A. Introduction

New Jersey’s Vibrio Control Plan (VCP) addresses program coordination; response to potential outbreaks; shellfish 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 VCP 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 et al., 2018), and *Vp* has become a significant problem for both regulators and the shellfish industry. Despite the implementation of *Vp* Control Plans by states and industries, as well as 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* 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 at 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, as per Section IV, Chapter IV of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (NSSP Guide): 2019 Revision, available at [www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm](http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm).

*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.

*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, such as New Jersey. The mortality rate from *Vv* ingestion 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.

The Interstate Shellfish Sanitation Conference (ISSC) has developed procedures to address *Vp* and *Vv*, which are part of the NSSP Guide.

B. Overview - 2022 Vibrio Season

New Jersey shellfish were implicated in nine (9) potential shellfish related *Vp* illness cases in 2022, seven (7) of which were confirmed by culture testing. Seven of the nine were single source cases (*i.e.*, only from New Jersey), and two were multiple source cases. A multiple source case occurs when the consumer eats a mixed plate of oysters sourced from more than
one state that includes an oyster which may have been harvested from New Jersey waters. In these multiple source cases, it is hard to accurately determine which oyster is responsible for the illness unless directly linked to an outbreak. Five of the seven New Jersey single source cases involved oysters harvested by dredge from the New Jersey portion of the Delaware Bay. Three (3) cases were from the same harvest bed, Ship John, within a 30-day span from late July into August. Based on harvest numbers, the calculated risk per serving was lower than the one illness in 100,000 servings risk level required by the NSSP. According to the requirements in the NSSP Guide: 2019 Revision, Section II, Chapter II, @.02 A. (1): “When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.” In response to these sporadic \( Vp \) cases, the New Jersey Department of Environmental Protection (NJDEP) and the New Jersey Department of Health (NJDOH) ensured that all harvesters and dealers were following the VCP. Two cases involved oysters from Scull Bay and Ludlam Bay on the Atlantic Coast.

New Jersey was implicated in one single source case of \( Vv \) in July 2022, also harvested from the Ship John in the Delaware Bay. The risk assessment showed less than one (1) case per 100,000 servings based on the water temperature range of 75°F to 80°F, requiring no action. An evaluation was made by the NJDEP and NJDOH, and all harvesters and dealers were following all requirements in the VCP.

As part of the annual Vibrio sampling regime, the NJDEP collected oyster tissue samples from June to August 2022 (Vibrio season). These 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 Next Generation Sequencing. A summary of the data suggests that Vibrio levels in oyster tissue may be higher following a rapid rise in water temperature than during months with the warmest water and air temperatures. In New Jersey, a quick rise in water temperature is commonly observed in June. In 2022, the highest levels of the virulent trh and tdh genes occurred during the month of June, consistent with the observation of rapidly rising water temperatures.

C. Coordination of New Jersey Agencies Responsible for Shellfish Sanitation

The requirements set forth in the NSSP Guide are accomplished through a coordinated effort by four agencies in New Jersey. These agencies, their physical locations, their role in shellfish sanitation, and their relationship to one another are described below. Implementation of the VCP requires cooperation and communication among these agencies.

New Jersey Department of Environmental Protection (NJDEP)
The following agencies have primary responsibility for decision making and implementation of the following aspects of the VCP:

**NJDEP Bureau of Marine Water Monitoring.**
- Develop and coordinate the VCP.
- Monitor and analyze water and air temperature data and conduct a risk assessment as the basis for developing a VCP to control naturally occurring pathogens.
- Develop control strategies to minimize potential *Vibrio* illnesses.
- Close affected growing areas if outbreaks are epidemiologically associated.

**NJDEP 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.

**NJDOH – 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 certified dealers’ operations and ensure required cooling times and temperatures are met and all HACCP plans are updated and implemented.
- Epidemiologically confirm, document, and conduct trace back for each *Vibrio* species illness case 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.
- Notify the NJDEP and the U.S. Food and Drug Administration (FDA) of 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.

**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 NJDEP and the NJDOH will respond in accordance with the requirements at N.J.A.C. 7:12, N.J.A.C. 8:13, the latest edition of the NSSP Guide, and the VCP.

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

In 2023, 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. Polymerase Chain Reaction and Next Generation Sequencing will be performed to evaluate the different genetic strains present in the Delaware Bay. Periodic oyster samples will also be collected from the Barnegat Bay. This data will provide information on whether specific
Vp and Vv genetic strains, identified in isolation from illness investigations, are also found in oysters harvested from implicated harvest areas.

F. Harvest, Transport, and Temperature Control Measures

N.J.A.C. 7:12-8 establishes the harvest, handling and transport requirements for shellfish license holders. Any person who violates any requirement of N.J.A.C. 7:12-8 may be subject to prosecution and/or penalties pursuant to N.J.S.A. 23:2B-14, 50:1-5 et seq., 58:24-9, 58:24-10, 58:24-10.1, and 2C:64-1 et seq., including the forfeiture of shellfish, which may be seized and returned to the water or destroyed.

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:

<table>
<thead>
<tr>
<th>Dates of harvest</th>
<th>Maximum hours to refrigeration¹</th>
<th>Start of harvest²</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 1 - June 14</td>
<td>7</td>
<td>Sunrise</td>
</tr>
<tr>
<td>June 15 - July 14</td>
<td>6</td>
<td>Sunrise</td>
</tr>
<tr>
<td>July 15 - August 31</td>
<td>7</td>
<td>Sunrise</td>
</tr>
</tbody>
</table>

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 NJDEP’s Division of Fish and Wildlife and online at [https://www.nj.gov/dep/fgw](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 NJDOH approved refrigeration unit;
ii. Notify the NJDEP'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 NJDOH; 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 NJDEP'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 the NJDOH.

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 NJDOH 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 2023 VCP:

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°F, is the most effective way to maintain low Vibrio levels 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.

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

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 NJDOH.

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 of holding a day’s harvest while holding other products;
d) Compressor is sized adequately and can cool product down to 50°F or less (40°F is optimum) in 8 hours in June, and 6 hours in July and August;
e) Time to temperature requirements are met. The NJDOH wholesale temperature requirement is 45°F in 10 hours (overnight) to ship from a certified dealer. Due to the 2018 Vv cases, oysters shipped from a certified dealer will be required to be cooled down to 50°F or less (40°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 NJDOH;
f) NJDOH verification of adequate refrigeration and cooling prior to certification for the 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 NJDOH has resource information to assist the purchase and installation of a recording thermometer on the forced air unit. The cost is inexpensive to install this device.
a) The NJDOH will not certify the Certified Dealer operation unless a continuous recording thermometer is installed on the forced air unit. This will allow the NJDOH to inspect the forced air unit and ensure that it 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 holding 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 NJDOH.
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.
L. References