

South Carolina Vibrio Control Plan

April 2023

South Carolina Department of Health and Environmental Control

The risk evaluation and regulatory controls for *Vibrio vulnificus* are presented in Section I. The risk evaluation and regulatory controls for *Vibrio parahaemolyticus* are presented in Section II.

I. *Vibrio vulnificus* Risk Evaluation and Regulatory Controls

Introduction

Section II, Risk Assessment and Risk Management, @ .06 Vibrio vulnificus Control Plan, as adopted by the Interstate Shellfish Sanitation Conference for inclusion in the 2019 National Shellfish Sanitation Program Model Ordinance (Model Ordinance), states the following:

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio vulnificus* illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program that includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation

Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *Vibrio vulnificus* risk evaluation annually. The evaluation shall consider seven factors, including seasonal variations for those factors, in determining whether the risk of *Vibrio vulnificus* illness from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur. For the purposes of this section, “reasonably likely to occur” shall mean that the risk constitutes an annual occurrence of an illness.

The factors are as follows:

- (1) The number of *Vibrio vulnificus* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State;
- (2) Levels of total and tdh+ *Vibrio vulnificus* in the area, to the extent that such data exists;
- (3) The water temperatures in the area;
- (4) The air temperatures in the area;

- (5) Salinity in the area;
- (6) Harvesting techniques in the area;
- (7) The quantity of harvest from the area and its uses (i.e. shucking, half-shell, PHP).

B. Control Plan

A *Vibrio vulnificus* Control Plan is required if any of the following conditions occur in a state:

- (1) If a State's *Vibrio vulnificus* risk evaluation determines that the risk of *Vibrio vulnificus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio vulnificus* Control Plan, or
- (2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures* exceed those listed below, the State shall develop and implement a *Vibrio vulnificus* Control Plan.

The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

- (a) Waters bordering the Pacific Ocean 60°F*
- (b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F*
- (c) Waters bordering the Atlantic Ocean (NY and north): 60°F*

However, development of a Plan is not necessary if the State conducts a risk evaluation (as described in A. Risk Evaluation) that determines that it is not reasonably likely that *Vibrio vulnificus* illness will occur from the consumption of oysters or hard clams harvested from those areas.

- (a) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section.
- (b) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that

have been epidemiologically linked to cases of *Vibrio vulnificus* illness; or

- (3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *Vibrio vulnificus* within the prior five (5) years, the State shall develop and implement a *Vibrio vulnificus* Control Plan for the area.
- (4) For States required to implement *Vibrio vulnificus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:
 - (a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.
 - (b) Implement one or more control measures to reduce the risk of *Vibrio vulnificus* illness at times when it is reasonably likely to occur. The control measures may include:
 - (i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio vulnificus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio vulnificus* illness is not reasonably likely to occur;
 - (ii) Closing the area to oyster and clam harvest;
 - (iii) Restricting oyster and clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;
 - (iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;
 - (v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio vulnificus* after the completion of initial cooling to 50 degrees F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;
 - (vi) Other control measures that based on appropriate scientific

studies are designed to ensure that the risk of Vv illness is no longer reasonably likely to occur, as approved by the Authority.

- (vii) Require the original dealer to cool oysters and/or clams to an internal temperature of 50 degrees F or below within 10 hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.
- (c) Evaluate the effectiveness of the Plan.
- (d) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.
- (e) Optional cost benefit analysis of the *Vibrio vulnificus* Control Plan.

Risk Evaluation for South Carolina

The seven risk evaluation factors listed above are considered for South Carolina as follows:

- (1) South Carolina has 25 separate shellfish growing areas. No illnesses have been epidemiologically linked to the consumption of commercially harvested South Carolina oysters during this five-year review period. A single case of *Vibrio vulnificus* with the consumption of oysters on October 4, 2019 and clams on October 7, 2019 was reported and the traceback indicated 7 different growing areas over three different states as possible sources. Oysters from SCS194W, NC-B3, NC-C3, and VA James River. Clams from NC-C2, NC-C3, NC-D4 and VA Hog Island Bay.
- (2) A study was conducted during the summer of 2015 to establish some baseline levels of total and pathogenic *Vibrio parahaemolyticus* and total *Vibrio vulnificus* in different types of shellfish. The data will also be used to further refine the *Vibrio* calculators being provided to states by the U.S. Food and Drug Administration (USFDA.)
- (3) NOAA inshore water temperature data are extremely limited and often unreliable. SCDHEC water temperature data are recorded to the nearest degree Centigrade during each shellfish water quality-sampling event. This data has been averaged by month for the period January 2018 - December 2022. Data were analyzed and are summarized for the month of September below in Table 4.

