



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, 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 *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 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 northeast states such as New Jersey. The mortality rate from *Vv* ingestion is approximately 50 percent in healthy people, 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 - 2021 *Vibrio* Season

New Jersey shellfish were implicated in six potential shellfish related *Vp* illness cases in 2021; all six cases were confirmed by culture testing. Two of the six cases were New Jersey-only source cases (single source) and the four remaining cases were multiple source cases. A multiple source case occurs when the consumer eats a mixed plate of oysters from a variety of States that includes an oyster which may have been harvested from NJ 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 six cases involved oysters harvested by dredge from the New Jersey portion of the Delaware Bay. One case involved an oyster from aquaculture in Barnegat Light / Little Egg Harbor. The two single source cases were from the same harvest bed, Shell Rock, during the month of June on different days, one in early June, one in late June. Shell Rock is the most widely harvested bed, and the calculated risk per serving was lower than 1/100,000 servings recommended by NSSP Guide. Based on the NSSP Guide requirements: "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 (DEP) and the New Jersey Department of Health (DOH) ensured that all harvesters and dealers were following the *Vibrio* Control Plan.

New Jersey was implicated in one single source case of *Vibrio vulnificus* in July 2021, also harvested from the Shell Rock in the Delaware Bay. The risk assessment showed <1 case per 100,000 servings based on the water temperature range of 75- 80° F, requiring no action. An evaluation was made by DEP and DOH, and all harvesters and dealers were following all requirements in the *Vibrio* Control Plan.

As part of the annual *Vibrio* sampling regime, the DEP collected oyster tissue samples between the months of June and August 2021. 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 Pulsed-Field Gel Electrophoresis (PFGE). A summary of 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. In 2021, the 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 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 VCP requires cooperation and communication among these agencies.

NJ Department of Environmental Protection (DEP)

Bureau of Marine Water Monitoring (BMWM)
Division of Water Monitoring Standards and Pesticide Control
P.O. Box 405
929 Stoney Hill Road
Leeds Point, NJ 08220
609-748-2000

<https://www.nj.gov/dep/bmw>

(Water monitoring, tissue monitoring, growing water classification, shellfish classification charts, and permits issued under N.J.A.C. 7:12)

Bureau of Shellfisheries
Division of Fish and Wildlife
P.O. Box 418
360 North Route 9
Port Republic, NJ 08241
609-748-2020

<https://www.nj.gov/dep/fgw/shelhome.htm>

(Licensing, shellfish leases, and resource management)

NJ Division of Fish and Wildlife
Bureau of Law Enforcement
2434 Route 563
Egg Harbor City, NJ 08215
Phone: 609.748.2050

<https://www.njfishandwildlife.com/lawhome.htm>

(Patrol, enforcement, and inspections)

NJ 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

<https://www.state.nj.us/health/ceohs/food-drug-safety/industry-service-programs/#3>

(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 VCP:

DEP Bureau of Marine Water Monitoring (BMWM)

- 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.

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 updated 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 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 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 VCP.

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

In 2022, 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 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* and *Vv* 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.

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.

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 BMW 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 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 2022 VCP.

*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 from 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) 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 the 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.