

MEMORANDUM

DATE: Revised May 9, 2016
TO: Division of Shellfish Sanitation Staff
FROM: B. Keith Skiles, Director
Division of Shellfish Sanitation
SUBJECT: Virginia's *Vibrio* Control Plan



Purpose:

The purpose of this protocol is to establish the Department of Health's policy for the control of naturally occurring *Vibrios* in shellfish.

Description:

The 2016 Virginia *Vibrio* Control Plan (VCP), developed pursuant to the requirements of the 2013 National Shellfish Sanitation Program Model Ordinance, as amended is attached. Except for those requirements adopted by the Marine Resources Commission as regulations, this policy memo establishes the requirements of the VCP as standards pursuant to §28.2-806 of the *Code of Virginia*.

Virginia Department of Health
Division of Shellfish Sanitation
Vibrio Control Plan

2016

Forward

The National Shellfish Sanitation Program (NSSP) requires every shellfish producing state to conduct *Vibrio parahaemolyticus* and *Vibrio vulnificus* risk evaluations annually. This report is intended to present data collected and evaluated by the Division of Shellfish Sanitation, in cooperation with the Interstate Shellfish Sanitation Conference (ISSC), to identify and control *Vibrio parahaemolyticus* and *Vibrio vulnificus* risks associated with the consumption of oysters or clams.

Available Data

Total number of *Vibrio parahaemolyticus* and *Vibrio vulnificus* illnesses. VDH has received reports of 19 *Vibrio parahaemolyticus* illness (2013 8 cases, 2014 6 cases, 2015, 5 cases) from the consumption of shellfish harvested solely in Virginia in the past three years. Investigations identified post-harvest handling and shipping violations in four of the 2013 cases. No post-harvest handling or shipping violations were found concerning the six cases from 2014. Post-harvest handling and shipping violations were found while investigating one of the 2015 cases. In addition, Virginia growing areas have been identified as the source of six cases of *Vibrio vulnificus* illness in the past ten years (2006, 1 case; 2011, 1 case; 2012, 2 cases, 2013, 1 case, 2015, 1 case). Data on other cases has been inconclusive either because shellfish from multiple sources were also consumed by the patient, or because the restaurant serving the shellfish handled product from two or more areas and could not identify which was served to the patient.

Outbreaks. One confirmed outbreak of *Vibrio parahaemolyticus* illness from shellfish harvested from Virginia waters has occurred in the past five years. The incident involved 2 confirmed and one suspected cases associated with oysters consumed in Massachusetts (1 confirmed, 1 suspected) and Maryland (1 confirmed).

Water Temperatures. VDH obtained water temperature data from NOAA sites distributed throughout Virginia coastal waters. The data was queried to provide the average of daily maximum (AMM) temperatures by month for all sites, and separately for the average of maximum temperatures during established harvest curfew times (Table 1).

Table 1. Water temperatures from NOAA buoys for the years 2011 through 2015.

	Daily AMM	Curfew (5-10am)	Curfew (5-11am)	Curfew (6am-12pm)
January	42.4			
February	42.0			
March	48.0			
April	58.7			
May	70.0		67.9	
June	78.5	76.4		
July	83.0	81.1		
August	81.4	79.9		
September	77.5			76.3
October	67.6			
November	55.6			
December	50.1			

Air Temperatures. VDH acquired temperature data from the NOAA National Weather Service. Norfolk International Airport site was chosen as a reference site since it is centrally located in the Eastern Virginia region. The average monthly maximum (AMM) daily values as well as maximum curfew time values are presented in Table 2.

Table 2. Air temperatures from NOAA-NWS at Norfolk International Airport for the years 2011 through 2015.

	Daily AMM	Curfew (5-10am)	Curfew (5-11am)	Curfew (6am-12pm)
January	49			
February	50			
March	58			
April	69			
May	77		74	
June	85	80		
July	88	83		
August	84	81		
September	80			79
October	70			
November	60			
December	58			

Salinities. Salinities range from near zero to near 35 PPT.

