* sale, each container, or if a single bulk dealer tag\* is used each lot\*, of oysters available for on-water retail off-lease/after landing\* shall be accompanied with a dealer tag\* which shall accompany the lot\* until sale and after sale shall remain in the possession of the dealer\*.

E. **RECORDKEEPING:** At the time of the on-water retail, the dealer\* shall record these sales on their Dealer Sales Log\*, as is done for normal off-water sales, and note on the Dealer Sales Log\* that the sales occurred on the water but off the lease.

F. **BILL OF SALE:** Upon purchase by a consumer of oysters sold in this way, the dealer\* shall provide the consumer with a bill of sale listing the name of the certified shellfish dealer\*, the harvest date, the harvest location\*, the shellfish type (“Oysters”), the shellfish quantity, the date of sale, the name of the consumer, and the statement “Perishable – Keep Iced or Refrigerated at 50°F or below”.