

MEMORANDUM

DATE: October 1, 2012

TO: Division of Shellfish Sanitation Staff

FROM: B. Keith Skiles, Classification Chief
Division of Shellfish Sanitation



THROUGH: Robert E. Croonenberghs, PhD, 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 2012 Virginia *Vibrio* Control Plan (VCP), developed pursuant to the requirements of the 2009 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 for Oysters

2012

Forward

The National Shellfish Sanitation Program (NSSP) requires every state from which oysters are harvested 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

Available Data

Total number of *Vibrio parahaemolyticus* illnesses. VDH has received very few reports of illness from the consumption of oysters in the past three years. Investigation of these reports has implicated five cases (2009, 0 cases; 2010, 1 case; 2011, 4 cases) of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested solely from Virginia waters during this time period. Data on other cases has been inconclusive either because shellfish from multiple sources was also consumed by the patient, or because the restaurant serving the oysters handled product from two or more areas and could not identify which was served to the patient.

VDH received notice in early 2012 of a case of *Vibrio vulnificus* illness that had occurred in Maryland from the consumption of oysters reported to have been harvested in Virginia waters. Investigation by the Maryland Department of Health and Mental Hygiene later concluded that Virginia was the source of oysters, making this the second Vv case solely attributed to oysters from Virginia within the past ten years. VDH received correspondence from the ISSC dated March 28, 2012 (attached) confirming that the Vv Illness Review Subcommittee had also concluded that Virginia met the Vv threshold for the development of a Vv control plan.

2. Outbreaks. There have been no confirmed outbreaks of *Vibrio parahaemolyticus* illness from oysters harvested from Virginia waters in the past five years.

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 temperatures by month for all sites, and separately for the average of maximum temperatures during a variety of potential harvest curfew times. These data are presented in Figure 1.

Figure 1

Month	Daily				<u>6am-12pm</u>
	<u>AMM</u>	<u>5-9am</u>	<u>5-10am</u>	<u>5-11am</u>	
January	42.66	41.5	41.58	41.64	
February	41.49	41.16	41.15	41.15	
March	50.86	49.14	49.25	49.37	
April	60.54	58.11	58.27	58.46	
May	69.67	67.25	67.44	67.62	
June	79.26	77.09	77.21	77.36	
July	82.06	80.09	80.21	80.36	
August	82.35	80.63	80.71	80.84	
September	77.24	75.92	75.97	76.05	76.14
October	68.05	66.98	67.02	67.09	
November	56.45	55.63	55.68	55.74	
December	47.87	46.76	46.83	46.91	

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

Figure 2

Month	Daily				<u>6am-12pm</u>
	<u>AMM</u>	<u>5-9am</u>	<u>5-10am</u>	<u>5-11am</u>	
January	48.3	38.8	39	39.3	
February	52.3	40	40.2	40.5	
March	60.1	47.6	48	48.1	
April	70	56.5	56.8	57	
May	76.9	63.27	63.34	63.72	
June	86.48	73.12	73.22	73.55	
July	88.14	75.08	75.15	75.37	
August	86.21	75.33	75.44	75.55	
September	80.29	70.52	70.6	70.74	71.45
October	71.93	60.68	60.8	60.98	
November	61.08	51.4	51.56	51.73	
December	53.07	44.35	44.54	44.72	

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. Travel times to harvest sites generally do not exceed one hour. Although seasonal restrictions apply to harvest from public grounds, oysters may be harvested from private leases at all times of the year. Warm Weather Harvest Regulations (WWHR), attached as appendix A, limit the times from harvest to refrigeration during the months of May through September, and require that all harvest vessels provide shading over shellfish storage areas. 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 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. No product is currently marketed as post harvest processed for reduction of vibrios.

Risk Evaluation.

There are few confirmed cases of *Vibrio parahaemolyticus* illness from consumption of oysters harvested from Virginia harvest areas. No *Vibrio parahaemolyticus* outbreak has ever been documented from oysters harvested from Virginia growing areas. In addition, very few isolated cases have been reported, with only five of which occurred within the last three years. Two cases of *Vibrio vulnificus* illness have been attributed to oysters harvested in Virginia within the last ten years.

Evaluation based solely on the salinities, water temperatures and air temperatures indicates that *Vibrio parahaemolyticus* and *Vibrio vulnificus* risks are likely for a portion of the year. Illness reporting information, while limited, also supports the implementation of Vibrio controls. Comparison of the highest average water temperature measurements to the risk assessment guidelines of the *Vibrio parahaemolyticus* Control Plan Template, the months

of June, July, and August exceed the triggers requiring *Vibrio parahaemolyticus* controls. These data were further evaluated using the FDA *Vibrio parahaemolyticus* Risk Evaluation Worksheet (see appendix B), which also incorporated established harvest time limitations. Using this method, a reasonable likelihood of *Vibrio parahaemolyticus* risk was identified for the months of July and August. 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 WWHR.