Harvest Techniques

Oysters are grown on natural reefs, and are cultivated in floats, cages, and loose on bottom. Clam harvest is primarily on-bottom aquaculture and to a lesser degree wild harvest.

Travel times to harvest sites generally do not exceed one hour. Although seasonal restrictions apply to harvest from public grounds, shellfish may be harvested from private leases at all times of the year. Warm Water Harvest Regulations (WWHR), attached as Appendix A, limit times from harvest to refrigeration during the months of May through September for oysters, and require that all harvest vessels provide shading over shellfish storage areas. Oyster harvesters without a means of cooling oysters on the vessel must either:

- A. land and refrigerate their catch by 11:00am from May 1 through May 31, 10:00am from June 1 through August 31, and by 12:00pm from September 1 through September 30; or
- B. limit harvest and transportation to refrigeration times to five hours for the months of May and September, three hours for June, and two hours for July and August; or
- C. Label oysters with a green restricted use tag indicating that the oysters are for shucking by a certified dealer or post-harvest processing only.

Any oyster harvest after curfew times requires either a special permit for the use of ice or mechanical refrigeration; requires that the harvester carry a GPS tracking device to confirm that harvest and transportation times did not exceed time limits; or requires that the dealer use state-issued green restricted use tags. White shellstock harvester tags are required to document compliance with the time to temperature controls by placing the start time of harvest and when oysters are offloaded and placed into refrigeration.

Post-harvest Handling requirements. All land-based deliveries of shellfish greater than one hour must be in mechanically refrigerated conveyances or iced beginning May 1 through September 30 each year. In addition, all certified shellfish dealers handling oysters must cool oysters to 55° F or below within 5 hours of being placed into refrigeration from May 1 to October 31 (i.e. onboard a vessel, in a truck or at a facility).

Quantity of Harvest and Uses. Quantities of harvest vary greatly through the region. Oysters harvested are used for both shucking and box (halfshell) trade, and most clam harvest is sold as shellstock. No product is currently marketed as post harvest processed for reduction of Vibrios.

Risk Evaluation

Oyster harvest in Virginia has increased from an annual harvest of 23,523 bushels in 2004 to 660,624 bushels for the 2014-2015 season. Relative to production, there continues to be a low incidence of *Vibrio parahaemolyticus* illness from consumption of oysters. However, the incidence continues to be an annual occurrence and supports the continuation of established harvest controls.

Clam harvest has averaged 138 million clams per year since 2010. During this period, three cases of *Vibrio parahaemolyticus* illness from consumption of clams harvested solely in Virginia have been reported for an estimated risk per serving of 1 case in 30,650,714 servings, and is not an annual occurrence. Additional harvest controls are not indicated at this time.

Evaluation based solely on the water temperatures and air temperatures suggests that *Vibrio* risks are possible for a portion of the year. Illness reporting information, while limited, also supports the implementation of *Vibrio* controls for oyster harvest. These data were evaluated using the FDA *Vibrio parahaemolyticus* Risk Calculation Worksheet (see Appendix B), which incorporated established harvest time limitations in order to minimize risk. Using this method, a reasonable likelihood of *Vibrio parahaemolyticus* risk was not identified based on air and water temperatures. In addition, the FDA *Vibrio vulnificus* Risk Calculator was utilized to determine appropriate harvest control times for both all day harvest and for harvest limited to morning curfew hours. These are attached as Appendix C, and were used to establish the harvest controls adopted in the Warm Water Harvest Regulations.

Summary

Shellfish are grown and harvested in Virginia waters year round, and are often shipped to markets intended for raw consumption. Virginia meets the NSSP triggers for implementation of *Vibrio parahaemolyticus* and *Vibrio vulnificus* control plans for oysters. Environmental conditions exist during a portion of the year that would support *Vibrio parahaemolyticus* and *Vibrio vulnificus* growth to the extent that it presents a reasonable likelihood of risk in oysters and supports the mandatory implementation of the WWHR harvest controls to minimize these risks during the warm weather season. Illness data for cases of *Vibrio* illness from clam consumption do not constitute an annual occurrence, and no additional WWHR controls are indicated.