- (4) Air temperatures data are available from the National Weather Service and SCDHEC. Internal data was used in the determination of the 5-year monthly averages that are summarized in Table 2.
- (5) The average salinity in South Carolina is 26 parts per thousand based on data collected from all 468 sampling stations over the last 5 years (Table 3).
- (6) Oyster and hard clam harvesting of wild stock in South Carolina is closed for approximately one third of the year (typically from May 15 through September 30) to avoid harvesting during the warmest time of year. Most oyster and clam harvest are accomplished through the use of hand labor. The majority of commercial harvest occurs in areas having semi-diurnal tides ranging from approximately 1.5 meters to slightly more than 2 meters. Harvest typically takes place from approximately one-half ebb until one-half flood; a period of approximately 6 hours.

In 2017, the South Carolina Legislature passed amendments to the state's Shellfish Regulation R. 61-47 to allow for the summer harvest of only maricultured triploid oysters during the Vibrio control months as well as preserve the harvest of hard clams during the Vibrio control months. Oysters permitted to be harvested during the Vibrio control months will be required to be continuously submerged for 14 days in approved waters of a growing area prior to harvest. These oysters will also be required to be delivered to a Certified Shipper before 10:00 AM on the same day of harvest. If delivered after 10:00 AM the same day of harvest, oysters will have to be immediately iced upon removal from the water and delivered to a certified dealer no more than four hours from the start of harvest. Upon receipt the Certified Shipper has only two hours to reduce the internal temperature of the oysters to less than 50 degrees F.

- (7) Most oysters produced in South Carolina are used for oyster "roasts", although limited quantities of single oysters are being produced annually. Unlike oysters from most other regions of the country, South Carolina wild stock oysters typically develop as "clusters" and cannot easily be shucked for the raw market. More stringent requirements will be imposed on industry to provide for protection of consumers of the maricultured triploid oysters that will be harvested during the Vibrio control months as described in item six (6) above. Although these triploid oysters are being grown specifically for the raw market, the production amounts will be very limited and time to temperature controls will be straight forward to implement and achieve.

In taking into consideration all the information gathered in the Risk Evaluation for 2023, South Carolina is in a Low Risk Category for having a Vv illness, and extremely low risk for an outbreak. Based upon observed water and air temperatures, additional harvest restrictions will be implemented from May 28 thru September 30, 2023. The Department may modify the border months (currently May and September) based on daily average

water and air temperatures to determine the suitability of harvest. In accordance with state regulation amendments passed in 2017, the Department has the authority to impose additional time restrictions on harvest to refrigeration in the event that we have two or more illnesses from a growing area.

Annual risk evaluations will be conducted simultaneously with the state's annual growing area sanitary surveys.

Vibrio Related Illness Response

In the event that a *Vibrio Sp.* illness is associated with the consumption of shellfish that has been commercially harvested in South Carolina, the Department will follow the established protocols as described in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2019 Revision.

II. *Vibrio parahaemolyticus* Risk Evaluation and Regulatory Controls

Introduction

Section II, Risk Assessment and Risk Management, @ .07 *Vibrio parahaemolyticus* Control Plan, as adopted by the Interstate Shellfish Sanitation Conference for inclusion in the 2019 National Shellfish Sanitation Program Model Ordinance (Model Ordinance), states the following:

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program that includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider seven factors, including seasonal variations for those factors, in determining whether the risk of *Vibrio parahaemolyticus* infection illness from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur. For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence of an illness. The factors are as follows:

- (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State;
- (2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists;

- (3) The water temperatures in the area;
- (4) The air temperatures in the area;
- (5) Salinity in the area;
- (6) Harvesting techniques in the area;
- (7) The quantity of harvest from the area and its uses (i.e. shucking, half-shell, PHP).

B. Control Plan

A *Vibrio parahaemolyticus* Control Plan is required if any of the following conditions occur in a state:

- (1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan, or
- (2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures* exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan.

The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

- (a) Waters bordering the Pacific Ocean 60°F*
- (b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) 81°F*
- (c) Waters bordering the Atlantic Ocean (NY and north): 60°F*

However, development of a Plan is not necessary if the State conducts a risk evaluation as described in Section A. Risk Evaluation that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters or hard clams harvested from those areas.

- (a) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section.