Summary

Oysters are grown and harvested in Virginia waters year round, and are often shipped to markets intended for raw consumption. Case data of reported illness alone would not trigger the implementation of controls for *Vibrio parahaemolyticus* for oysters harvested in Virginia waters, however, as a result of the recent *Vibrio vulnificus* case, Virginia does meet the NSSP trigger for implementation of a *Vibrio vulnificus* control plan. 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 and supports the mandatory implementation of the WWHR harvest controls to minimize these risks during the warm weather season.

The adoption and implementation of the Warm Water Harvest Regulations and post-harvest handling controls limits times from harvest to refrigeration for the months from 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 Weather Harvest Regulations 4VAC20-1230-10 et.seq, effective May 1, 2012

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 4VAC 20-1230-10 et seq., which was adopted April 26, 2011 and made effective May 1, 2011. The effective date of this chapter is May 31, 2012.

4VAC20-1230-10. Purpose.

The purpose of this chapter is to establish harvest times and handling procedures for shellfish, excluding seed oysters, harvested for commercial purposes or any other use. The time, from initial harvest to when temperature control of that harvest is required, begins once the first shellstock harvested is no longer submerged and extends to the time that any harvested oysters are placed in mechanical refrigeration or are continuously and completely covered by a layer of ice in a storage container that has been approved by the Virginia Department of Health, Division of Shellfish Sanitation.

4VAC20-1230-20. Definitions.

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

“*Container*” means any bag, sack, tote, or conveyance, such as a boat or truck, or other receptacle that contains shellfish to be held or transported. 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, either mechanical, such as a boat or truck, or non-mechanical, that is used to transport shellfish from the harvest area to the landing site or from the landing site to a certified dealer or other use.

“*Direct marketing*” means any shellfish or shellstock that is landed and sold without shucking or post-harvest 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.

“*Layer*” means a single thickness or coating spread out and covering a 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 degrees F or less.

“*Oysters*” mean those oysters greater than 2-½ inches in shell length.

“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 certified dealer 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, and use of any such tag indicates that shellstock is intended for further processing prior to distribution to retail or food service.

“Seed Clams” means those clams less than 30 mm in shell length and more than six months from harvest for human consumption.

“Seed Oysters” mean those oysters less than 2-1/2 inches in shell length and more than six months 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.

“Temperature control” means the use of ice or mechanical refrigeration, which is capable of lowering the temperature of the shellstock and maintaining it at 50°F (10°C) or less, as approved by the Virginia Department of Health, Division of Shellfish Sanitation.

4VAC20-1230-30. Public Health and Warm Water Harvest Restrictions.

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

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

C. 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.

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

E. From May 1 through September 30, all land-based deliveries of shellfish requiring more than 60 minutes after offloading is complete shall be made aboard trucks or conveyances equipped with mechanical refrigeration capable of maintaining 45°F or less, except that shellfish may be continuously and completely covered by a layer of ice, according to procedures approved by the Virginia Department of Health, Division of Shellfish Sanitation. Mechanically refrigerated containers of shellfish shall be in operation during transport. Any operator of a truck that is delivering shellfish using a truck not owned by a certified shellfish dealer shall possess a truck

refrigeration certificate issued by the Virginia Department of Health, Division of Shellfish Sanitation. Upon receipt of any shellfish, certified shellfish dealers shall immediately place any shellfish received from the harvester under temperature control.

F. From June 15 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 oysters from private grounds.

G. From May 1 to September 30, except for those persons permitted in accordance with subsections H or I of this section, it shall be lawful for any person to harvest oysters from open areas of public or private ground, provided those oysters are fully offloaded and placed into Virginia Department of Health, Division of Shellfish Sanitation-approved mechanical refrigeration or continuously and completely covered by a layer of ice in a Virginia Department of Health, Division of Shellfish Sanitation-approved storage container, only under the following designated curfew schedule that specifies an end to harvest time, 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 p.m.

H. It shall only be lawful to harvest oysters from open areas of public or private ground, as an exception to the provisions of subsections G and I of this section, provided:

1. The harvester has applied for, and been granted, a permit by the Virginia Marine Resources Commission to harvest oysters after the designated curfew harvesting times, as provided in subsection G 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 harvester and must be in continuous operation from the time that vessel or harvester leaves the dock or shore until the vessel or harvester returns to the dock or shore, and the oysters harvested are offloaded from that vessel or onto the dock or shore and placed into mechanical refrigeration or continuously and completely covered by a layer of ice in a storage container, approved by the Virginia Department of Health, Division of Shellfish Sanitation.