The adoption and implementation of the WWHR and post-harvest handling controls limits times from harvest to refrigeration for the months May through September. These regulations provide harvest restrictions that are in place each year throughout the period of the year when conditions promoting *Vibrio parahaemolyticus* and *Vibrio vulnificus* risks occur. Data available at this time indicate that no additional controls are required.

Appendix A

Warm Water Harvest Regulations (<http://mrc.virginia.gov/regulations/FR1230.shtm>) 4VAC20-1230-10 et.seq, effective October 1, 2014

PREAMBLE

This chapter establishes, for the public health, harvest restrictions for shellfish taken from Virginia waters. This chapter is promulgated pursuant to the authority contained in §§ 28.2-201 and 28.2-801 of the Code of Virginia. This chapter amends and re-adopts, as amended, previous Chapter 4 VAC 20-1230-10 et seq., which was adopted April 22, 2014 and made effective May 1, 2014. The effective date of this chapter is October 1, 2014.

4 VAC 20-1230-10. Purpose.

The purpose of this chapter is to establish harvest times and handling procedures for shellfish, excluding seed oysters and seed clams, harvested for commercial purposes or any other use.

4 VAC 20-1230-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

“Clam” means any shellfish of the species *Mercenaria mercenaria* and genera Noetia and Anadara.

"Container" means any bag, box, sack, tote, or other receptacle that contains shellfish to be held, in any type of conveyance, for transport from the harvest area to the landing site and from the landing site to the point of sale or other use.

“Conveyance” means any form of transport, such as a boat, truck or other vehicle, or trailer that is used to transport shellfish from the harvest area to the landing site or from the landing site to a licensed buyer or other use.

“Direct marketing” means any shellfish or shellstock that is landed and sold without shucking or postharvest processing.

"Harvest" means the act of removing any shellfish or shellstock from a designated harvest area and placing that shellfish or shellstock in a container or on or in a conveyance.

“Harvest Time” means the time from initial harvest to when temperature control of that harvest is required. Harvest time begins once the first harvested shellstock is no longer submerged and extends to the time that any harvested shellstock is placed in Virginia Department of Health, Division of Shellfish Sanitation-approved temperature controlled storage.

“Layer” means a single thickness or coating spread out and covering an entire surface.

“Mechanical refrigeration” means storage in a container that is approved by the Virginia Department of Health, Division of Shellfish Sanitation and capable of cooling to and maintaining an ambient temperature of 45° F or less.

“Oyster” means any shellfish of the species *Crassostrea virginica*.

“Restricted-use shellstock” means shellstock or shellfish harvested from approved shellfish growing areas that shall not be sold for raw consumption or directly marketed for raw consumption.

“Restricted-use shellstock tag” means a Virginia Marine Resources Commission-issued green tag that shall only be used by a licensed buyer who has a current certificate of inspection as a shucker packer for shellstock or shellfish harvested from a single harvest area in any one day. Use of any such tag indicates that shellstock is intended for further processing prior to distribution to retail or food service.

“Seed Clams” means any shellfish of the species *Mercenaria mercenaria* that is less than 30 mm in shell length and more than six months from harvest for human consumption.

“Seed Oyster” means any oyster taken, by any person, from natural beds, rocks, or shoals that is more than 30 days from harvest for human consumption.

“Shading” means to shelter by intercepting the direct rays of the sun to protect the shellfish from heat using a tarp or cover.

“Shellfish” or “shellstock” means all species of bivalve molluscan shellfish.

“Shucker packer” means a person who shucks and packs shellfish under a certificate of inspection issued by the Virginia Department of Health, Division of Shellfish Sanitation.

“VDH-approved temperature controlled storage” means a container or conveyance that is equipped with mechanical refrigeration capable of maintaining 45°F or less or is continuously and completely covering shellfish with a layer of ice, according to procedures approved by the Virginia Department of Health, Division of Shellfish Sanitation.