- (b) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or
- (3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

- (a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.
- (b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:
 - (i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;
 - (ii) Closing the area to oyster harvest;
 - (iii) Restricting oyster and clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;
 - (iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;
 - (v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 50 degrees F (internal temperature of the oysters) do not exceed the average levels from the harvest

water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

- (vi) Other control measures that are based on appropriate scientific studies that are designed to ensure that the risk of Vp illness is no longer reasonably likely to occur, as approved by the Authority.
 - (vii) Require the original dealer to cool oysters and/or clams to an internal temperature of 50 degrees F or below within 10 hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.
- (c) Evaluate the effectiveness of the Plan.
 - (d) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.
 - (e) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

Risk Evaluation for South Carolina

The seven risk evaluation factors listed above are considered for South Carolina as follows:

- (1) South Carolina has 25 separate shellfish growing areas. No illness outbreaks have occurred during this five-year review period. Three separate illnesses have been reported for oysters and one from clams during last five years. A single case linked to oysters harvested from SCS206E or SCS106 in December 2018. Another single case linked to oysters harvested from SCS205 in March 2019. A single case linked to oysters harvested from SCM704F in July 2022. Lastly, a single case was linked back to clams eaten raw from SCS117 in January 2019.

There were nine other instances of single cases reported but in all these instances, multiple states and harvest areas were possible sources. A single case from the consumption of raw oysters that were harvested in May 2022 were traced back to 9 different growing areas in several states which were CCB31 MA, Watt's Bay and Hog Island Bay VA, PE-3E, NB5G – Lease# MS-0370, PE12B, SCM702F, SCM705F, and SCM138. A single case with consumption in July 2022 with 4 different growing areas from multiple states which were Watt's Bay, Nandus Creek, and the Rappahannock River in Virginia and SCM703F. A single case

with consumption from two states and 5 growing areas which were SCM703F, SCS058, SCC277, Damariscotta River ME and CCB 23 MA. A single case with consumption occurring in August 2021 of raw oysters and the traceback indicated 5 different growing areas which were Canada – NB-4B and St. Anna Bay 2B, Massachusetts – MA CCB-45 and MA CCB-23 and South Carolina – SC-M157. A single case with consumption occurring on June 8, 2020 of raw oysters from an unknown harvest area in Virginia and/or from a cooked dish with mussels traced back to MDI Narrows in Maine. A single case with consumption of raw oysters on April 19, 2019 was reported and the traceback indicated 6 different growing areas over three states as the possible sources. SCM126, SCM009, VA324, VA343, CT170 Westport and CT626 Westport. In November 2019, a single case with the consumption of raw oysters was traced back to SCM702F, PE3E-Canada, VA Milford Haven, and VA Watt's Bay. A single case with consumption on November 4, 2018 also had multiple states included in the traceback with the harvest areas being SC100, SCC273, and VA James River. Lastly, in November 2018 a case which involved cooked product and most likely a cross contamination issue was associated with SC S519W and VA James River.

No other illnesses have been epidemiologically linked to the consumption of commercially harvested South Carolina oysters or clams from any other harvest areas.

- (2) Only limited monitoring for *Vibrio parahaemolyticus* in oyster tissue has been conducted. A project by the NOAA/NCCOS National Centers for Coastal Ocean Science, (Gooch et al.) continues to monitor oyster tissue and surface waters for *Vibrio parahaemolyticus* densities "...to better ascertain the degree of risk posed by ballast water as well as the degree of public health hazards naturally present in U.S. coastal waters." Samples were collected monthly from five sites during 2001 and 2002. Two tdh+ colonies were isolated from a single site (non-commercial harvest area in Shellfish Management Area 05) during July and August 2001, which is when wildstock harvest season is closed. A study was conducted during the summer of 2015 to establish some baseline levels of total and pathogenic *Vibrio parahaemolyticus* and total *Vibrio vulnificus* in different types of shellfish. The data is used to further refine the *Vibrio* calculators being provided to states by the USFDA.
- (3) NOAA inshore water temperature data are extremely limited and often unreliable. SCDHEC water temperature data are recorded to the nearest degree Centigrade during each shellfish water quality-sampling event. These data have been averaged by month for the period January 2018 – December 2022. Data were analyzed and are summarized for the month of September below in Table 4.
- (4) Air temperatures data are available from the National Weather Service and SCDHEC. Internal data was used in the determination of the 5-year monthly averages that are summarized in Table 2.

- (5) The average salinity in South Carolina is 26 parts per thousand, based on data collected from all 468 sampling stations over the last 5 years (Table 3).
- (6) Wild caught oyster harvesting in South Carolina is closed for approximately one third of the year (typically from May 15 through September 30) to avoid harvesting during the warmest time of year. Most oyster and clam harvest are accomplished through the use of hand labor. The majority of commercial harvest occurs in areas having semi-diurnal tides ranging from approximately 1.5 meters to slightly more than 2 meters. Harvest typically takes place from approximately one-half ebb until one-half flood; a period of approximately 6 hours.

