



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 time to temperature control 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>), 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 the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2019 Revision Section IV. Guidance Documents - Chapter IV. Naturally Occurring Pathogens, .01 *Vibrio parahaemolyticus* (V.p.) Control Plan Guidance, 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. Each year, there are cases of Vv that are not related to the consumption of molluscan shellfish but rather are due to this bacterium entering the bloodstream through a cut or wound. Individuals with certain medical conditions are more susceptible to the impacts of this pathogen than others.

Procedures for limiting exposure to *Vp* and *Vv* have been developed over the past several years through the Interstate Shellfish Sanitation Conference (ISSC, www.issc.org/) and are part of the National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish (NSSP Guide). The NJDEP and NJDOH have performed risk assessments and utilized NSSP guidelines as well as NJ specific *Vibrio* studies to develop and update the annual VCP.

B. Overview - 2023 *Vibrio* Season

New Jersey shellfish were implicated in twelve potential shellfish related *Vibrio species* illness cases in 2023, five of which were confirmed by culture testing to be *Vp*, two of which were culture confirmed to be *Vv*, and five of which were not culture confirmed and reported only as *Vibrio* species by CIDT+. Four of the five culture confirmed *Vp* cases were traditional single source cases (*i.e.*, only from New Jersey), and one was a single/multiple source hybrid case where all of the oysters implicated were from New Jersey (which would typically make it a single source case) but they were harvested from more than one location in New Jersey and even further they were harvested from two different coasts within New Jersey, one from Delaware Bay and one from Little Egg Harbor Bay on the Atlantic Coast.

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. Three of the four New Jersey single source cases involved oysters harvested by dredge from the New Jersey portion of Delaware Bay (two cases involving the Cape Shore three months apart in July and October and one case from the Cohansey Bed). The final single source case was harvested from Barnegat Light on the Atlantic Coast, but the case investigation revealed mishandling at the restaurant where the oysters were served. In response to these sporadic and generally disparate *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.

New Jersey was implicated in two *Vv* cases, one single source case of *Vv* in June 2023 and one multiple source case of *Vv* in July 2023. The single source *Vv* case was harvested from Shell Rock in 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 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 2023 (*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 2023, the highest levels of the virulent *trh* and *tdh* genes occurred during the later part of June and early July, 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 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.

New Jersey Department of Environmental Protection (NJDEP)

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

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://dep.nj.gov/njfw/about/bureau-of-marine-habitat-and-shellfisheries/>

(Licensing, shellfish leases, and resource management)

NJ Division of Fish and Wildlife
Bureau of Law Enforcement
2434 Route 563
Egg Harbor City, NJ 08215
609-748-2050

<https://dep.nj.gov/njfw/conservation/bureau-of-law-enforcement/>

(Patrol, enforcement, and inspections)

New Jersey Department of Health (NJDOH)

Public Health and Food Protection Program, Division of Consumer Environmental and Occupational Health
P.O. Box 369

Trenton, NJ 08625-0369
609-826-4935

<https://www.nj.gov/health/ceohs/phfpp/> (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:

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 shall comply 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 2024, BMWB 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 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

Subchapter 8 of N.J.A.C. 7:12 deals with 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:

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 NJDEP’s Division of Fish and Wildlife and on-line at <https://dep.nj.gov/njfw/digests/>.

- 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 into 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 BMWWM 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 2024 VCP.

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

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.
7. Do not place tarps onto flatbed truck directly onto the containers of shellstock without adequate air space to allow for the free flow of air.

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 a 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 on the day of harvest. 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.