3. The total time, from the time the vessel or harvester leaves the dock or shore until the oysters are placed in Virginia Department of Health, Division of Shellfish Sanitation-approved mechanical refrigeration or continuously and completely covered by a layer of ice in a Virginia Department of Health, Division of Shellfish Sanitation-approved storage container, shall not exceed the following:

- 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.

I. It shall only be lawful to harvest oysters from open areas of public or private ground, as an exception to the provisions of subsections G and H of this section, provided:

1. The harvester has applied for and 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. Oysters are placed in mechanical refrigeration or continuously and completely covered by a layer of ice in a storage container, on board the vessel, from the start of harvest and throughout the harvest period, until the oysters are offloaded.

J. From May 1 through September 30, oysters may be harvested from open areas of private or public ground as restricted-use shellstock, provided:

1. The harvester 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 harvester 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 p.m. and placed in mechanical refrigeration or continuously and completely covered by a layer of ice in a storage container, both approved by the Virginia Department of Health Division of Shellfish Sanitation, by noon that same day.

K. From May 1 through September 30, a Bulk Seed Permit shall be obtained from the Virginia Marine Resources Commission for the harvest of any natural (wild) seed oysters that include oysters greater than 2-½ inches. Any person who harvests any natural (wild) seed oysters that include oysters greater than 2-½ inches and is not in possession of a Bulk Seed Permit issued by the Virginia Marine Resources Commission shall be in violation of this chapter.

L. Any person may handle oysters as part of a cage aquaculture operation for husbandry purposes after the designated harvesting times described in subsections G of this section, provided that person possesses a valid Cage Aquaculture Husbandry Permit from the Virginia Marine Resources Commission. Any person who handles oysters in cage oyster aquaculture operations after the designated harvesting times described in subsection G of this section and does not possess a Cage Oyster Aquaculture Husbandry Permit issued by the Virginia Marine Resources Commission shall be in violation of this chapter.

4VAC20-1230-35. [Repealed]

4VAC20-1230-40. 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 Virginia 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

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	42.66	48.3	11	0.0026	0.00021	N	
Feb	41.49	52.3	12	0.0029	0.00023	N	
Mar	50.86	60.1	13	0.025	0.002	N	
Apr	60.54	70.0	14	0.6	0.048	N	
May	69.67	76.9	6	1.3	0.1	N	
Jun	79.26	86.5	3	6.7	0.53	N	
July	82.06	88.1	2	7.9	0.63	N	
Aug	82.35	86.2	2	6.4	0.51	N	
Sep	77.24	80.3	4.5	3.6	0.29	N	
Oct	68.05	71.9	10	1.1	0.087	N	
Nov	56.45	61.1	11	0.05	0.004	N	
Dec	47.87	53.1	10	0.0068	0.00054	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	48.3	36	10	48.3	24	10	-1.1	0.00	1.75
Feb	50	52.3	36	10	52.3	24	10	-1.1	0.00	1.75
Mar	50.86	60.1	36	10	60.1	24	10	-0.75	0.00	1.75
Apr	60.54	70	14	10	70	24	10	1.7	0.29	1.75
May	69.67	76.9	12	10	76.9	5	5	2.6	1.03	1.75
Jun	79.26	86.48	12	10	86.48	3	5	3.5	2.88	2.50
July	82.06	88.14	10	10	88.14	2	5	3.6	2.99	3.00
Aug	82.35	86.21	10	10	86.21	2	5	3.6	2.91	3.00
Sep	77.24	80.29	12	10	80.29	4.5	5	3.4	2.49	2.50
Oct	68.05	71.93	12	10	71.93	12	10	2.7	1.35	1.75
Nov	56.45	61.08	14	10	61.08	12	10	0.36	0.01	1.75
Dec	50	53.07	36	10	53.07	36	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	48.3	36	10	48.3	24	10	-1.1	0.00	1.75
Feb	50	52.3	36	10	52.3	24	10	-1.1	0.00	1.75
Mar	50.86	60.1	36	10	60.1	24	10	-0.75	0.00	1.75
Apr	60.54	70	14	10	70	24	10	1.7	0.29	1.75
May	67.62	63.72	12	10	63.72	5	6	2	0.37	1.75
Jun	77.21	73.22	12	10	73.22	5	6	3.2	2.10	2.50
July	80.21	75.15	10	10	75.15	5	6	3.4	2.63	3.00
Aug	80.71	75.44	10	10	75.44	5	6	3.5	2.70	3.00
Sep	76.14	71.45	12	10	71.45	5	6	3.1	1.82	2.50
Oct	68.05	71.93	12	10	71.93	12	10	2.7	1.35	1.75
Nov	56.45	61.08	14	10	61.08	12	10	0.36	0.01	1.75
Dec	50	53.07	36	10	53.07	36	10	-1.1	0.00	1.75