In 2017, the South Carolina Legislature passed amendments to the state's Shellfish Regulation R. 61-47 to allow for the summer harvest of only maricultured triploid oysters during the *Vibrio* control months as well as preserve the harvest of hard clams during the *Vibrio* control months. Oysters permitted to be harvested during the *Vibrio* control months will be required to be continuously submerged for 14 days in approved growing area waters prior to harvest. These oysters will also be required to be delivered to a Certified Shipper before 10:00 AM on the same day of harvest. If delivered after 10:00 AM the same day of harvest, oysters will have to be immediately iced upon removal from the water and kept completely covered with ice until delivered to a certified dealer no more than four (4) hours from the start of harvest. Upon receipt the Certified Shipper has only two hours to reduce the internal temperature of the oysters to less than 50 degrees F.

- (7) Most oysters produced in South Carolina are used for oyster "roasts", although limited quantities of single oysters are being produced annually. Unlike oysters from most other regions of the country, South Carolina wild stock oysters typically develop as "clusters" and cannot easily be shucked for the raw market. More stringent requirements will be imposed on industry to provide for protection of consumers of the maricultured triploid oysters that will be harvested during the *Vibrio* control months as described in item six (6) above. Although these triploid oysters are being grown specifically for the raw market, the production amounts will be very limited and time to temperature controls will be straight forward to implement and achieve.

In taking into consideration all of the information gathered in the Risk Evaluation for 2023, South Carolina is in a Low Risk Category for having *Vp* illnesses, and extremely low risk for an outbreak. Based upon observed water and air temperatures, additional harvest prohibitions will be implemented from May 28 thru September 30, 2023. The Department may modify the border months (currently May and September) based on daily average water and air temperatures to determine the suitability of harvest. In accordance with state regulation amendments passed in 2017, the Department has the authority to impose additional time restrictions on harvest to refrigeration in the event that we have two or more illnesses from a growing area.

Annual risk evaluations will be conducted simultaneously with the state's annual growing area sanitary surveys.

Vibrio Related Illness Response

In the event that a *Vibrio Sp.* illness is associated with the consumption of shellfish that has been commercially harvested in South Carolina. The Department will follow the established protocols as described in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2019 Revision.

Table 1

**South Carolina Shellfish Growing Area
5 Year Monthly Average
Water Temperatures
2018-2022**

Month	Degrees Fahrenheit
January	52
February	55
March	59
April	66
May	75
June	81
July	85
August	84
September	81
October	75
November	63
December	56

Table 2

**South Carolina Shellfish Growing Area
5 Year Monthly Average
Air Temperatures
2018-2022**

Month	Degrees Fahrenheit
January	54
February	59
March	59
April	67
May	77
June	82
July	85
August	84
September	81
October	75
November	62
December	55

Table 3

**South Carolina Shellfish Growing Area
5 Year Monthly Average
Salinity
2018-2022**

Month	PPT
January	25
February	25
March	24
April	25
May	26
June	26
July	27
August	26
September	27
October	27
November	27
December	26

Table 4

**South Carolina Shellfish Growing Area
5 Year Daily Average Water and Air Temperatures for the Month of September
2018-2022**

Day	Avg Water Temp C	Avg Air Temp C	Avg Water Temp F	Avg Air Temp F
1	29.26	29.84	84.68	85.71
2	31.13	30.52	88.03	86.93
4	28.72	29.20	83.70	84.55
5	29.74	30.10	85.54	86.17
6	27.99	27.24	82.38	81.03
7	29.09	29.43	84.36	84.98
8	28.35	28.35	83.04	83.04
9	27.54	26.16	81.56	79.09
10	29.37	29.99	84.86	85.99
11	28.78	30.56	83.81	87.01
13	27.24	27.94	81.04	82.29
14	28.13	28.51	82.63	83.31
15	28.77	27.59	83.78	81.66
16	27.90	26.50	82.22	79.70
17	28.26	30.40	82.87	86.72
18	27.39	28.26	81.30	82.86
19	27.14	26.70	80.85	80.05
20	27.58	26.73	81.65	80.11
21	25.22	23.63	77.39	74.54
22	24.12	23.10	75.41	73.57
23	25.42	23.67	77.76	74.60
24	27.47	28.40	81.45	83.12
25	26.89	26.35	80.40	79.43
26	27.40	27.58	81.32	81.64
27	26.26	26.94	79.27	80.50
28	25.68	24.97	78.22	76.95
29	25.50	27.00	77.90	80.60
30	26.96	26.24	80.52	79.24