4 VAC 20-1230-30. Public health and warm water harvest restrictions for shellfish.

A. Beginning December 1, 2014, it shall be unlawful for any Commission employee or representative to issue any shellfish license, shellfish permit, or oyster resource user fee to any person, unless that person has successfully completed the Shellfish Harvest Safety Training Certification Course. Beginning January 1, 2015, it shall be unlawful for any person to harvest or attempt to harvest shellfish unless that person has successfully completed the Shellfish Harvest Safety Training Certification Course. The Shellfish Harvest Safety Training Certification shall be valid from the date of issuance through the next two calendar years.

B. No provisions in this chapter shall apply to seed clams or seed oysters.

C. It shall be unlawful for any person to have any cat, dog, or other animal on board a vessel during the harvest of shellfish.

D. From May 1 through September 30, any vessel used for the harvest of shellfish, from either public or private grounds, shall provide shading over the area that serves as storage for the shellfish when the shellfish are on board that vessel. All shellfish in the vessel shall be offloaded every day. Shading shall not be required for vessels transporting clam seed or seed oysters for replanting.

E. From May 1 through September 30, all shellfish shall be shaded during land-based deliveries.

F. From June 1 through August 31, it shall be unlawful for any person to leave the dock or shore, prior to one hour before sunrise, to harvest or attempt to harvest shellfish from private grounds.

4 VAC 20-1230-31. Public health and warm water harvest restrictions for oysters.

A. From May 1 through September 30, all land-based deliveries of oysters shall be made aboard trucks or other conveyances equipped with VDH-approved temperature controlled storage. Mechanically refrigerated containers for oysters shall be in operation during transport. Any operator of a truck who is delivering oysters, using a truck not owned by a licensed shellfish buyer, shall possess a truck refrigeration certificate issued by the Virginia Department of Health, Division of Shellfish Sanitation. Upon receiving any oysters, licensed shellfish buyers shall immediately place any oysters received from any individual under temperature control.

B. From May 1 to September 30, it shall be unlawful for any individual to harvest oysters from open areas of public or private ground after any monthly curfew harvest time described in (i) subdivisions 1 through 5 of this subsection or (ii) subsections C and D of this section. All oysters shall be placed into trucks or other conveyances equipped with VDH-approved temperature controlled storage, no later than the following designated curfew harvest times, by month:

1. May 1 through May 31, by 11:00 a.m.;
2. June 1 through June 30, by 10:00 a.m.;
3. July 1 through July 31, by 10:00 a.m.;
4. August 1 through August 31, by 10:00 a.m.; and
5. September 1 through September 30, by 12:00 noon.

C. It shall be unlawful for any individual to harvest oysters from open areas of public or private ground, except as described in (i) subsection B or D of this section or (ii) subdivisions 1 through 3 of this subsection.

1. The individual has applied for and been granted a permit by the Virginia Marine Resources Commission to harvest oysters after the designated monthly curfew harvest times, as provided in subsection B of this section.

2. A Virginia Marine Resources Commission-approved global positioning system tracking device shall be on board the harvest vessel or with the individual and must be in continuous operation from the time that vessel or individual leaves the dock or shore until the vessel or individual returns to the dock or shore, and the oysters harvested are offloaded from that vessel or onto the dock or shore and placed into trucks or other conveyances equipped with VDH-approved temperature controlled storage.

3. The total time, from the time the vessel or individual leaves the dock or shore until the oysters are placed into trucks or other conveyances equipped with VDH-approved temperature controlled storage, shall not exceed the following amount of time, by month:

- a. 5 hours during the months of May and September;
- b. 3 hours during the month of June; and
- c. 2 hours during the months of July and August.

D. It shall be unlawful for any individual to harvest oysters from open areas of public or private ground, except as described in (i) subsection B or C of this section or (ii) subdivisions 1 through 3 of this subsection.

1. The individual has applied for and has been issued a Virginia Department of Health, Division of Shellfish Sanitation vessel approval certificate for mechanical refrigeration or icing in a storage container that is on board the vessel at all times during the harvest of oysters;

2. The individual has applied for and has been issued a Marine Resources Commission Shellfish Harvester Icing Permit; and

3. Oysters are placed in VDH-approved temperature controlled storage on board the vessel from the start of harvest and throughout the harvest period until the oysters are offloaded.

E. From May 1 through September 30, it shall be unlawful for any individual to harvest oysters from open areas of public or private ground, as restricted-use shellstock, except as described in subdivisions 1 through 3 of this subsection.

1. The individual has been issued green restricted-use shellstock tags by a Virginia Department of Health, Division of Shellfish Sanitation-certified shucker packer and has tagged all oysters with restricted-use shellstock tags;

2. The individual does not possess on board the vessel any oysters designated for direct marketing or raw consumption; and

3. All oysters are harvested no later than 12:00 noon and are placed into trucks or other conveyances equipped with VDH-approved temperature controlled storage, no later than noon that same day.

F. From May 1 through September 30, it shall be unlawful for any individual to harvest any amount of natural (wild) seed oysters that include oysters greater than 2-1/2 inches, without first obtaining a valid Bulk Seed Permit from the Virginia Marine Resources Commission. Any individual who harvests any natural (wild) seed oysters that include oysters greater than 2-1/2 inches and is not in possession of a valid Bulk Seed Permit issued by the Virginia Marine Resources Commission shall be in violation of this chapter.

G. It shall be unlawful for any individual to handle oysters, as part of a cage aquaculture operation for husbandry purposes, after the designated harvesting times described in subsection B of this section without first obtaining a valid Cage Oyster Aquaculture Husbandry Permit from the Virginia Marine Resources Commission. Any individual who handles oysters in cage oyster aquaculture operations after the designated harvesting times described in subsection B of this section and does not possess a valid Cage Oyster Aquaculture Husbandry Permit issued by the Virginia Marine Resources Commission shall be in violation of this chapter.

4 VAC 20-1230-32. Public health and warm water harvest restrictions for clams.

From May 1 through September 30, all land-based deliveries of clams requiring more than 60 minutes after offloading is complete shall be made aboard trucks or other conveyances equipped with VDH-approved temperature controlled storage. Mechanically refrigerated containers for clams shall be in operation during transport. Any operator of a truck who is delivering clams using a truck not owned by a licensed shellfish buyer shall possess a truck refrigeration certificate issued by the Virginia Department of Health, Division of Shellfish Sanitation. Upon receiving any clams, licensed shellfish buyers shall immediately place any clams received from the individual under temperature control.

4 VAC 20-1230-35. [Repealed]

4 VAC 20-1230-40. Penalty.

A. In addition to the penalty prescribed by law, any person violating any provision of this chapter shall destroy, in the presence of a marine police officer, all shellfish in his possession, or, at the direction of the marine police officer, shall place the shellfish overboard on the nearest oyster sanctuary or closed shellfish area and shall cease harvesting on that day. All harvesting apparatus may be subject to seizure, and, pursuant to § 28.2-232 of the Code of Virginia, all licenses and permits may be subject to revocation following a hearing before the Marine Resources Commission.

B. As set forth in § 28.2-903 of the Code of Virginia, any person violating any provision of this chapter shall be guilty of a Class 3 misdemeanor, and a second or subsequent violation of any provision of this chapter committed by the same person within 12 months of a prior violation is a Class 1 misdemeanor.

Appendix B

FDA VPCP Risk Calculation Worksheets

Worksheet for monthly average of 24 hour maximum temperatures:

Atlantic (subtidal harvest)							
month	water temperature (F)	air temperature (F)	maximum time unrefrigerated (hr)	expected cases per 100,000 (servings)	lower confidence limit on expected cases per 100,000	VPCP needed?	maximum time (hr) for lower confidence of 1 per 100,000
Jan	42.4	49	10.33	0.0026	0.00021	N	
Feb	42.0	50	11.37	0.0026	0.00021	N	
Mar	48.0	58	12.58	0.012	0.00095	N	
Apr	58.7	69	13.68	0.36	0.029	N	
May	70.0	77	4.50	0.94	0.075	N	
Jun	78.5	85	2.50	4.2	0.33	N	
July	83.0	88	1.50	7.1	0.56	N	
Aug	81.4	84	1.50	3.7	0.29	N	
Sep	77.5	80	4.50	3.6	0.29	N	
Oct	67.6	70	11.78	0.99	0.079	N	
Nov	55.6	60	10.62	0.038	0.003	N	
Dec	50.1	58	9.82	0.014	0.0011	N	

Worksheet for temperatures during harvest curfew times:

Atlantic (subtidal harvest) - curfew							
month	water temperature (F)	air temperature (F)	maximum time unrefrigerated (hr)	expected cases per 100,000 (servings)	lower confidence limit on expected cases per 100,000	VPCP needed?	maximum time (hr) for lower confidence of 1 per 100,000
Jan	42.4	49	10.33	0.0026	0.00021	N	
Feb	42.0	50	11.37	0.0026	0.00021	N	
Mar	48.0	58	12.58	0.012	0.00095	N	
Apr	58.7	69	13.68	0.36	0.029	N	
May	67.9	74	5.20	0.57	0.045	N	
Jun	76.4	80	4.25	2.9	0.23	N	
July	81.1	83	4.17	7.8	0.62	N	
Aug	79.9	81	3.82	4.5	0.36	N	
Sep	76.3	79	5.40	3.5	0.28	N	
Oct	67.6	70	11.78	0.99	0.079	N	
Nov	55.6	60	10.62	0.038	0.003	N	
Dec	50.1	58	9.82	0.014	0.0011	N	

Appendix C

FDA *Vibrio vulnificus* Risk Calculators

V. Vulnificus Risk Calculator										
Monthly average of 24 hour daily maximum										
month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	air (oyster) temperature during harvest (F)	maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	mean log ₁₀ Vv/g at retail	risk (per 100,000 servings)	from baseline
Jan	50	49	24	10	49	10.33	10	-1.1	0.00	1.75
Feb	50	50	24	10	50	11.37	10	-1.1	0.00	1.75
Mar	50	58	24	10	58	12.58	10	-1.1	0.00	1.75
Apr	58.7	69	14	10	69	13.68	10	1.3	0.12	1.75
May	70.0	77	12	10	77	4.50	5	2.6	1.04	1.75
Jun	78.5	85	12	10	85	2.50	5	3.4	2.57	2.50
July	83.0	88	10	10	88	1.50	5	3.6	2.92	3.00
Aug	81.4	84	10	10	84	1.50	5	3.4	2.62	3.00
Sep	77.5	80	12	10	80	4.50	5	3.4	2.51	2.50
Oct	67.6	70	12	10	70	11.78	5	2.4	0.85	1.75
Nov	55.6	60	14	10	60	10.62	10	0.12	0.01	1.75
Dec	50.1	58	24	10	58	9.82	10	-1.1	0.00	1.75

V. Vulnificus Risk Calculator - curfew temperatures										
month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	air (oyster) temperature during harvest (F)	maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	mean log ₁₀ Vv/g at retail	risk (per 100,000 servings)	from baseline
Jan	50	49	24	10	49	10.33	10	-1.1	0.00	1.75
Feb	50	50	24	10	50	11.37	10	-1.1	0.00	1.75
Mar	50	58	24	10	58	12.58	10	-1.1	0.00	1.75
Apr	58.7	69	14	10	69	13.68	10	1.3	0.12	1.75
May	67.9	74	12	10	74	5.20	5	2.3	0.67	1.75
Jun	76.4	80	12	10	80	4.25	5	3.3	2.29	2.50
July	81.1	83	10	10	83	4.17	5	3.6	3.09	3.00
Aug	79.9	81	10	10	81	3.82	5	3.5	2.76	2.50
Sep	76.3	79	12	10	79	5.40	5	3.3	2.40	2.50
Oct	67.6	70	12	10	70	11.78	5	2.4	0.85	1.75
Nov	55.6	60	14	10	60	10.62	10	0.12	0.01	1.75
Dec	50.1	58	24	10	58	9.82	10	-1.1	0.00	1.75